

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**ACCLARENT, INC.**  
Petitioner,

v.

Ford Albritton, IV  
Patent Owner

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**CASE IPR: UNASSIGNED**  
U.S. Patent No. 9,011,412

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**PETITION FOR *INTER PARTES* REVIEW**

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Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

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**List of Exhibits**

- Ex. 1001 U.S. Patent No. 9,011,412 to Albritton, IV *et al.*
- Ex. 1002 U.S. Provisional Application No. 61/127,848
- Ex. 1003 File History of U.S. Patent No. 9,011,412 to Albritton, IV *et al.*
- Ex. 1004 Declaration of Dr. Howard L. Levine, M.D.
- Ex. 1005 Declaration of Randy J. Kesten
- Ex. 1006 U.S. Publication No. 2007/0250105 of Ressemann *et al.*
- Ex. 1007 U.S. Patent No. 8,747,389 of Goldfarb *et al.*
- Ex. 1008 U.S. Patent Pub. No. 2006/0063973 of Makower *et al.*
- Ex. 1009 U.S. Patent No. 4,915,691 of Jones *et al.*
- Ex. 1010 U.S. Patent Pub. No. 2006/0252993 of Freed *et al.*
- Ex. 1011 U.S. Patent No. 5,697,159 of Linden
- Ex. 1012 First Amended Complaint, Albritton v. Acclarent, Inc., Case No. 3:16-cv-03340-M, Docket Entry No. 25 filed Jun. 13, 2017 (N.D. Tex.).
- Ex. 1013 Transcript of Motion Hearing held on Oct. 24, 2017 Re Acclarent's Motion to Dismiss First Amended Complaint, Albritton v. Acclarent, Inc., Case No. 3:16-cv-03340-M (N.D. Tex.).
- Ex. 1014 U.S. Patent No. 7,654,997 of Makower *et al.*
- Ex. 1015 Definition of "allow" from Webster's Third New International Dictionary (2002).

## I. INTRODUCTION

U.S. Patent No. 9,011,412 (“Albritton”) is directed to systems and methods that include a guide catheter apparatus that is insertable through an external body passage of a subject. *See* Ex. 1001. Surgical catheters or guides and methods for using the same are nothing new and have been around since the 1920s. *See* Ex. 1004, ¶ 18, and Ex. 1005, ¶¶ 44-45. In fact, Albritton acknowledges that many of the claimed components used to perform a procedure in an external body passage - including the guide catheter having proximal and distal openings with a lumen extending therebetween, the handle coupled to the guide catheter for positioning the catheter in an external body passage, and a working device insertable through the handle and into the lumen of the guide catheter - were “typical” and well known in the art at the time of Albritton. *See* Albritton, 1:30-43; *see also* Ex. 1004, ¶ 18, and Ex. 1005, ¶ 47. Other elements such as the shaft of the guide catheter being substantially *rigid* were also well known and commonplace in the art. *See* Ex. 1004, ¶ 19, and Ex. 1005, ¶ 50. It was also common to include a source of suction for suctioning fluid and debris from a surgical site. *See* Ex. 1004, ¶ 21, and Ex. 1005, ¶ 51.

The purported novelty of the method claims of Albritton is the ability to manipulate a working device extending through the handle and the guide catheter

with a thumb and index finger of the same hand holding the device via a portion of the working device immediately adjacent to a handle opening, and to also use the thumb or index finger to control an amount of suction. *See e.g.*, Ex. 1001, 1:51-67 (“This disclosure provides an apparatus, system and method for manipulating a surgical catheter and working device with a single hand. ...The handle has a structure that allows a position of the guide catheter to be controlled by some or all of three fingers of one hand of an operator of the handle. The structure of the handle is adapted to permit the operator to position a thumb and index finger of the hand to manipulate the working device via a portion of the working device that is immediately adjacent to the handle.”).

During prosecution, Albritton distinguished a reference to Wild on the basis that “Wild does not disclose that the an operator is permitted to position a ***thumb and index finger*** of the hand to manipulate the working device ***via a portion of the working device immediately adjacent to the handle opening*** as recited in Claim 1.” Ex. 1003. (Amendment and Response filed on April 23, 2012, pp. 10-11) (emphasis in original). Albritton also distinguished a reference to Freed by adding the limitation “to control, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen,” arguing that this element was absent from the cited references. *See id.* (Amendment and Response filed on

October 29, 2012, pp. 10-11).

The Examiner failed to consider numerous prior art references that teach all of the limitations of the claimed method. Ressemann was not cited during prosecution, and is far more relevant than any reference relied on by the Examiner. As we explain below, Ressemann teaches all of the elements of the claimed method with the exception of suction, which was well-known at the time. Goldfarb is an example of a reference that taught that suction was commonly used on devices of the type disclosed in Ressemann. Goldfarb was cited during prosecution, however it was never relied on as part of the basis for a rejection. Makower is another reference that teaches all of the elements of claimed method, but was only relied on as a secondary reference to teach certain dependent claim features. While Makower discloses the use of a thumb/finger port for suction, Makower does not explicitly teach using the thumb or finger of the same hand to control suction. Jones is yet another reference that was not cited that eliminates any doubt that it was well known at the time of Albritton to use a thumb or finger to control suction. When these prior art references are properly considered, it is clear that Albritton's method claims should not have issued as these references teach the claimed method.

## **II. GROUNDS FOR STANDING**

Petitioner hereby certifies that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

## **III. MANDATORY NOTICES**

### **A. Real Party-In-Interest**

Acclarent, Inc., 33 Technology Drive, Irvine, CA 92618, is a wholly owned subsidiary of Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, N.J. 08933. Both entities are real parties-in-interest for this petition to institute *inter partes* review.

### **B. Related Matters**

“System” claims 1-7 and 14-20 of the Albritton Patent are the subject of pending *Inter Partes Review* No. 2017-00498.

Both the system and method claims of the Albritton Patent are the subject of a patent infringement lawsuit brought by the Patent Owner against Acclarent in *Dr. Ford Albritton IV v. Acclarent, Inc.*, Civil Action No. 3:16-cv-03340-D, filed in the United States District Court for the Northern District of Texas Dallas Division on December 1, 2016 (hereinafter “the Litigation”).



**C. Notice of Lead and Backup Counsel**

Lead Counsel	Backup Counsel
Lisa Adams Reg. No. 44,238 Mintz Levin Cohn Ferris Glovsky and Popeo PC One Financial Center Boston, MA 02111 T: (617) 348-3054 F: (617) 542-2241	Peter Cuomo Reg. No. 58,481 Mintz Levin Cohn Ferris Glovsky and Popeo PC One Financial Center Boston, MA 02111 T: (617) 348-1854 F: (617) 542-2241

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this  
Petition.

**D. Notice of Service Information for Petitioner**

Please address all correspondence to Lead Counsel at the address shown  
above. Petitioner also consents to electronic service by email to:  
[ladams@mintz.com](mailto:ladams@mintz.com) and [pjcuomo@mintz.com](mailto:pjcuomo@mintz.com).

**E. Service On The Patent Owner**

Dr. Ford Albritton, IV is the inventor and, by virtue of an assignment from  
Bryan Lunsford to Dr. Fold Albritton, IV, as recorded at Reel 035665, Frame 0801  
at the USPTO's assignment database, is the current owner of record of the  
Albritton patent. Pursuant to 37 C.F.R. § 105(a), service of this Petition has been  
made simultaneously with this filing to the current correspondence address for the  
Albritton patent and Dr. Albritton's current counsel in the Litigation and IPR No.

2017-00498, as shown in the Certificate of Service.

#### **IV. THRESHOLD REQUIREMENT FOR *INTER PARTES* REVIEW**

A petition for *inter partes* review must demonstrate “a reasonable likelihood that the Petitioner would prevail with respect to at least one of the claims challenged in the petition.” 35 U.S.C. § 314(a). This Petition meets that threshold. All of the elements of claims 8-13 of Albritton are taught and/or disclosed in the prior art as explained below, and reasons to combine the prior art teachings and/or disclosures, where necessary, are established for each proposed ground under 35 U.S.C. § 103(a).

#### **V. SUMMARY OF THE ALBRITTON PATENT**

##### **A. Overview of Albritton**

Albritton is directed to systems and methods that include a guide catheter apparatus that is insertable through an external body passage of a subject. As shown in Figure 3 (reproduced below with markings), the apparatus has a guide catheter (302, red) with a substantially rigid shaft and proximal and distal openings with a lumen extending therebetween. The guide catheter is coupled to a handle (350, blue) having an opening (318) for receiving a working device. The handle (blue) includes a coupling (310 and 320, orange) configured to couple the lumen in the guide catheter (red) to a suction source.

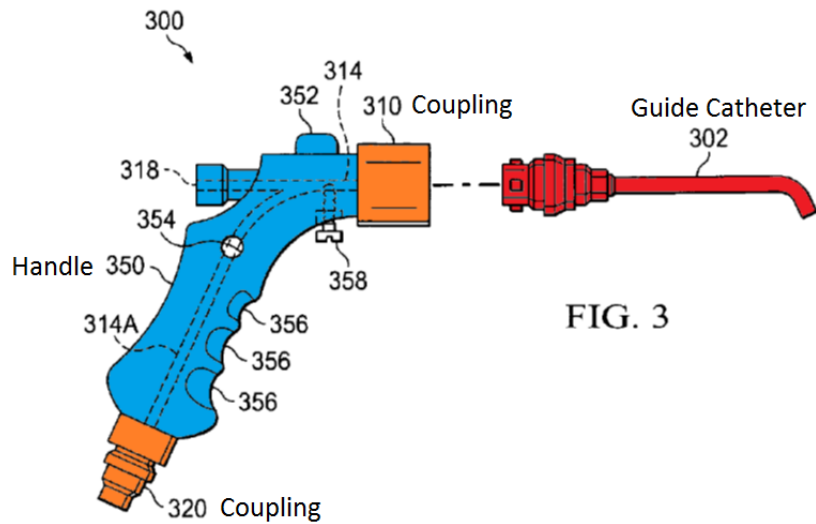
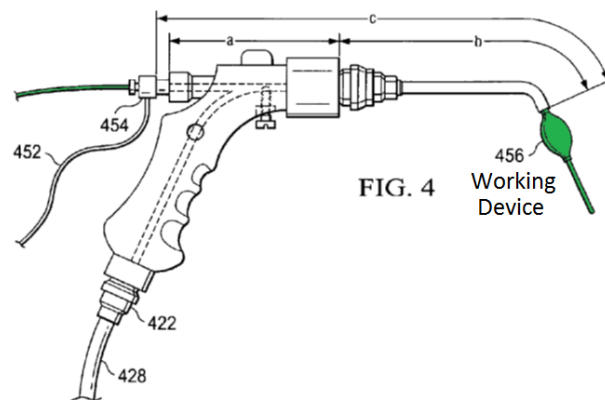
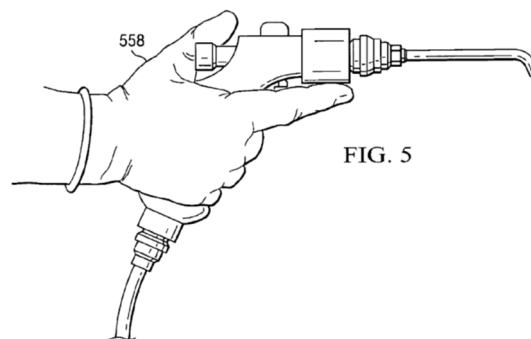


Figure 4 (reproduced below with markings) illustrates a working device (green) inserted through the handle opening (318) and into the lumen in the guide catheter.



The handle is purportedly formed to allow the position of the guide catheter to be controlled by some or all of three fingers of a hand, while substantially simultaneously manipulating the working device with a thumb and index finger of the hand via a portion of the working device immediately adjacent to the handle

opening. *See* Albritton, claim 8. The handle is also purportedly formed to allow the position of the guide catheter to be controlled while substantially simultaneously controlling, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen. *See id.* While the method of manipulating the working device adjacent to the handle opening is not shown in the drawings of the issued Albritton patent, Figure 5 (reproduced below) illustrates the device being held by a user.



Moreover, the original Figure 5 from the provisional (reproduced below) appears to show a thumb and forefinger manipulating a portion of the device in the vicinity of the opening at the distal end of the handle, which is consistent with the Albritton specification describing the claimed method. *See* Albritton, 4:67-5:4 (“The fore finger and thumb are left free to manipulate a working device inserted into the opening 318 or to cover the opening 318 to redirect suction to the distal end of the guide 302, as described with reference to FIG. 2.”); *see also*, Albritton, Figure 3 (above).

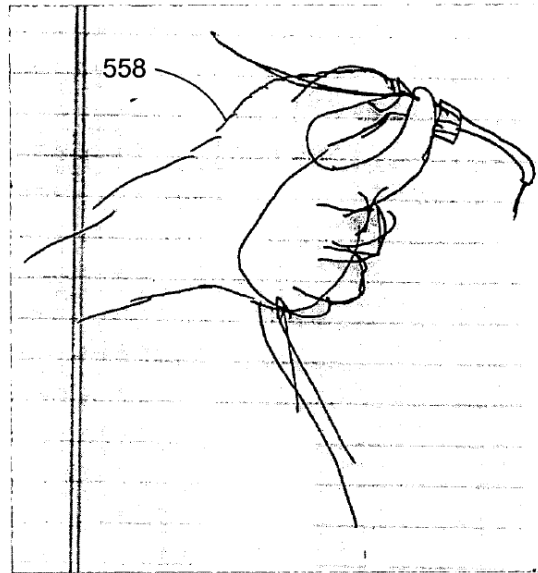


FIGURE 5

Albritton has a total of 20 claims, with claims 1, 8, and 14 being independent. Claims 1 and 14 each define the basic guide catheter system or apparatus, while claim 8 defines a method of inserting the guide catheter through an external body passage of a subject.

#### **B. Summary of the Prosecution History**

Albritton was filed on May 18, 2009 and claims priority from a provisional patent application filed on May 16, 2008, attached hereto as Ex. 1002. Albritton was filed with 20 claims, of which claims 1, 8, and 14 were independent.

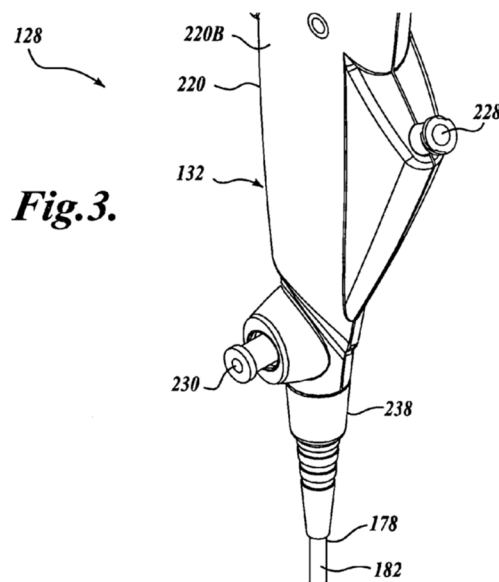
In a first Office Action mailed December 22, 2011, claims 1-4, 7-11, 13-17, and 19-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,605,036 to Wild (“Wild”), and claims 5, 12, and 18 were rejected under 35 U.S.C. § 103(a) for obviousness over Wild in view of Makower. *See* Ex.

1003 (Dec. 22, 2011 Office Action, pp. 2-5).

In a response filed on April 23, 2012, independent claim 8 was amended to recite inserting the working device “through a handle opening in a handle coupled to the guide catheter and into” the lumen of the guide catheter. Ex. 1003 (Apr. 23, 2012 Amendment and Response, p. 5). Amendments were also made to independent claims 1 and 14. The applicants argued that Wild does not teach a working device adapted to be insertable through the handle opening into the lumen of the guide catheter, or that the structure of the handle is adapted to permit the operator to position a thumb and index finger of the hand to manipulate the working device via a portion of the working device immediately adjacent to the handle opening. *See id.*, p. 11. The applicants asserted that the thumb and index finger of an operator “would not be able to reach a portion of the working device *immediately adjacent to the handle opening* utilizing the handle top by Wild.” *Id.* (emphasis in original). As to the rejection of claims 5, 12, and 18 under 35 U.S.C. § 103(a) as being unpatentable over Wild in view of Makower, the applicants did not address Makower on any of the merits.

In a final Office Action mailed August 27, 2012, claims 1-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Pub. No. 2006/0252993 of Freed (hereafter “Freed”). *See* Ex. 1003 (Aug. 27, 2012 Office

Action, pp. 2-6). In response, the applicants amended claim 8 to recite “coupling a source of suction to the lumen through the handle,” and to recite “controlling the position of the guide catheter using the handle, while substantially simultaneously controlling, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen.” *See id.* (Oct. 29, 2012 Amendment and Response, p. 5). Similar amendments were made to claims 1 and 14. The applicants argued that Freed discloses “a catheter handle 132 with an irrigation/suction port 230 that has luer style fittings 258” which define port 230, as seen in Figure 3 of Freed (partially reproduced below) (*see* Ex. 1010, Fig. 3), and fails to disclose that “the structure of the handle permits an operator to use a thumb or index finger to control the amount of suction.” *Id.*, p. 11.



In a further non-final Office Action mailed June 10, 2014, claims 1-20 were rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Publication No. 2009/0143645 of Matthes (“Matthes”). *See* Ex. 1003 (Jun. 10, 2014 non-final Office Action, pp. 2-7). The applicants responded by arguing that Matthes did not qualify as prior art. *See id.* (Nov. 10, 2014 Request for Reconsideration, pp. 8-9).

Albritton issued on April 21, 2015.

## **VI. PERSON OF ORDINARY SKILL IN THE ART**

A person of ordinary skill in the art is a hypothetical person presumed to know the relevant prior art. *See Gnosis S.p.A. v. South Alabama Med. Sci. Found.*, IPR2013-00116, Paper No. 68, p. 9 (PTAB Jun. 20, 2014). Such a person is of ordinary creativity, not merely an automaton, and is capable of combining teachings of the prior art. *See id.* (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421-21 (2007)). A person of ordinary skill in the art as of May 16, 2008 (hereinafter a “POSA”) would have had at least a bachelor’s degree in either electrical engineering or mechanical engineering, or equivalent, with at least four years’ experience designing surgical instruments, or a doctor of medicine (M.D.) and at least 2 years of experience with laparoscopic or endoscopic surgical procedures. *See* Ex. 1004, ¶¶ 16-17, and Ex. 1005, ¶ 42.



## VII. CLAIM CONSTRUCTION

### A. Applicable Legal Standards

Solely for purposes of this review, Petitioner construes the claim language such that the claim terms are given their broadest reasonable interpretation in light of the Albritton specification. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 2016 U.S. LEXIS 3927 at \*24 (U.S. June 20, 2016); *see also*, *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012). Also, the claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *See In re Translogic Technology, Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

For terms not specifically construed below, Petitioner interprets them for purposes of this review in accordance with their plain and ordinary meaning under the required broadest reasonable construction in light of the patent specification. 37 C.F.R. § 42.100(b). Because that legal standard for claim construction differs from the one applied in U.S. District Court litigation, *see In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364, 1369 (Fed. Cir. 2004), Petitioner expressly reserves the right to advocate a different construction in any subsequent litigation for any term found in Albritton.

**B. Proposed Constructions**

**1. “formed to allow”**

**Proposed Construction:** capable of.

The construction of this term comes from the plain and ordinary meaning in light of its use in the patent specification. The plain language of claim 8 states that the handle is “formed to allow” the position of the guide catheter to be controlled by some or all of three fingers of a hand, while substantially simultaneously manipulating the working device with a thumb and index of the hand. The term “formed to allow” is a functional limitation that should be construed broadly and analogously with “configured to allow” and adapted to permit” which are used by Albritton in the same manner to describe purely functional and allowable (or permissive) language in independent claims 1 and 8 (*see below*):

Claim 1: “...the structure is *configured to allow* a position of the guide catheter *to be controlled by some or all of three fingers of one hand* of an operator of the handle...wherein the structure of the handle is *adapted to permit* the operator to *position a thumb and index finger of the hand to manipulate the working device...*”

Claim 8 “...controlling a position of the guide catheter using the *handle that is formed to allow* the position of the guide catheter to be *controlled by some or all of*

*three fingers of a hand*, while substantially simultaneously *manipulating the working device with a thumb and index finger of the hand...*”

Claim 14: “...the structure is *configured to allow* a position of the guide catheter apparatus to be controlled by some or all of three fingers of one hand of an operator of the handle...wherein the structure of the handle is *adapted to permit* the operator to *position a thumb and index finger of the hand to manipulate* a working device...”

Albritton claims 1, 8, and 14 (emphasis added to each). The terms “configured to” and “adapted to” can either have a narrow meaning (e.g., “made to,” “designed to”) or a broad meaning (e.g., “capable of” or “suitable for”). *See, e.g., Ex. Parte Hanni*, Appeal No. 2015-002410, 2016 Pat. App. LEXIS 12392, at \*11-12 (PTAB Dec. 19, 2016); *In re Man Machine Interface Techs. LLC*, 822 F.3d 1282, 1286 (Fed. Cir. 2016). One should look to the claims and the written description of the patent to determine whether the claim scope should be broad or narrow. *Id.* In particular, one should look for language imposing particular structural features required for performing the claimed function or other language expressly disclaiming a particular configuration. *Id.*; *see also, Ex. Parte Warren*, Appeal 2015-003359; 2016 Pat. App. LEXIS 11253, at \*13-15 (PTAB Nov. 23, 2016)

(holding “configured to” meant “capable of” because “configured to” was not defined by the patent specification nor was there “any particular configuration required by the Specification other than that the device function.”). As addressed in the Kesten Declaration, the Albritton patent does not disclose any features required to perform the claimed functions. *See* Ex. 1005, ¶ 69. Indeed, the terms “configured to allow” and “formed to allow” appear nowhere but the claims where neither is linked to any specific structural distinctions. Albritton uses the term “adapted to permit” in two places in the specification but not in relation to any particular structures.

The handle has a structure *that allows* a position of the guide catheter to be controlled by some or all of three fingers of one hand of an operator of the handle. The structure of the handle is *adapted to permit* the operator to position a thumb and index finger of the hand to manipulate the working device via a portion of the working device that is immediately adjacent to the handle.

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The handle has a structure *to allow* a position of the guide catheter to be controlled by some or all of three fingers of one hand of an operator of the handle. The structure of the handle is *adapted to permit* the operator

to position a thumb and index finger of the hand to manipulate a working device inserted into the lumen of the guide catheter, where the working device is manipulable via a portion of the working device immediately adjacent to the handle.

Albritton, 1:61-67 and 2:15-23 (emphasis added). As can be seen above, Albritton does not require any particular configuration and only describes the function of the handle structure. Further, the plain meaning of the modifier “allow” which means “to make possible” (not mandatory) dictates the broader construction. *See* Ex. 1015 (Webster's Third New International Dictionary, at 58 (“allow” means “to make a possibility; provide opportunity or basis.”)).

Moreover, the Albritton specification contains language that demonstrates that no particular configuration is required other than that the device function:

Although the present invention and its advantages have been described in the foregoing detailed description and illustrated in the accompanying drawings, it will be understood by those skilled in the art that the invention is not limited to the embodiment(s) disclosed but is capable of numerous rearrangements, substitutions and modifications without departing from the spirit and scope of the invention as defined by the appended claims.

Albritton, 5:47-54; compare with *Warren*, 2016 Pat. App. LEXIS 11253, at \*14 (noting similar language while concluding that the broader “capable of”

interpretation should apply to the claim term “configured to”). While the Albritton specification does state that “the [handle] angle may be selected to place the user’s thumb and forefinger in comfortable proximity to the opening 318, and the handle shaped to permit easy motion of the thumb and forefinger towards and away from the opening 318 while securely grasping a working device inserted through the handle 350 into the guide 302,” it goes on to say that any angle between 0-90 degrees, including 60, may be used. *See* Albritton, 6:19-22. Albritton’s disclosure of any angle from 0-90 degrees provides no direction or guidance and instead leaves one of ordinary skill confronted with virtually every possible angular option. *See* Ex. 1005, ¶ 69.

Accordingly, the term “formed to allow” should be given the broader “capable of” or “suitable for” interpretation, and thus the claimed handle merely needs to be *capable of* allowing the guide catheter to be being controlled by some or all of three fingers of one hand, while substantially simultaneously controlling the working device with a thumb and index finger. *See* Ex. 1005, ¶¶ 67-72.

**2. “manipulating the working device with a thumb and index finger”**

**Proposed Construction:** using one of the thumb and index finger to move the working device while the other one of the thumb and index finger provides oppositional force and stabilizing force.

In a First Amended Complaint filed in the Litigation by Dr. Albritton, it was asserted that “even when an operator uses the thumb (as advertised) to manipulate the Balloon Slider or the Wire Slider, the operator also uses his or her forefinger to apply *oppositional force and stabilizing force* that is part of the manipulation of the working device ....” *See* Ex. 1012 (emphasis added.) In other words, Albritton asserts that “manipulating the working device with a thumb and index finger of the hand,” as recited in claim 8, includes applying oppositional force to the handle with one of the thumb and index finger and using the other of the thumb and index finger to advance the working device.

This was reiterated by counsel for Dr. Albritton during a hearing on a motion to dismiss in the Litigation. *See* Ex. 1013. In particular, Patent Owner’s counsel pointed to Figure 5 of Albritton, and argued that “the hand positioning indicated in Figure 5 provides for a thumb that is positioned immediately adjacent to the portion of the working device extruding from the handle, and an index finger that is used to provide oppositional and directional force.” *See id.*, p. 45.

The Patent Owner's interpretation, as set forth in the complaint in the Litigation, constitutes a binding judicial admission. *See Gordon Kruse Constr. Co. v. United States*, Appeal No. 92-5093, 1992 U.S. App. LEXIS 32832 at \*5 (Fed. Cir. Dec. 14, 1992). ("This court has held that pleadings are judicial admissions which render the facts therein indisputable.") (citations omitted). Accordingly, while we believe that claim 8 requires *both* the thumb and index finger to engage the working device, for purposes of this IPR only, we apply Patent Owner's claim interpretation herein.

#### **VIII. PRIOR ART REFERENCES RELIED ON BY PETITIONER**

1. U.S. Patent No. Publication No. 2007/0250105 of Ressemann et al., entitled "Device and Method for Treatment of Sinusitus" (Ex. 1006) ("Ressemann") was published on October 25, 2007. It is prior art under pre-AIA 35 U.S.C. § 102(b).

2. U.S. Patent No. 8,747,389 of Goldfarb et al., entitled "Systems for Treating Disorders of the Ear, Nose, and Throat" (Ex. 1007) ("Goldfarb") was filed on August 24, 2007 and issued on June 10, 2014. It is pre-AIA 35 U.S.C. § 102(e) prior art for claims entitled to the benefit of the May 16, 2008 provisional filing date, and § 102(b) prior art for claims that are not so entitled.

3. U.S. Patent No. Publication No. 2006/0063973 of Makower et al.,



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entitled “Methods and Apparatus for Treating Disorders of the Ear Nose and Throat” (Ex. 1008) (“Makower”) was published on March 23, 2006. It is prior art under pre-AIA 35 U.S.C. § 102(b).

4. U.S. Patent No. 4,915,691 of Jones entitled “Aspirator” (Ex. 1009) (“Jones”) issued on April 10, 1990. It is prior art under pre-AIA 35 U.S.C. § 102(b).

## **IX. STATEMENT OF NON-REDUNDANCY**

At the outset, we note that ongoing IPR2017-00498 only addresses Albritton device claims 1-7 and 14-20, whereas the present petition addresses method claims 8-13. This Petition thus involves a different group of claims.

The grounds in this Petition also rely upon different references and combinations of references.

Ground 1 relies on Ressemann and Goldfarb to render claims 8 and 11-13 unpatentable for obviousness under 103(a). Ressemann, a prior art reference that was not cited during prosecution of the Albritton patent, teaches the claimed method, and in particular teaches grasping a handle and simultaneously advancing a working device with a single hand. Ressemann, however, does not teach the use of suction. Goldfarb is a 102(e) prior art reference (for claims entitled to the benefit of the May 16, 2008 provisional filing date) that discloses a device similar

to Ressemann, but that includes a thumb/finger port for controlling suction.

Goldfarb was cited during prosecution, however it was never relied on as the basis for a rejection.

Ground 2 relies on Makower and Jones to render obvious claims 8-13.

Makower teaches a method that includes use of a guide catheter having a handle that is formed to allow a working device to be controlled in the claimed manner, and that includes a thumb/finger port for controlling suction. Makower, however, does not explicitly state that the thumb or index finger of the same hand are used to control an amount of suction coupled to the distal opening of the lumen. Jones, a 102(b) prior art reference that was not cited, teaches using the thumb to cover a thumb port in the handle for controlling suction.

Thus the references disclose certain different elements with proposed invalidity grounds presented in different ways. The grounds are also directed to different groups of claims and contain different teachings regarding use of different guide catheter systems and thus, could not be considered redundant.

## **X. STATEMENT OF PRECISE RELIEF REQUESTED**

Petitioner respectfully requests that claims 8-13 of Albritton (Ex. 1001) be held invalid based on the following grounds of unpatentability:

Ground	Relied-on Reference	Statutory Basis	Claims
1	Ressemann and Goldfarb	35 U.S.C. § 103	8 and 11-13
2	Makower and Jones	35 U.S.C. § 103	8-13

## XI. CLAIM-BY-CLAIM EXPLANATION OF GROUNDS FOR UNPATENTABILITY

### A. Ground I - Claims 8 and 11-13 Are Obvious Over Ressemann in view of Goldfarb

#### 1. Independent Claim 8

As demonstrated below, claim 8 should be found to be invalid pursuant to 35 U.S.C. § 103(a) as being obvious over Ressemann in view of Goldfarb. *See also*, Ex. 1004, ¶ 51, and Ex. 1005, ¶ 81.

##### *a. Limitation: “A method, comprising:”*

8. A method comprising:	<i>See, e.g., Ressemann, Abstract (“[a] method of treating a constricted sinus passageway of a patient ....”).</i>
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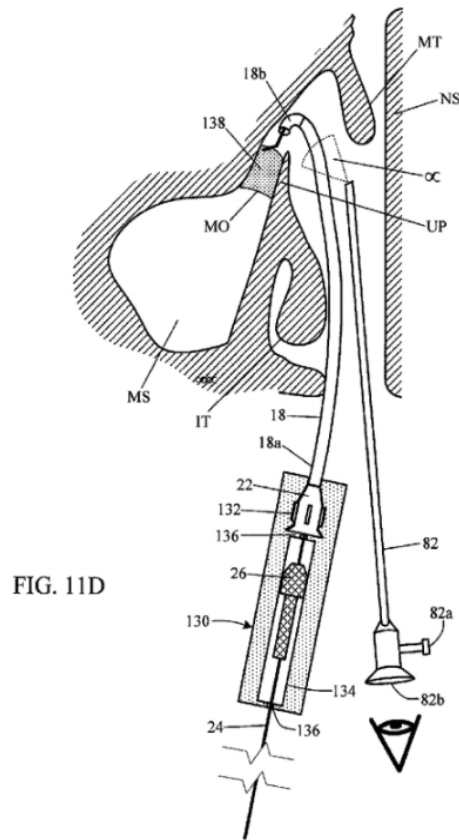
To the extent the preamble is considered to be a limitation of the claim, Ressemann discloses a method. *See also*, Ex. 1004, ¶ 52, and Ex. 1005, ¶ 84.

##### *b. Limitation: “inserting a guide catheter ...”*

inserting a guide catheter through an external body passage of a subject, wherein the guide catheter comprises a substantially rigid shaft, a	“A guide catheter is inserted through the nasal passageway, the guide catheter including a wire guide slidably disposed within a lumen contained therein.” Ressemann, ¶ [0012]; <i>see also id.</i> , Figure 11D (reproduced below showing the guide catheter
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proximal opening, a distal opening and a lumen extending between the proximal opening and the distal opening;

18 inserted through a sinus passage).



“[T]he guide catheter 18 includes a shaft portion 18a and a flexible tip portion 18b. The tip portion 18b is preferably of a softer material than the shaft portion 18a.” Ressemann, ¶ [0099].  
 “Alternatively, the shaft portion 18b of the guide catheter 18 can be formed of a metallic tube.” *Id.*, ¶ [0101].

As shown in Figure 11D above, Ressemann teaches inserting a guide catheter 18 through an external body passage (the maxillary sinus ostium MO) of a subject. Since the tip portion 18b is more flexible than the shaft portion 18a, and can be made from a metallic tube, the guide catheter 18 is substantially rigid. Ressemann, ¶ [0101]. As further shown in Figure 11D above, a wire guide 24

extends from both ends of the guide catheter 18, and thus the guide catheter 18 has a lumen extending between a proximal opening and a distal opening. Ex. 1004, ¶ 54, and Ex. 1005, ¶ 86; *see also id.*, ¶ [0028] (“a guide catheter for guiding one or more devices ... includes an elongate shaft ... including a lumen passing from the proximal region to the distal region ...”).

Accordingly, Ressemann teaches the guide catheter inserting step of claim 8. *See also*, Ex. 1004, ¶ 55, and Ex. 1005, ¶ 87.

*c. Limitation: “coupling a source of suction to the lumen through the handle”*

coupling a source of suction to the lumen through the handle;	Goldfarb explains that “[a]n irrigation and/or suction tube 54 may be attached to the handle member 48a to infuse fluid through or suction fluid and debris through the fluid channel 52.” Goldfarb, 11:19-22.
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At the outset, this limitation refers to “the handle,” however there is no antecedent basis for the handle. For purposes of this Petition, we assume that claim 8 should read “a handle.”

While Ressemann does not teach the use of suction, it would have been obvious to modify Ressemann in view of Goldfarb to couple a source of suction to the lumen through the handle for suctioning fluid through the lumen of the guide catheter.

At the outset, Ressemann explains that the devices can be configured to “facilitate the infusion and delivery of one or more therapeutic and/or diagnostic agents at the site of the dilation balloon 10.” Ressemann, ¶ [0110]. As explained in the attached Levine Declaration, saline can be considered to be an adjunct to a diagnostic agent, and any delivery of saline would require suction to remove the saline and maintain a dry field. *See* Ex. 1004, ¶¶ 56-57. Accordingly, Ressemann’s teaching to deliver a diagnostic agent as a fluid would require suction.

Goldfarb, like Ressemann, discloses various devices and methods for treating sinusitis. *See, e.g.*, Ressemann, ¶ [0001] (“The field of the invention generally relates to devices and methods for the treatment or amelioration of sinusitis.”); *see also* Goldfarb, 1:25-28 (“The present invention relates generally to medical devices and methods and particularly to balloon catheters [or] other devices that may be inserted through the nose and used to dilate the ostia of paranasal sinuses for treatment of sinusitis.”). In particular, Ressemann and Goldfarb both disclose guide catheters that receive a guide wire for guiding a balloon catheter into a body passage. *Compare, e.g.*, Ressemann, ¶ [0024] (“[A] system for manipulating a guide catheter within a patient’s nasal passages or sinus cavities is provided.... The system include a guide catheter ... having a lumen

passing therethrough and a wire guide slidably disposed within the lumen ...."); *with* Goldfarb, 2:32-33 and 46-47 ("[T]here is provided a dilation catheter device and system ... [having] a guide catheter through which the dilation catheter is inserted ...."). Accordingly, Ressemann and Goldfarb are analogous and in the same field of endeavor.

While Ressemann and Goldfarb disclose similar methods and devices, Goldfarb further discloses the use of suction. In discussing a guide catheter having an optional handle, Goldfarb explains that "a pinch valve or hole can be strategically placed in handle 48 to actuate/allow control of suction or fluid delivery via handle device (e.g., the user may pinch the handle with fingers to restrict flow through handle) or the handle 48 may have a suction hole where the user must cover the suction hole to actuate suction through the optional handle 42." Goldfarb, 11:6-12. Goldfarb further explains that "[a]n irrigation and/or suction tube 54 may be attached to the handle member 48a to infuse fluid through or suction fluid and debris through the fluid channel 52." *Id.*, 11:19-22. Goldfarb therefore discloses coupling a source of suction to the lumen through a handle.

It would have been obvious to a POSA to modify Ressemann in view of Goldfarb to couple a source of suction to the lumen through the handle because such a modification is merely a use of known technique to improve a similar

device or method in the same way. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (“[I]f 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 his or her skill.”); Ex. 1004, ¶ 57. As explained in the attached declarations, the use of suction was well known in the art at the time of any invention in Albritton, and Goldfarb is just one example of a prior art reference that teaches the use of suction. *See* Ex. 1004, ¶¶ 20-24, and Ex. 1005, ¶ 88.

A POSA would have been motivated to make the proposed modification because the prior art makes it clear that suction was often required in order to improve visibility and maintain a dry field. Ex. 1004, ¶ 57. Visibility is important since sinus surgery is performed using a very small endoscope (2.7-4 mm). *See Id.*, ¶ 22. As Dr. Levine testified, any blood, mucus, or fluid in the sinuses will hinder visibility and even small amounts of blood and fluid can interfere with visibility. *See id.* Suction is used to enable the surgeon to clearly view the normal anatomy being operated upon and pathology to be removed. *See id.* Ressemann recognized the importance of visibility as demonstrated by the disclosed use of an illumination member (158) designed to improve visibility. *See* Ressemann, ¶ [0125] (“To further aid in the identification of the maxillary sinus ostium MO,



particularly in the case of occlusion (156) associated with sinusitis, the maxillary sinus MO is illuminated with the placement of a small illumination member (158) into the sinus.”); *see also* Ex. 1004, ¶ 57. Further, as explained in the Kesten Declaration, “rhinologists realize the vital *necessity* of a clean field in which to work.” Ex. 1005, ¶ 88, citing Putney (Kesten Declaration Ex. AB) at 206 (emphasis added); *see also, e.g.*, U.S. Patent No. 7,654,997 of Makower et al., 20:44-50 (attached hereto as Ex. 1014) (explaining that a suction tube can be used during sinus surgery “for maintenance of a substantially dry environment ....”); Ex. 1004, ¶¶ 22, 27 and 69.

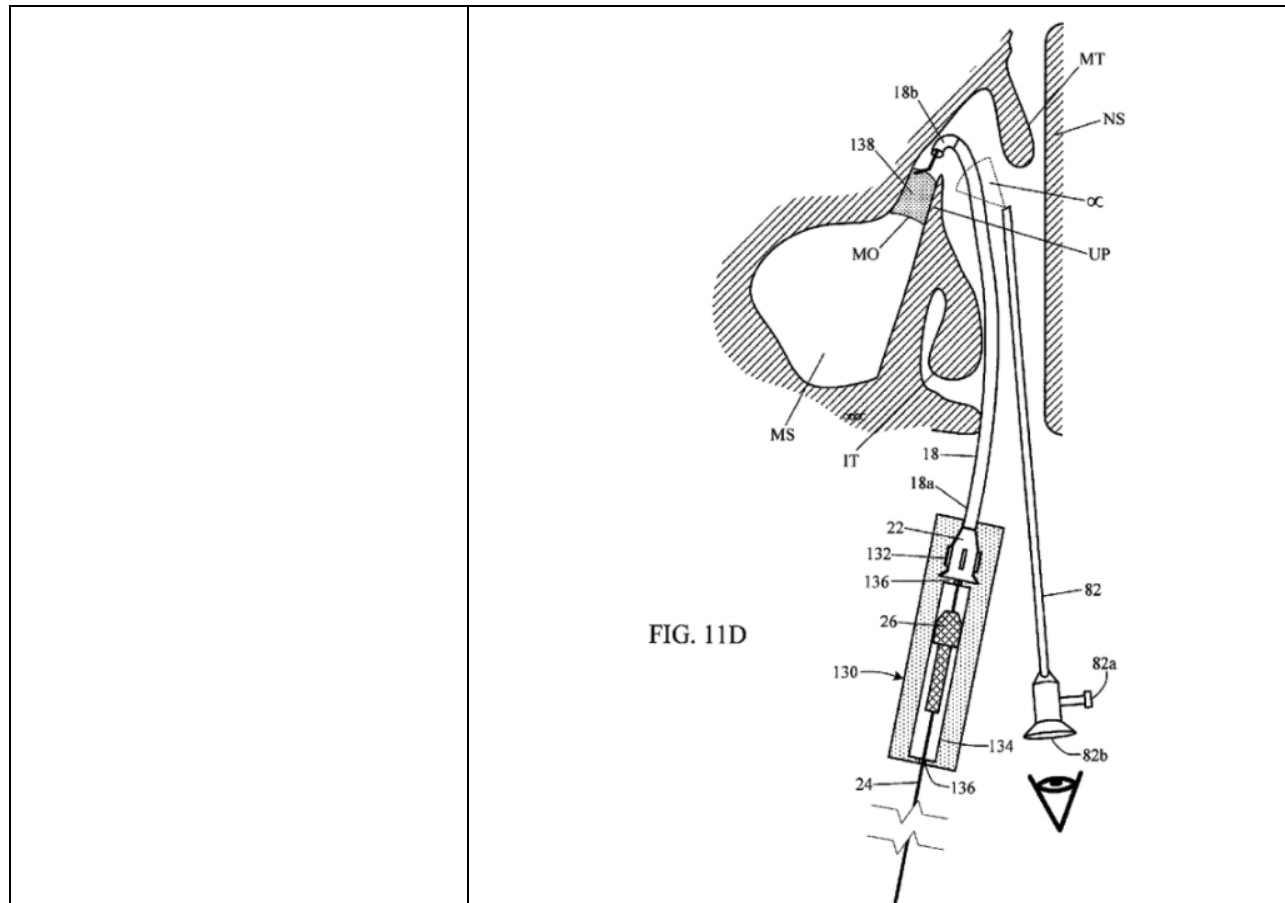
Given a POSA’s knowledge that suction was well known and often required, especially in the field of sinus surgery, there were only a finite number of identified, predictable solutions with a reasonable expectation of success. While a separate suction apparatus could be used, we explain in more detail below in Section XI.A.1.f that both Ressemann and Goldfarb tout devices operable with a single-hand. As such, a POSA would *not* have been motivated to use a separate suction device that would require use of an additional hand, especially considering that the other hand is already in use holding an endoscope. Ex. 1004, ¶ 24. Instead, a POSA would have been motivated to add suction in a manner that continued to allow for single-handed operation of the device. *Id.* The addition of a

suction hole, as taught by Goldfarb, to the handle of Ressemann would allow the user to simply position the thumb or finger of the hand holding the device over the hole to control suction, while simultaneously controlling the position of the guide catheter. A POSA would understand that this would simplify the procedure, and allow for improved visibility. Ex. 1004, ¶ 57.

Accordingly, Ressemann and Goldfarb teach this limitation of claim 8 and provide the requisite motivation to combine. *See also*, Ex. 1004, ¶ 57, and Ex. 1005, ¶ 88.

- d. Limitation: “inserting a working device through a handle opening in a handle coupled to the guide catheter and into the lumen of the guide catheter,”*

inserting a working device through a handle opening in a handle coupled to the guide catheter and into the lumen of the guide catheter;	“[W]ire movement guide 130 may be formed as a recessed handle” that has a “hub recess 132 that is sized to receive the hub 22 of the guide catheter 18 ....” Ressemann, ¶ [0117]; <i>see also</i> Figure 11D (reproduced below showing working device (wire guide 24) inserted through a handle opening (134) in the handle (wire movement guide 130) coupled to the guide catheter 18 and into the lumen of the guide catheter 18).
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Ressemann teaches a “wire movement guide 130 [that] may be formed as a recessed handle or the like.” Ressemann, ¶ [0117], Ex. 1004, ¶58, Ex. 1005, ¶89. The handle (wire movement guide 130) has a “hub recess 132 that is sized to receive the hub 22 of the guide catheter 18,” thereby coupling the handle 130 to the guide catheter 18. *Id.* The handle (wire movement guide 130) “also includes a recess 134 for receiving the steering device 26” that “is secured to the wire guide 24.” *Id.* The recess 134 thus forms the claimed handle opening and the wire guide 24 forms the claimed working device. As shown in Figure 11D, the working

device (wire guide 24) is inserted through the handle opening (recess 134) in the handle 130 coupled to the guide catheter 18 and into the lumen of the guide catheter 18. The distal tip of the working device (wire guide 24) is shown exiting the distal end of the guide catheter 18.

Ressemann therefore teaches this limitation of claim 8. *See also*, Ex. 1004, ¶ 59, and Ex. 1005, ¶¶ 89-90.

*e. Limitation: “controlling a position of the guide catheter ... while substantially simultaneously manipulating the working device ...”*

controlling a position of the guide catheter using the handle that is formed to allow the position of the guide catheter to be controlled by some or all of three fingers of a hand, while substantially simultaneously manipulating the working device with a thumb and index finger of the hand via a portion of the working device immediately adjacent to the handle opening; and	“With the use of a wire movement guide 130, the physician can move the guide catheter 18 into a desired position (preferably with the use of endoscopic imaging, as depicted in FIG. 11D), while <b><i>simultaneously</i></b> advancing and/or rotating the wire guide 24 with a <b><i>single hand</i></b> . For example, the fingers could be manipulating the wire movement guide 130 and therefore the guide catheter 18, while the thumb is able to manipulate the wire guide 24 to a desired position in the nasal cavity or sinus.” Ressemann, ¶ [0119] (emphasis added).
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Ressemann teaches controlling the guide catheter 18 using the handle (wire movement guide 130). Ressemann, ¶ [0119] (“With the use of a wire movement guide 130, the physician can move the guide catheter 18 into a desired position[.]”). Ex. 1004, ¶ 60, Ex. 1004, ¶ 91.

While the remainder of this limitation of Albritton merely recites functional language, Ressemann is not only capable of performing the claimed function, but Ressemann explicitly teaches performing the claimed function. In particular, Ressemann teaches a handle (wire movement guide 130) that is grasped such that the position of the guide catheter 18 is controlled by some or all of three fingers of a hand, and the working device (wire guide 24) is simultaneously manipulated with the thumb of the hand via a portion of the working device (wire guide 24) immediately adjacent to the handle opening (recess 134). *See* Ex. 1004, ¶ 62, Ex. 1004, ¶ 93. Thus, Ressemann would disclose this element under any construction applied to claim 8. Moreover, since the index finger would have supported the handle by applying oppositional force while the thumb would have been manipulating the working device (wire guide 24), under Patent Owner's claim interpretation which Petitioner adopts herein, Ressemann teaches "manipulating the working device with a thumb and index finger of the hand." Ex. 1004, ¶¶ 63-64.

Accordingly, Ressemann teaches this limitation of claim 8 of Albritton. *See also*, Ex. 1004, ¶ 65, and Ex. 1005, ¶¶ 91-95.

*f. Limitation: "controlling the position of the guide catheter ... while substantially simultaneously controlling ... an amount of suction"*

controlling the position of the guide catheter using the handle, while substantially simultaneously controlling, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen.	“[S]ome embodiments may have just a valve and a thumb/finger hole to control the suction force as described above.” Goldfarb, 11:33-35; <i>see also id.</i> 11:6-12 (“a pinch valve or hole can be strategically placed in handle 48 to actuate/allow control of suction or fluid delivery via handle device (e.g., the user may pinch the handle with fingers to restrict flow through handle) or the handle 48 may have a suction hole where the user must cover the suction hole to actuate suction through the optional handle 42.”)
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As explained above, Ressemann does not teach the use of suction, but Goldfarb is an analogous device and provides just one example of a prior art reference that teaches the use of suction. A POSA would have found it obvious to add a suction vent or hole in the handle (wire movement guide 130) of Ressemann, as taught by Goldfarb. *See* Ex. 1004, ¶¶ 66-67; Ex. 1005, ¶¶ 96-97. Such a POSA would have controlled the guide catheter and simultaneously controlled suction with the thumb or index finger of the same hand. *See* Ex. 1004, ¶ 68.

At the outset, both Ressemann and Goldfarb make it clear that single-handed use of the device is desirable. Ressemann explains that “[t]he wire movement guide 130 advantageously permits the physician to use his or her other hand to independently manipulate another tool ...[.]” Ressemann, ¶ [0119]. Ressemann further explains that the “wire movement guide 130 . . . is used to facilitate **one-handed** movement of both the wire guide 24 and the guide catheter 18.” *Id.* at ¶

[0117] (emphasis added). Goldfarb similarly explains that “an optional handle may be attached to the dilation catheter or to a guide catheter through which the dilation catheter is inserted and such handle may be graspable along with another device (e.g., an endoscope) by a *single hand*. In this manner, the operator may control the dilation catheter and another device (e.g., an endoscope) with *one hand* while being free to use his other hand for other purposes.” Goldfarb, 2:45-51 (emphasis added); *see also, id.*, 9:34-37 (“Because the exteriorized portion of the system is substantially rigid and is typically less than 15 cm in length, the operator may use a single hand to hold the endoscope as well as the dilation catheter/guide catheter system.”). In discussing one embodiment of the handle, Goldfarb explains that “[t]he handle 48 serves to facilitate grip and control to manipulate the dilation catheter along with a separate device (e.g., an endoscope or other tool) *without having to use second hand*. In this manner, the user may adjust rotation of a guide catheter while observing under endoscope (*all with one hand*) and use other hand to advance and place the guidewire or other device.” *Id.*, 10:63-11:2 (emphasis added).

Goldfarb further teaches that “a *pinch valve or hole* can be strategically placed in handle 48 to actuate/allow control of suction or fluid delivery via handle device (e.g., the user may pinch the handle with fingers to restrict flow through

handle) or the handle 48 may have a suction hole where the user must cover the suction hole to actuate suction through the optional handle 42.” Goldfarb, 11:6-12 (emphasis added). Goldfarb additionally states that “some embodiments may have just a valve and a thumb/finger hole to control the suction force as described above.” *Id.*, 11:32-34. Thus, Goldfarb provides ample motivation for adding suction to a balloon catheter. Taking into consideration Goldfarb’s desire to grasp and control the guide catheter device using a single hand, in combination with Goldfarb’s teaching of a thumb/finger hole for controlling suction, a POSA would have recognized that Goldfarb teaches a device that allows for *simultaneous* manipulation of the guide catheter while controlling suction using a thumb or finger of the same hand. *See* Ex. 1004, ¶ 68.

A POSA would have found it obvious to modify Ressemann in view of Goldfarb to include a thumb/finger hole in the handle for controlling suction through the lumen of the guide catheter for all of the same reasons set forth above in Section XI.A.1.c. *See also*, Ex. 1004 ¶ 57, and Ex. 1005, ¶ 88. In particular, control of suction using a thumb/finger of a hand holding a device equipped with suction was well known in the art at the time of any invention in Albritton, as explained in the Levine and Kesten Declarations. *See* Ex. 1004, ¶¶ 21-24, and Ex. 1005, ¶¶ 51-53. These types of ports or vents were commonly applied in the field



and described extensively in the prior art. Numerous references, collectively referred to in the Levine and Kesten Declarations as the “suction port references,” disclosed such openings or vents. *See* Ex. 1004, ¶ 69, and Ex. 1005, ¶ 53.

A POSA would have been motivated to add suction to the Ressemann device at least because the use of suction was standard, especially in the field of sinus surgery. *See supra* section XI.A.1.c; *see also* Ex. 1004, ¶ 21. Moreover, Goldfarb suggested the use of suction in a device used for the same type of procedure as Ressemann.

Given a POSA’s knowledge that suction was well known and required, there were only a finite number of identified, predictable solutions with a reasonable expectation of success. Since both Ressemann and Goldfarb disclose similar devices designed to be operated using a single hand, and Goldfarb makes it clear that a thumb/finger hole can be used on such devices for controlling suction, the addition of such a feature to Ressemann would have been obvious and predictable. Ex. 1004, ¶¶ 57 and 66-67; Ex. 1005, ¶ 97. Moreover, the addition of such a suction port would result in substantially simultaneous control of the guide catheter and suction, as required by claim 8. *See* Ex. 1004, ¶ 68.

Accordingly, for all of these reasons as discussed above, claim 8 is invalid under 35 U.S.C. § 103(a) as being obvious over Ressemann in view of Goldfarb.

*See also*, Ex. 1004, ¶ 70, and Ex. 1005, ¶ 98.

## **2. Dependent Claims 11-13**

### *a. Dependent Claim 11*

Claim 11 depends from claim 8 and recites that the opening is a first opening, and wherein controlling the amount of suction comprises controlling the amount of suction coupled to the distal opening of the lumen using a second opening in the opening.

At the outset, Petitioner notes that claim 11 recites a feature (namely, a second opening) that was not disclosed in the provisional application filed on May 16, 2008, and therefore claim 11 has an earliest priority date of May 18, 2009. Goldfarb is thus prior art pursuant to 35 U.S.C. § 102(b) with respect to claim 11, as well as claims 12-13 which depend therefrom.

Petitioner also notes that claim 11 recites “a second opening in the opening.” Petitioner assumes this is a typographical error, and that Albritton intended to recite a second opening *in the handle*, similar to claim 4. To the extent that the Patent Owner asserts otherwise, Petitioner reserves the right to rebut any contrary interpretations.

Petitioner further notes that it is unclear which “opening” of claim 8 the present claim is referring to – the proximal opening, the distal opening, or the

handle opening.

Regardless, as explained above Ressemann discloses a proximal opening, a distal opening, and a handle opening. Any one of these forms a first opening, as required by claim 11. As further explained above with respect to claim 8, it would have been obvious to modify Ressemann to add a “thumb/finger hole to control the suction force,” as taught by Goldfarb. Goldfarb, 11:33-34. The thumb/finger hole would form a second opening used to control suction. *See* Ex. 1004, ¶ 73, and Ex. 1005, ¶ 101.

Accordingly, Ressemann and Goldfarb teach a first opening and a second opening (“thumb/finger hole”) in the handle for controlling an amount of suction using a thumb or finger, as required by claim 11.

Claim 11 is therefore invalid under 35 U.S.C. § 103(a) as being obvious over Ressemann in view of Goldfarb. *See also*, Ex. 1004, ¶ 74, and Ex. 1005, ¶ 102.

*b. Dependent Claim 12*

Claim 12 depends from claim 11 and recites that the second opening is positioned in a path of a flow of suction between the distal opening of the guide catheter and the source of suction.

The second opening, i.e., the thumb port, in Ressemann (as modified in view of Goldfarb) would have had to be positioned in a path of a flow of suction

between the distal opening of the guide catheter and the source of suction, as required by claim 12. Such a configuration would have been required in order to allow an amount of suction to be controlled. *See also*, Ex. 1004, ¶ 76, and Ex. 1005, ¶ 104.

Claim 12 is therefore invalid under 35 U.S.C. § 103(a) as being obvious over Ressemann in view of Goldfarb. Ex. 1004, ¶ 77, and Ex. 1005, ¶ 105.

*c. Dependent Claim 13*

Claim 13 depends from claim 11 and recites coupling the handle to the guide catheter.

Resseman teaches a hub recess 132 for seating the hub on the guide catheter. Ressemann, ¶ [0117] (“In a preferred embodiment, the recessed handle 130 includes a hub recess 132 that is sized to receive the hub 22 of the guide catheter 18. For example, the hub recess 132 may be sized to frictionally secure the hub 22 within the same. Alternatively, one or more detents, tabs, or the like may be positioned on the hub recess 132 and/or hub 22 to releasably secure wire movement guide to the hub 22 of the guide catheter 18.”). Since the hub on the guide catheter is *releasably secured* within the hub recess in the handle 130, Ressemann teaches coupling the handle to the guide catheter. Ex. 1004, ¶ 79; Ex. 1005, ¶ 107.

Claim 13 is therefore invalid under 35 U.S.C. § 103(a) as being obvious over Ressemann in view of Goldfarb. *See also*, Ex. 1004, ¶ 80, and Ex. 1005, ¶ 108.

In sum, claims 8 and 11-13 should be found to be invalid pursuant to 35 U.S.C. § 103(a) as being obvious over Ressemann in view of Goldfarb.

**B. Ground II – Claims 8-13 Are Obvious Over Makower in view of Jones**

**1. Independent Claim 8**

As demonstrated below, Makower in view of Jones provides another example of prior art that renders invalid claim 8 of Albritton. *See also*, Ex. 1004, ¶¶ 81-84 and 105, and Ex. 1005, ¶¶ 109-112.

*a. Limitation: “A method, comprising:”*

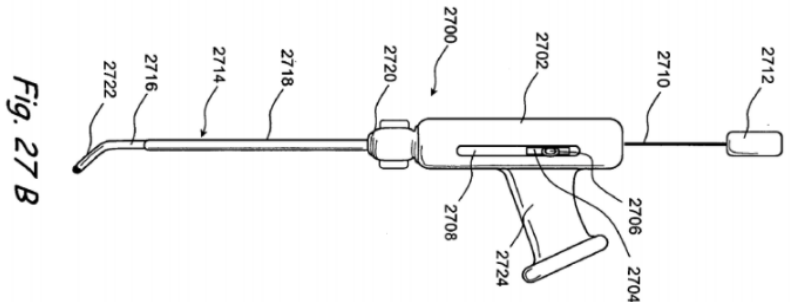
8. A method comprising:	<i>See, e.g.</i> , Makower, Abstract (“Methods and apparatus for treating disorders of the ear, nose, throat or paranasal sinuses.”). “FIGS. 27C through 27D show various steps of a method of dilating an anatomical region using the surgical hand tool shown in FIGS. 27A and 27B.” <i>Id.</i> at ¶ [0222].
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To the extent the preamble is considered to be a limitation of the claim, Makower discloses a method. *See also*, Ex. 1004, ¶ 85, and Ex. 1005, ¶ 113.

*b. Limitation: “inserting a guide catheter ...”*

inserting a guide catheter through an external body passage of a subject, wherein the guide catheter	“Surgical hand tool 2700 is positioned such that the distal tip of surgical hand tool 2700 is located near an anatomical region to be accessed.” Makower, ¶ [0223]; <i>see also</i> , Fig. 27B (reproduced below).
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comprises a substantially rigid shaft, a proximal opening, a distal opening and a lumen extending between the proximal opening and the distal opening;



“[G]uide catheter 2714 comprises an elongate tubular element 2716 .... The proximal region of tubular element 2716 may be covered by a hypotube 2718 made of ... metals ....” Makower, ¶ [0222].

Makower discloses “endoscopic guide systems that generally comprise tubular guides (e.g., rigid, flexible and/or malleable guide catheters) ....”

Makower, ¶ [0009]. “[S]uch guide systems are used to facilitate trans-nasal advancement of a guidewire, catheter, instrument or other device to a position within or near an opening or a paranasal sinus (e.g., any transnasally accessible opening ...).” *Id.* Makower therefore discloses a substantially rigid guide catheter that is inserted through an external body passage of a subject. Ex. 1004, ¶¶ 87-88, Ex. 1005, ¶¶ 114-16. Since the guide catheter is an elongate tubular element, and receives a guidewire and balloon catheter therethrough, as shown in Figure 27B, the guide catheter 2714 has a proximal opening, a distal opening, and a lumen extending between the proximal opening and the distal opening. Ex. 1004, ¶ 89, and Ex. 1005, ¶ 117.

Accordingly, Makower teaches the guide catheter inserting step of claim 8.

See also, Ex. 1004, ¶ 90, and Ex. 1005, ¶ 118.

*c. Limitation: “coupling a source of suction to the lumen through the handle”*

coupling a source of suction to the lumen through the handle;	“Any of the guide catheters or other luminal devices disclosed herein may comprise an arrangement for suctioning an anatomical region through the distal end of the guide catheter or device unless to do so would render the device unuseable for its intended purpose.” Makower, ¶ [0167].
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At the outset, this limitation refers to “the handle,” however there is no antecedent basis for the handle. For purposes of this Petition, we assume that claim 8 should read “a handle.”

Figure 27B of Makower illustrates a surgical hand tool that includes an elongate body 2702 and a handle 2724, which together form the claimed handle. Makower explains that “[i]n embodiments where the catheter or other balloon equipped device has a lumen useable for passage of a guidewire or other device or substance, the inflator handpiece device may incorporate a port or passage to permit a guidewire or other device to be advanced through that lumen and/or to permit fluids to be infused or suction applied through that lumen.” Makower, ¶ [0016]. Since Makower teaches that any of the guide catheters can include an arrangement for suctioning an anatomical region, and that the handpiece device

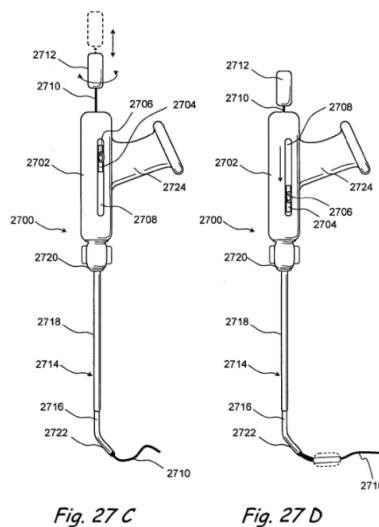
may incorporate a port for suction, Makower therefore teaches coupling a source of suction to lumen through the handle. Ex. 1004, ¶ 91, Ex. 1005, ¶ 120.

Accordingly, Makower teaches this limitation of claim 8. *See also*, Ex. 1004, ¶ 91, and Ex. 1005, ¶ 121.

- d. *Limitation: “inserting a working device through a handle opening in a handle coupled to the guide catheter and into the lumen of the guide catheter,”*

inserting a working device through a handle opening in a handle coupled to the guide catheter and into the lumen of the guide catheter;

“Surgical hand tool 2700 is positioned such that the distal tip of surgical hand tool 2700 is located near an anatomical region to be accessed. Thereafter, a guidewire 2710 is introduced through surgical hand tool 2700 such that the distal tip of guidewire 2710 is located near an anatomical region to be accessed.... Thereafter, in FIG. 27D, balloon catheter 2704 is advanced over guidewire 2710 into the anatomy.” Makower, ¶ [0223]; *see also*, Figures 27C and 27D, reproduced below.





Makower explains that the surgical hand tool 2700 shown in Figure 27A-27D comprises a hollow proximal body 2702 having a handle 2724. *See* Makower, ¶ [0224]. As previously explained herein, the body 2702 and handle 2724 form the claimed handle. Since the body 2702 is hollow, Makower discloses a handle having a handle opening. Ex. 1004, ¶ 92, Ex. 1005, ¶ 123.

As noted above, Makower further teaches introducing a guidewire 2710 through the surgical hand tool 2700, and also advancing a balloon catheter 2704 over the guidewire. This is illustrated in Figures 27C and 27D above, which show both the guidewire and the balloon catheter being advanced through the handle and guide catheter. Accordingly, the guidewire and the balloon catheter are both working devices that are inserted through a handle opening in the handle and through a lumen of the guide catheter coupled to the handle. Ex. 1004, ¶ 93, Ex. 1005, ¶ 124.

Makower therefore teaches this limitation of claim 8. *See also*, Ex. 1004, ¶ 94, and Ex. 1005, ¶ 124.

*e. Limitation: “controlling a position of the guide catheter ... while substantially simultaneously manipulating the working device ...”*

controlling a position of the guide catheter using the handle that is formed to allow the position of the guide catheter to be controlled by some or all	“[T]here are provided inflator handpiece devices that are ... configured to be <b><i>useable by a single hand</i></b> , thereby freeing the operators other hand for
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of three fingers of a hand, while substantially simultaneously manipulating the working device with a thumb and index finger of the hand via a portion of the working device immediately adjacent to the handle opening; and	handling of other instruments or performing other tasks.” Makower, ¶ [0016]. “[I]n FIG. 27D, balloon catheter 2704 is advanced over guidewire 2710 into the anatomy. This is done by pushing balloon inflation port 2706 in the distal direction.” <i>Id.</i> ¶ [0223].
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Since Makower teaches a hand piece, e.g., hand tool 2700, formed in the shape of a pistol that is intended to be used by a single hand, and Makower teaches that surgical hand tool 2700 (and thus the guide catheter 2714 of the hand tool) is “positioned such that the distal tip of surgical hand tool 2700 is located near an anatomical region to be accessed,” Makower therefore teaches controlling a position of the guide catheter 2714 using the handle. Makower, ¶ [0223].

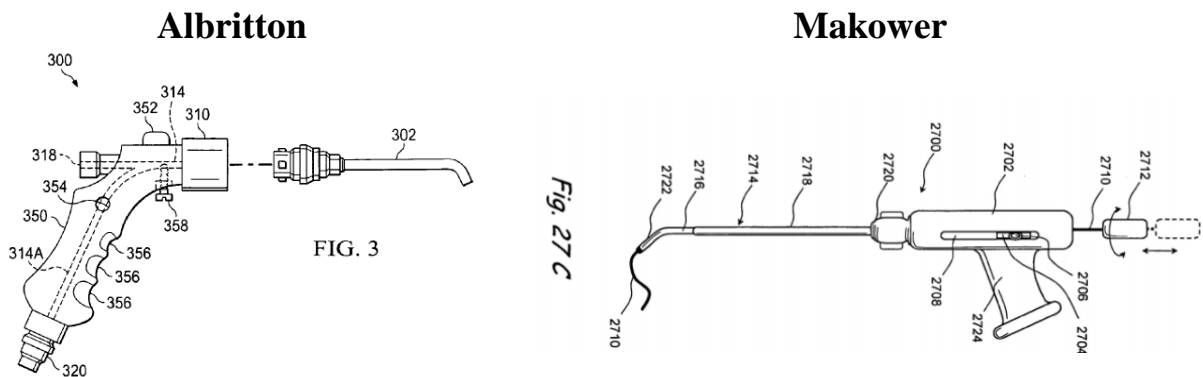
While the remainder of this limitation is merely functional language, Makower teaches that the handle is “formed to allow” the position of the guide catheter to be controlled by some or all of three fingers of a hand, while substantially simultaneously manipulating the working device with a thumb and index finger of the hand via a portion of the working device immediately adjacent to the handle opening. In fact, not only is Makower’s pistol-grip handle *capable* of performing the claimed function, Makower’s handle has the same structure as the one disclosed by Albritton and was designed to perform the claimed function. Ex. 1004, ¶¶ 96-99, Ex. 1005, ¶ 109. Thus, Makower would disclose this element even

if a narrower interpretation is applied.

Since hand tool 2700 has a pistol-style configuration and is intended to be held by a single hand of a user, a POSA would have positioned some or all of three fingers of a hand around the handle 2724 to control the position of the guide catheter 2714. *See* Ex. 1004, ¶ 96, Ex. 1005, ¶ 126. A POSA would have also substantially simultaneously controlled a working device with the thumb and index finger of the same hand holding the device. *See* Ex. 1004, ¶ 97, Ex. 1005, ¶ 127. For example, Makower explains that the inflation port 2706 on the balloon catheter 2704 emerges through a slit 2708 formed in a side of the body, and is pushed in a distal direction to advance the balloon catheter. *See* Makower, ¶ [0223]. A POSA would have used one of the thumb or index finger of the hand holding the device to provide oppositional support to the handle, while the other one of the thumb or index finger is used to push the inflation port 2706 on the balloon catheter 2704. *See id.*, ¶ [0222]; *see also* Ex. 1004, ¶ 97, Ex. 1005, ¶ 127. Such control of the working device (balloon catheter) would have been done while holding and controlling the position of the guide catheter 2714, and thus would be done “substantially simultaneously.” *See* Ex. 1004, ¶ 97, Ex. 1005, ¶ 128. Moreover, since the inflation port 2706 extends from the handle opening in the hollow proximal body 2702, the user would have manipulated the working device (balloon

catheter) “immediately adjacent to the handle opening,” as further required by claim 8.

Similarly, a user could have manipulated the guide wire using the thumb and index finger of the hand holding the device. Makower explains that the guidewire includes a torqueing device 2712 and that “[a] user can use torqueing device 2712 to rotate, advance, retract, or torque the guidewire 2710.” Makower, ¶ [0222]. Since Makower’s handpieces are designed for single handed use, as noted above, a POSA could have used the thumb and index finger of the hand holding the device to grasp and control the torqueing device 2712 on the guidewire. Ex. 1004, ¶ 98; Ex. 1004, ¶ 129. This is especially evident when comparing the Makower device to the Albritton device, as follows:



As shown in Figure 27C of Makower, reproduced above, Makower’s pistol-grip handle has a structure that is similar to the structure of Albritton’s handle, shown in Figure 3 of Albritton (both reproduced above). To the extent that

Albritton's handle is "formed to allow" the guide catheter and working device to be controlled as claimed, then Makower's similar handle must likewise be "formed to allow" the guide catheter and working device to be controlled in the claimed manner. *See* Ex. 1004, ¶ 99; Ex. 1004, ¶ 130.

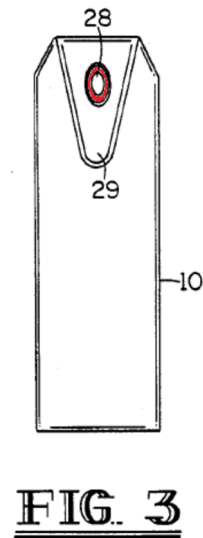
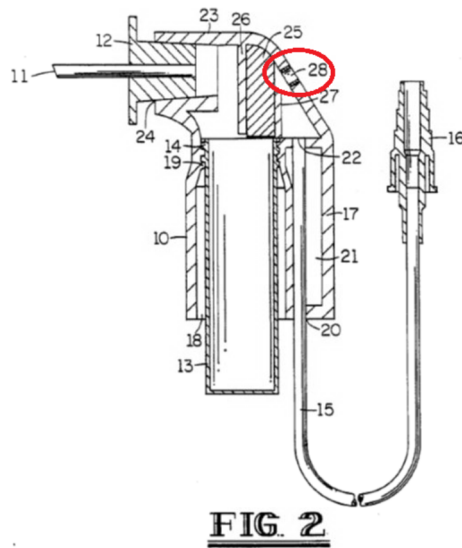
Accordingly, Makower teaches this limitation of claim 8 of Albritton. *See also*, Ex. 1004, ¶ 100, and Ex. 1005, ¶ 131.

*f. Limitation: "controlling the position of the guide catheter ... while substantially simultaneously controlling ... an amount of suction"*

controlling the position of the guide catheter using the handle, while substantially simultaneously controlling, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen.	Jones discloses a "thumb control hole 28 [that] may be partially closed off with one's thumb or fully closed off to vary the amount of suction that is applied through the catheter 11." Jones, 4:35-38.
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As noted above, Makower explains that any of the guide catheters can include an arrangement for suctioning an anatomical region through the distal end of the guide catheter. *See* Makower, ¶ [0167] and ¶ [0170]. Thus, Makower itself provides a suggestion or reason for adding suction. Jones provides one example of a prior art reference that teaches a well-known method for controlling suction. In particular, Jones discloses a medical aspiration device for use in surgical procedures that includes "a body member that has a pistol grip-like shape to

conveniently fit and be held and operated in one hand of a clinician.” Jones, 3:17-19. As shown in Figures 2 and 3 below (reproduced with markings), the handle includes a “thumb control hole 28 [that] may be partially closed off with one’s thumb or fully closed off to vary the amount of suction that is applied through the catheter 11.” *Id.*, 4:35-38.



Jones explains in the “Background” section that “suctioning, or the aspiration of body fluids in medical surgico-clinical procedures, is a critical, but necessary, routine occurrence ....” Jones, 1:26-28. “Most of the diverse tools that are currently utilized for suctioning body fluids in conjunction with mechanically produced vacuum (wall suction) use a thumb control or a finger-tip control as an add on to the plumbing ....” Jones, 2:5-8. Jones further explains that “[o]ne hand is generally necessary to regulate the amount of suction being delivered and the

other hand is usually used to manipulate the direction and placement of the catheter within the patient.” *Id.*, 2:9-13. Jones solves this problem by providing a suctioning device that “can be held and operated with one hand,” and that can “accurately vary the amount of suction through a catheter by means of a conveniently located thumb control port.” *Id.*, 2:49-50 and 2:52-54.

While Makower does not explicitly teach controlling suction with the thumb or index finger of the same hand holding and controlling the guide catheter, it would have been obvious to a POSA at the time of Albritton to include a suction hole in the handle at a location that would allow for control using the thumb, as taught by Jones. *See* Ex. 1004, ¶ 104, Ex. 1005, ¶ 132. The addition of a thumb hole in the handle would have necessarily resulted in the user controlling the guide catheter while simultaneously controlling, by the thumb, an amount of suction coupled to the distal opening of the lumen. *See* Ex. 1004, ¶ 103.

Jones provides both the missing element and method (an opening controlled using the thumb of a single hand) and an additional reason for a POSA to have made the modification to Makower (to remove fluids), which would have been routine. *See* Ex. 1004, ¶ 102, Ex. 1005, ¶ 134.

Any control of suction using a thumb/finger of a hand holding a device while simultaneously manipulating the device was also well known in the art at the

time of any invention in Albritton. As explained in the Levine and Kesten Declarations, the use of ports or vents to control suction would have been well known to a POSA long before the time of the purported invention in Albritton. *See* Ex. 1004, ¶¶ 23-24, and Ex. 1005, ¶ 53. Suction ports or vents were commonly applied in the field and well described in the prior art. Numerous references, collectively referred to in the Levine and Kesten Declarations as the “suction port references,” disclosed such openings or vents. *See* Ex. 1004, ¶ 69, and Ex. 1005, ¶¶ 53-61.

In conclusion, for all of these reasons discussed above, claim 8 is invalid under 35 U.S.C. § 103(a) as being obvious over Makower in view of Jones. *See* Ex. 1004, ¶ 105, and Ex. 1005, ¶ 137.

## **2. Dependent Claims 9-13**

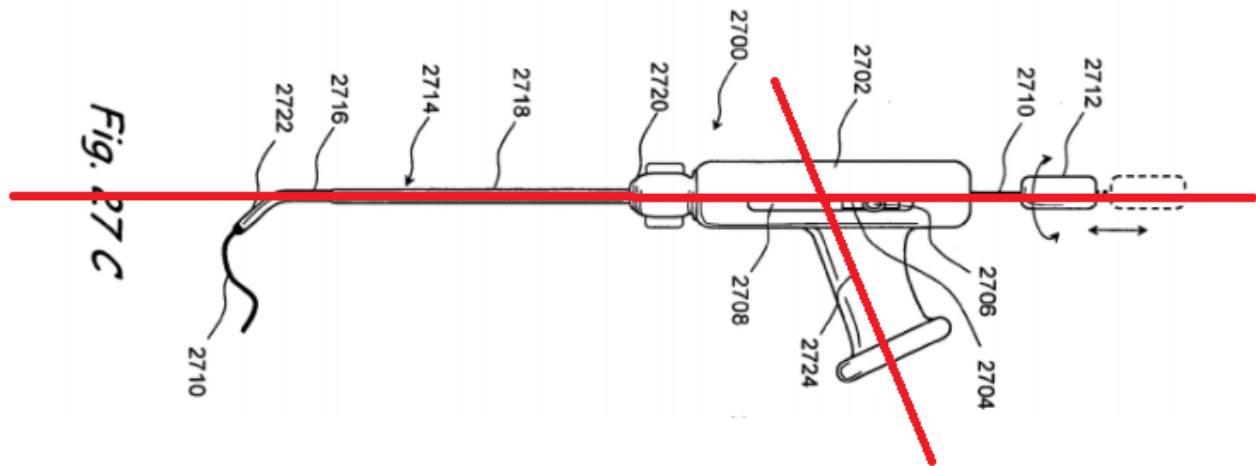
### *a. Dependent Claim 9*

Claim 9 depends from claim 8 and recites that a longitudinal axis of the handle forms an angle with a longitudinal axis of the guide catheter of less than ninety degrees and more than zero degrees.

Makower’s handle has a longitudinal axis that forms an angle with a longitudinal axis of the guide catheter of less than ninety degrees and more than zero degrees, as required by claim 9. *See* Ex. 1004, ¶ 106, and Ex. 1005, ¶ 138.



Figure 27C, reproduced below with markings, illustrates the angle.



Claim 9 is therefore invalid under 35 U.S.C. § 103(a) as being obvious over Makower in view of Jones. *See* Ex. 1004, ¶ 107, and Ex. 1005, ¶ 140.

*b. Dependent Claim 10*

Claim 10 depends from claim 8 and recites adjusting an angle between a longitudinal axis of the handle and a longitudinal axis of the guide catheter to a desired angle using a pivot on the handle.

As shown in Figure 6, reproduced below, Albritton discloses a lower portion of the handle and a “pivot 652 [that] allows the handle 650 to be rotated to a desired angular position relative to the upper portion and locked into a desired position.” Ex. 1001, 5:44-46.

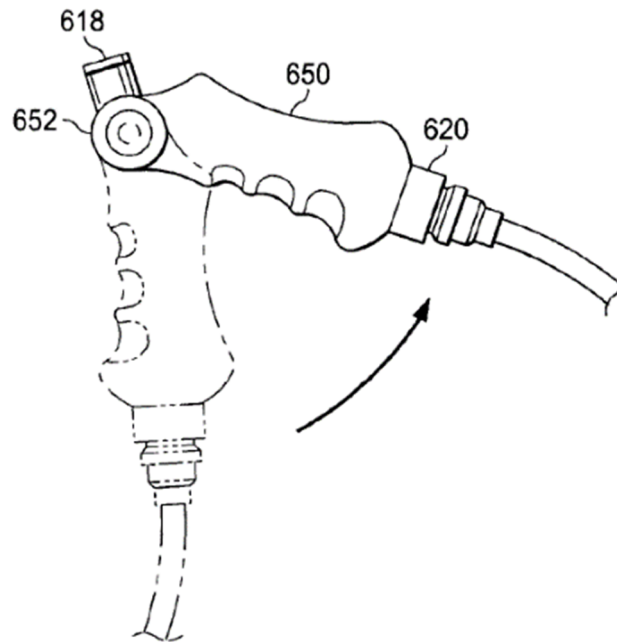
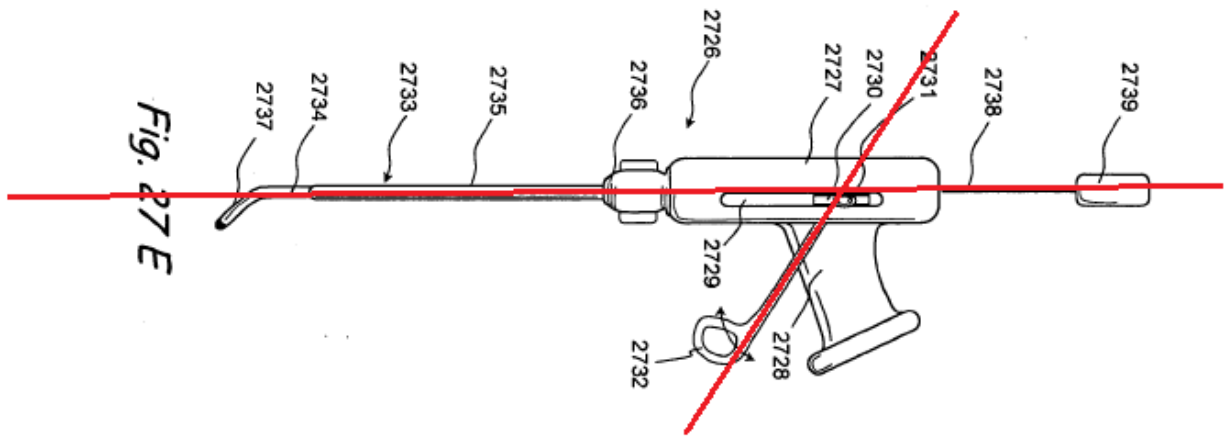


FIG. 6

Figure 6 thus illustrates a lower portion of the handle having a longitudinal axis that can be adjusted relative to a longitudinal axis of a guide catheter (not shown). Accordingly, when read in light of the specification, it is clear that the “longitudinal axis” of the handle is not the central longitudinal axis extending from the proximal end to the distal end, i.e., along the lumen, but instead can be any longitudinal axis of the handle.

Figure 27E of Makower illustrates a further embodiment of the surgical hand tool. As shown in Figure 27E, reproduced below with markings, the trigger 2732 defines a longitudinal axis of the handle that is adjustable about a pivot. *See* Makower, ¶ [0224] (“Trigger 2732 is pivoted on elongate body 2727 ...”).

Makower also states that “[a]ny of the handle assemblies of the tools described herein ... may comprise a rotatable handle,” citing to U.S. Patent No. 5,697,159 of Linden (attached hereto as Ex. 1011), which teaches pivotable joints for movement of a handle. *See* Ex. 1011, Abstract.



Accordingly, Makower teaches moving the trigger, which will adjust an angle between the longitudinal axis of the handle (i.e., of the trigger 2732 of the handle) and a longitudinal axis of the guide catheter to a desired angle using the pivot on the handle. Ex. 1005, ¶ 142.

Claim 10 is therefore invalid under 35 U.S.C. § 103(a) as being obvious over Makower in view of Jones. *See* Ex. 1004, ¶ 110, and Ex. 1005, ¶ 144.

*c. Dependent Claim 11*

Claim 11 depends from claim 8 and recites that the opening is a first

opening, and wherein controlling the amount of suction comprises controlling the amount of suction coupled to the distal opening of the lumen using a second opening in the opening.

At the outset, Petitioner again notes that claim 11 recites a feature (namely, a second opening) that was not disclosed in the provisional application filed on May 16, 2008, and therefore claim 11 has an earliest priority date of May 18, 2009. Goldfarb is thus prior art pursuant to 35 U.S.C. § 102(b) with respect to claim 11, as well as claims 12-13 which depend therefrom.

Petitioner also again notes that claim 11 recites “a second opening in the opening.” As previously discussed, Petitioner assumes this is a typographical error, and that Albritton intended to recite a second opening *in the handle*, similar to claim 4. To the extent that the Patent Owner asserts otherwise, Petitioner reserves the right to rebut any contrary interpretations.

As also discussed previously, Petitioner notes that it is unclear which “opening” of claim 8 the present claim is referring to – the proximal opening, the distal opening, or the handle opening.

Regardless, as explained above Makower discloses a proximal opening, a distal opening, and a handle opening. Any one of these forms a first opening, as required by claim 11. As further explained above with respect to claim 8, it would

have been obvious to modify Makower to add a “thumb control hole 28 [that] may be partially closed off with one’s thumb or fully closed off to vary the amount of suction that is applied through the catheter 11,” as taught by Jones. Jones, 4:35-38. The thumb/finger hole would form a second opening used to control suction. *See* Ex. 1004, ¶ 112, and Ex. 1005, ¶ 146.

Accordingly, Makower and Jones therefore teach a first opening, and a second opening (“thumb control hole”) in the handle for controlling an amount of suction using a thumb or finger, as required by claim 11.

Claim 11 is therefore invalid under 35 U.S.C. § 103(a) as being obvious over Makower in view of Jones. *See* Ex. 1004, ¶ 113, and Ex. 1005, ¶ 147.

*d. Dependent Claim 12*

Claim 12 depends from claim 11 and recites that the second opening is positioned in a path of a flow of suction between the distal opening of the guide catheter and the source of suction.

The second opening, i.e., the thumb port, in Makower (as modified in view of Jones) would necessarily have been positioned in a path of a flow of suction between the distal opening of the guide catheter and the source of suction, as required by claim 12. Such a configuration would have been required in order to allow an amount of suction to be controlled. *See* Ex. 1004, ¶ 115, and Ex. 1005, ¶

149.

Claim 12 is therefore invalid under 35 U.S.C. § 103(a) as being obvious over Makower in view of Jones. Ex. 1004, ¶ 116, and Ex. 1005, ¶ 150.

*e. Dependent Claim 13*

Claim 13 depends from claim 11 and recites coupling the handle to the guide catheter.

Makower explains that the “distal region of proximal body 2702 comprises a suitable hub that allows a guide catheter 2714 to attach to proximal body 2702.” Makower, ¶ [0222]. Makower further explains that “[h]ub 2720 allows the reversible attachment of guide catheter 2714 to proximal body 2702. In one embodiment, hub 2720 is a female luer lock that [is] attached to a suitable hub on proximal body 2702. Thus, various guide catheters can be attached to the distal region of proximal body 2702 to provide access to various anatomical regions.” *Id.* Accordingly, Makower discloses coupling the handle to the guide catheter. Ex. 1004, ¶ 118, and Ex. 1005, ¶ 152.

Claim 13 is therefore invalid under 35 U.S.C. § 103(a) as being obvious over Makower in view of Jones. Ex. 1004, ¶ 119, and Ex. 1005, ¶ 153.

## **XII. CONCLUSION**

For the foregoing reasons, Petitioner respectfully requests that Trial be instituted and that claims 8-13 of Albritton be canceled.

December 1, 2017

Respectfully submitted,

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**CERTIFICATE OF WORD COUNT**

Pursuant to 37 C.F.R. §42.24(d), Petitioner hereby certifies, in reliance on the word count of the word-processing system (Microsoft Office Word 2010) used to prepare this this petition, that the number of words in this paper is 11,871. This word count excludes the tables of contents, tables of authorities, grounds for standing, mandatory notices, certificate of word count, certificate of service, and list of exhibits.

Dated: December 1, 2017

/Lisa Adams/  
Lisa Adams, Reg. No. 44,238



**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing Petition for *Inter Partes Review* and all accompanying exhibits were served on December 1, 2017 by sending a copy by overnight courier, and electronic service by email where indicated, to:

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