WILLIAM C. ROOKLIDGE, SBN 134483
wrooklidge@gibsondunn.com
FRANK P. COTÉ, SBN 204529
fcote@gibsondunn.com
GIBSON, DUNN & CRUTCHER LLP
3161 Michelson Drive
Irvine, CA 92612-4412
Telephone: 949.451.3800
Facsimile: 949.451.4220

Attorneys for Plaintiff ACCLARENT, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

ACCLARENT, INC.,

Plaintiff,

v.

FORD ALBRITTON IV,

Defendant.

CASE NO. 5:16-cv-06919

**COMPLAINT FOR BREACH OF CONTRACT AND FOR DECLARATORY JUDGMENT FOR PATENT OWNERSHIP, DERIVATION, EQUITABLE ESTOPPEL, NONINFRINGEMENT, AND INVALIDITY OF U.S. PATENT NO. 9,011,412**

Plaintiff Acclarent, Inc. ("Acclarent") makes the following claims against Defendant Ford D. Albritton IV, M.D. ("Albritton"):

## NATURE OF THE ACTION

1. This is an action for breach of contract and declaratory judgment regarding patent ownership, derivation, equitable estoppel, noninfringement, and invalidity arising under California contract law and the patent laws of the United States, Title 35 of the United States Code. Acclarent requests this relief because Albritton has claimed and continues to claim that Acclarent infringes United States Patent No. 9,022,412 ("the '412 Patent") by making, using, selling, and/or offering for sale certain medical devices developed, produced, and sold by Acclarent. Albritton is contractually required to assign the '412 Patent to Acclarent. Further, Acclarent seeks declaratory judgment that it is the rightful owner of the '412 Patent by assignment, that Albritton derived many of the '412

Patent's claims from Acclarent, that the '412 Patent is unenforceable against Acclarent due to equitable estoppel, that Acclarent does not infringe the '412 Patent, and that the claims of the '412 Patent are invalid. In an attempt to resolve their dispute regarding the '412 Patent, the parties entered into a tolling and standstill agreement, but the parties' resolution efforts were not successful and the agreement expired on December 1, 2016, at 11:00 AM Pacific. Albritton's infringement allegations create a justiciable controversy between Acclarent and Albritton that the Court should resolve in Acclarent's favor.

## THE PARTIES

2. Plaintiff Acclarent, Inc. is a Delaware corporation with its principal place of business at 33 Technology Drive, Irvine, California 92618. Acclarent was founded in 2004, and it develops technology in the Otolaryngology (ear, nose and throat) medical field. Acclarent's products include, for example, balloon catheter systems that may be used to dilate a patient's sinuses. Prior to 2016, Acclarent's principal place of business was 1525 O'Brien Drive, Menlo Park, California 94025.

3. On information and belief, Defendant Albritton is a medical doctor and consultant specializing in Otolaryngology who maintains an office in Dallas, Texas.

## JURISDICTION AND VENUE

4. This action arises under the Declaratory Judgment Act, 28 U.S.C. § 2201; under the patent laws of the United States, 35 U.S.C. §§ 1-390; and under the laws governing contracts in the State of California.

5. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a). In addition, diversity jurisdiction exists pursuant to 28 U.S.C. § 1332 because (a) Acclarent is a California corporation whose principal place of business is Irvine, California; (b) Albritton is an individual whose principal place of business is, on information and belief, Dallas, Texas; and (c) the amount in controversy exceeds $75,000.

6. This Court has personal jurisdiction over Albritton. Albritton has continuous and systematic business contacts with California and this District since at least June 2008, when he began working as a consultant for Acclarent, Inc., a California corporation, pursuant to a consultancy agreement "governed by the laws of California." In support of his consulting services, Albritton has

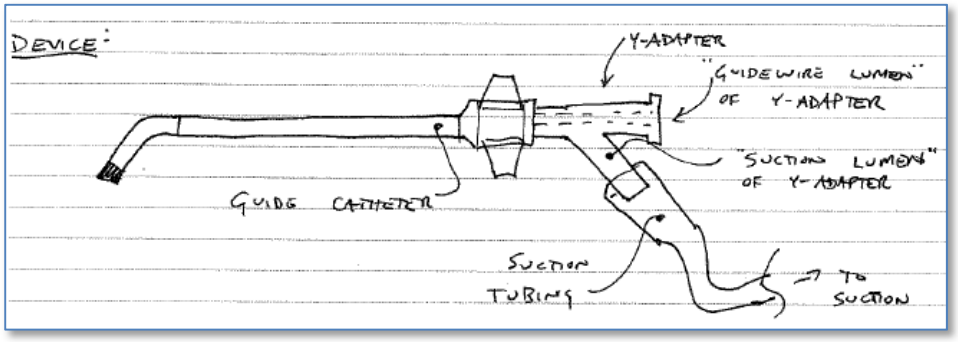
visited Acclarent in Menlo Park, California.

7. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c) because a substantial part of the events giving rise to Acclarent's claims occurred in this District, because Albritton is subject to personal jurisdiction here, and because the consulting agreement that underlies Acclarent's breach of contract claim is governed by the laws of the State of California.

8. An immediate, real, and justiciable controversy exists between Acclarent and Albritton as to whether Albritton breached his consulting agreement, who owns the '412 Patent; whether Albritton derived any claimed inventions from Acclarent; whether Albritton is equitably estopped from asserting the '412 Patent against Acclarent; whether Acclarent infringes the '412 Patent; and whether the '412 Patent is invalid.

## FACTUAL BACKGROUND

9. On or about July 24, 2006, John Morriss, who was then an Acclarent employee, recorded in his laboratory notebook drawings for a guide catheter system with a suction adapter. As shown below, the laboratory notebook disclosed a system with a "Y-adapter," wherein one branch of the Y-adapter includes a guidewire lumen and the other branch connects to suction tubing.




10. As shown below, Mr. Morriss's lab notebook contained an entry for the same day that shows how Acclarent's design contemplated using fingers on one hand to hold the catheter in place, while leaving the thumb and index finger of the same hand free for manipulation, e.g., using the thumb to create suction by occluding the guide lumen.

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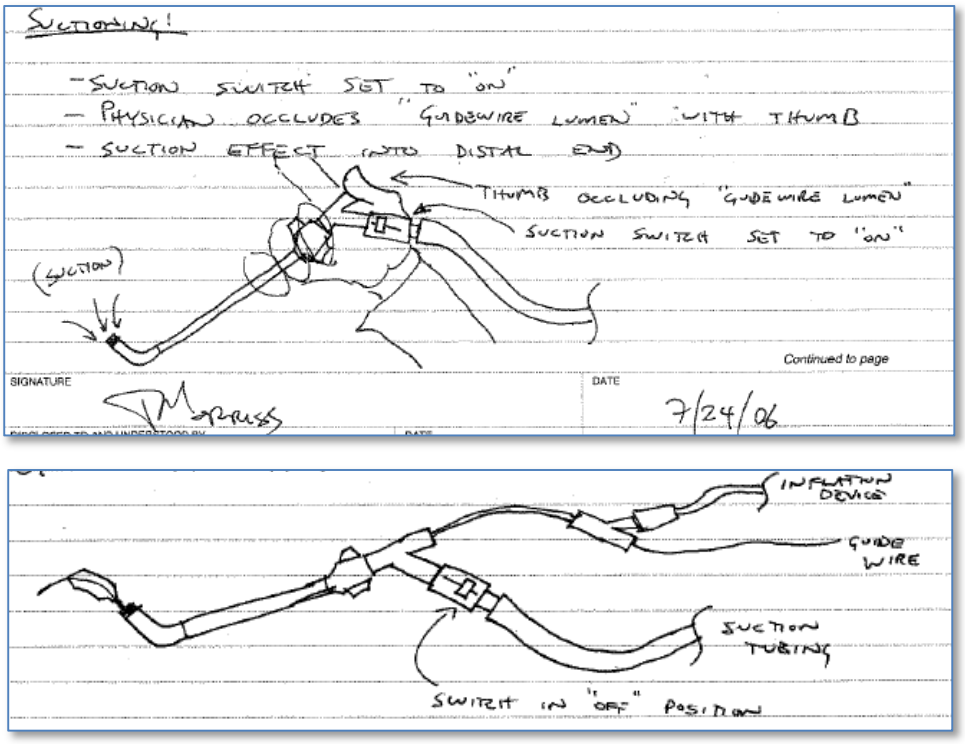
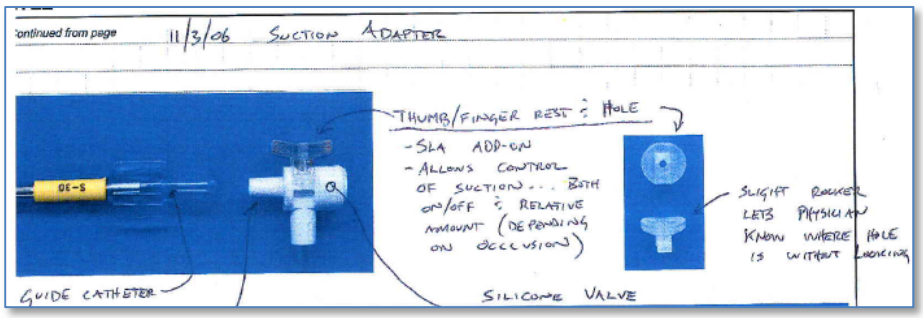



11. On or about November 3, 2006, Mr. Morriss recorded in his lab notebook evidence of development and testing efforts at Acclarent. As shown below, Mr. Morriss's work included modifying his July 2006 Y-adapter design to include a finger/thumb rest with a hole in it for controlling suction, wherein the suction-control hole is separate from the opening for receiving working devices such as guidewires.




12. On or about June 12, 2007, Albritton and Acclarent entered into a Mutual Non-Disclosure Agreement ("NDA") in which the parties agreed to protect the secrecy of one another's Confidential Information. The NDA provides, *inter alia*, that "Confidential Information shall not … include any information which … is already in the possession of the receiving party at the time of disclosure by the disclosing party as shown by the receiving party's files and records immediately

prior to the time of disclosure." On information and belief, Albritton and Acclarent discussed guide catheter designs utilizing suction and a Y-adapter in 2007 and early 2008 pursuant to the NDA, but did not discuss any such designs before entering into the NDA.

13. On or about May 16, 2008, Albritton, along with Bryan Lunsford, filed with the U.S. Patent Office a provisional patent application, No. 61/127,848, for an "Apparatus, System and Method for Controlling the Position of and Providing Suction in a Surgical Catheter or Guide." The provisional application's claims do not recite any particular structure or method steps; they were instead directed to a system, apparatus, method, and product "incorporating every feature shown and described" in the provisional application. Like the 2006 Acclarent design, the provisional application (as shown in the figures reproduced below) discloses a guide catheter system with suction that featured a Y-adapter, the ability to control suction by occluding the guide lumen with a thumb, and a handle design in which a user's thumb and index finger were free to manipulate working objects while other fingers of the same hand grasp the handle. The provisional application discloses controlling suction by blocking the hole that receives working devices (e.g., hole 216 or 318 below). The provisional application does not disclose, however, a second hole in the handle for controlling suction.

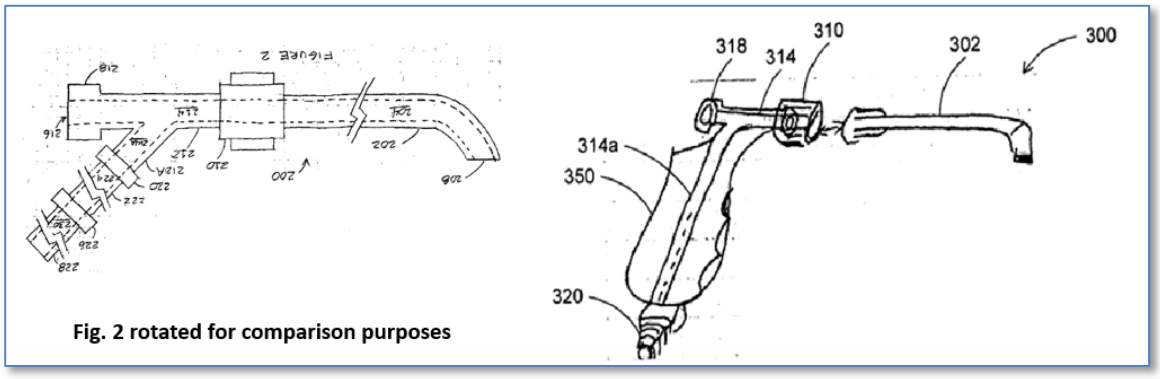



Fig. 2 rotated for comparison purposes

14. On or about May 19, 2008, Albritton had a discussion with then Acclarent employee Serena Swei, which Ms. Swei memorialized in a May 27, 2008 email to Albritton. Ms. Swei's email explains that she provided confidential information to Albritton at the May 19, 2008 meeting that "was generally related to the integration of suction with a sinus guide catheter—an invention conceived by Acclarent several years ago and described in some of our earliest patent applications

but not yet commercialized." Her email added that the Acclarent confidential information she shared included, *inter alia*, information about Acclarent's efforts to integrate suction into its guide catheter designs and its intention to add a "thumb port" hole, which, when closed, would draw suction through the guide catheter inner lumen.

15. On or about June 6, 2008, Albritton effectively entered into a consulting agreement with Acclarent (the "Consulting Agreement"). Pursuant to the Consulting Agreement, Acclarent paid Albritton to provide "[c]linical and product development consulting and conceptualization assistance relating to modifications of and improvements to" certain Acclarent projects, including the "Snorkel" project, which was directed to a guide catheter system with suction and a handle. A true and correct copy of the Consulting Agreement is attached hereto as Exhibit A.

16. The Consulting Agreement includes an Assignment clause under which Albritton assigns to Acclarent all "materials, … designs, inventions, improvements, developments, discoveries and trade secrets conceived, discovered, developed or reduced to practice" by him, "solely or in collaboration with others," during the agreement's term, that relate "in any manner" to confidential Acclarent information or his work for Acclarent.

17. On or about June 11, 2008, five days after the Consulting Agreement became effective, but before he signed the Consulting Agreement, Albritton disclosed to Acclarent his provisional patent application.

18. Albritton notified Acclarent in late March 2009 that he would be filing a non-provisional patent application (relying for its priority date on his May 16, 2008 provisional application) on what he referred to as his "suction handle" invention, and he requested a meeting with Acclarent regarding it.

19. Acclarent replied on or about March 31, 2009, that it had already filed various patent applications for products containing a guide with handles and suction capabilities, and it provided to Albritton a copy of the patent application to Goldfarb (U.S. Patent Appl. No. 11/789,704) as an example.

20. Albritton sent a responsive email the same day conceding that the practical use of suction was "thought out by the engineers and [Acclarent's] IP staff." In that email, Albritton also

explained that the unique aspects of his patent application were the guide and handle, not the suction component, and that the suction component was not a primary focus of the patent application.

21. Albritton explained in an email dated April 1, 2009, that he viewed "the handle and its consequent advantages/improvements to the facility of procedure performance the invention." In a responsive email of that same day, Acclarent explained that it was not interested in the invention Albritton described.

22. On or about May 18, 2009, Albritton filed the non-provisional application upon which the '412 Patent claims priority. In contrast to the provisional application filed before entering into the Consulting Agreement, Albritton added to the non-provisional application disclosure directed to a second opening in the handle to control suction, the very confidential design information that Ms. Swei conveyed to him. Over the next few years, Albritton's non-provisional application received a number of rejections from the Patent Examiner. In response, Albritton amended the non-provisional application by changing and adding claims to his application in order to overcome prior art. As a result, all of the claims that ultimately issued in the '412 Patent require suction functionality (which is what Albritton told Acclarent was *not* the focus of his patent), and 10 of the 20 issued claims are now supported *only* by the "second opening" information that Albritton added to the non-provisional application (claims 4-6, 11-13 and 17-19). The '412 Patent issued on April 21, 2015. A true and correct copy of the '412 Patent is attached hereto as Exhibit B.

23. Albritton contacted Acclarent in March 2015, and he suggested, for the first time, that the '412 Patent covers Acclarent's Relieva Spin Balloon Sinuplasty System, that is, that Acclarent's Relieva Spin Balloon Sinuplasty System infringes the '412 Patent. On or about January 14, 2016, Albritton and Acclarent entered into a tolling and standstill agreement, in which the parties agreed to refrain from litigating the '412 Patent until December 1, 2016 at 11:00AM, California time. A true and correct copy of the tolling and standstill agreement is attached hereto as Exhibit C. Subsequently, Albritton extended his infringement allegations to include the Relieva® SpinPlus™ Sinus Balloon Sinuplasty System, in addition to the Relieva Spin Balloon Sinuplasty System (collectively, the "Spin Devices").

24. The parties' tolling and standstill agreement has expired.

**FIRST CLAIM FOR RELIEF**

**(Breach of Contract – Failure to Assign Rights to '412 Patent)**

25. Acclarent restates and incorporates by reference the allegations in paragraphs 1 through 24 of this Complaint as if fully set forth herein.

26. There is an actual, substantial, and continuing case or controversy between Acclarent and Albritton regarding whether the Consulting Agreement requires Albritton to assign the rights to the '412 Patent, and any patents resulting from the non-provisional application underlying the '412 Patent, to Acclarent. A judicial declaration is necessary to determine the parties' respective rights regarding the '412 Patent.

27. Acclarent has performed all of its material obligations owed to Albritton pursuant to the Consulting Agreement.

28. Albritton breached the Consulting Agreement by failing to assign his rights to the '412 Patent, as well as any other patents arising from the '412 Patent, to Acclarent pursuant to Section 3.A regarding assignment.

29. Acclarent is informed and believes, and on that basis alleges, that Albritton has no valid legal excuse or justification for refusing to assign the '412 Patent to Acclarent because the Consulting Agreement obligated Albritton to assign the '412 Patent, or cause the '412 Patent to be assigned, to Acclarent.

30. Acclarent is informed and believes, and on that basis alleges, that the Consulting Agreement operates to assign the rights to the '412 Patent to Acclarent because the non-provisional application upon which the '412 Patent relies for priority includes material related to Albritton's consulting work for Acclarent that was added during the Consulting Agreement's term.

31. The Consulting Agreement contains a valid and enforceable assignment clause at Section 3.A., which in part states:

> Consultant [i.e., Albritton] agrees that all materials ... designs, inventions, improvements, developments, discoveries and trade secrets conceived, discovered, developed or reduced to practice by Consultant, solely or in collaboration with others, during the term of this Agreement that relate in any manner to the Company's Confidential Information or the business of the Company that Consultant may be directed to undertake, investigate or

> experiment with or that Consultant may become associated with in work, investigation or experimentation in the Company's line of business in performing the Services under this Agreement (collectively, "Inventions"), are the sole property of the Company. All Inventions are works made for hire to the extent allowed by law and, in addition, Consultant agrees to assign (or cause to be assigned) and hereby assigns fully to the Company, or its designee, all Inventions and any … patents … relating to all Inventions.

32. Exhibit A to the Consulting Agreement shows that Acclarent engaged Albritton to provide "[c]linical and product development consulting and conceptualization assistance relating to modifications of and improvements to" projects including the Snorkel project.

33. Albritton served as a paid consultant for Acclarent, and was subject to the Consulting Agreement's Assignment clause, for approximately eleven of the twelve months between the filing of the provisional and the non-provisional patent applications underlying the '412 Patent. Acclarent is informed and believes, and on that basis alleges, that during those eleven months, Albritton or his representatives created the non-provisional application; provided consulting services to Acclarent on various projects, and had access to Acclarent's Confidential Information relating to these highly confidential projects.

34. Acclarent is informed and believes, and on that basis alleges, the non-provisional application that Albritton developed and filed while subject to the Consulting Agreement is related to his consulting work for Acclarent and to Acclarent's Confidential Information. Furthermore, Acclarent is informed and believes, and on that basis alleges, the non-provisional application includes disclosure that does not appear in the provisional application, including the new disclosure and claims directed to a "second opening" in the handle for controlling suction.

35. Acclarent is informed and believes, and on that basis alleges, that because the '412 Patent contains and relies upon subject matter that Albritton added (and conceived and/or reduced to practice) while bound by the Consulting Agreement, Albritton automatically assigned, and is obligated to formally assign, to Acclarent his rights to the '412 Patent and any future patents resulting from the '412 Patent's non-provisional application.

36. Acclarent is informed and believes, and on that basis alleges, that Albritton's failure to formally assign the rights to the '412 Patent, and any applications claiming priority to the non-

provisional application, constitutes breach of the Consulting Agreement.

37. Acclarent is informed and believes, and on that basis alleges, that as a direct, proximate, and foreseeable result of Albritton's breach of the Consulting Agreement, Acclarent has been damaged by the defense costs associated with defending against Albritton's infringement allegations, including the attorney fees and costs that it would not have accrued but for the breach. Acclarent has also been damaged by not receiving the benefit to its rights in the '412 Patent.

38. Albritton's breach of the Consulting Agreement was willful and material and amounted to a failure of consideration such that Acclarent is relieved from any further performance under the Consulting Agreement.

**SECOND CLAIM FOR RELIEF**

**(Declaratory Judgment that Acclarent Owns the '412 Patent Through Assignment)**

39. Acclarent restates and incorporates by reference the allegations in paragraphs 1 through 38 of this Complaint as if fully set forth herein.

40. There is an actual, substantial, and continuing case or controversy between Acclarent and Albritton regarding which of them is the rightful owner of the '412 Patent (and any patents arising from the non-provisional application underlying the '412 Patent). A judicial declaration is necessary to determine the parties' respective rights regarding the '412 Patent and any such related patents.

41. Acclarent is entitled to a judicial declaration that it owns the '412 Patent, and any patents resulting from the non-provisional application for the '412 Patent, by operation of the assignment clause, Section 3.A., of the Consulting Agreement.

**THIRD CLAIM FOR RELIEF**

**(Declaratory Judgment that Equitable Estoppel Bars Albritton's Infringement Allegations)**

42. Acclarent restates and incorporates by reference the allegations in paragraphs 1 through 41 of this Complaint as if fully set forth herein.

43. There is an actual, substantial, and continuing case or controversy between Acclarent and Albritton regarding whether the doctrine of equitable estoppel bars Albritton from asserting claims of the '412 Patent against Acclarent. A judicial declaration is necessary to determine the

parties' respective rights regarding the '412 Patent.

44. Acclarent is informed and believes, and on that basis alleges, that Albritton's patent infringement claims against Acclarent are barred by equitable estoppel because Albritton misled Acclarent into believing, for almost seven years, that he had no intention of asserting what ultimately became the '412 Patent against the Spin Devices that he knew Acclarent was developing.

45. Acclarent is informed and believes, and on that basis alleges, that Albritton misled Acclarent through his words, conduct, and/or silence into believing that he had no intention of asserting what ultimately became the '412 Patent against the Acclarent Spin Devices. Acclarent is further informed and believes, and on that basis alleges, that Acclarent relied on Albritton's misleading words, conduct, and/or silence and would be materially harmed if Albritton is permitted to now assert the '412 Patent against Acclarent.

46. On information and belief, on or about March 28, 2009, Albritton notified Acclarent that he would be pursuing a non-provisional application. On information and belief, on or about March 31, 2009, then Acclarent employee Greg Garfield responded with an email informing Albritton that Acclarent had already filed various patent applications for a guide with suction capabilities, and Mr. Garfield attached two exemplary Acclarent applications to his email. On information and belief, Albritton replied on or about the same day and conceded that Acclarent's "engineers and … IP staff" were the ones who "thought out … the practical use of suction," and he explained that "suction is not the focus nor primary claim" of his patent application.

47. Acclarent is informed and believes, and on that basis alleges, that Albritton nonetheless added to the '412 Patent disclosure and claim language specifically directed to a "second opening" for controlling suction that is nowhere to be found in the provisional application, without telling Acclarent of his plans to do so.

48. Acclarent is informed and believes, and on that basis alleges that, since at least June 2008, Albritton served as a paid consultant for Acclarent guide catheter technology, and that, and even though Acclarent continued to invest in the research and development of the Spin Devices, Albritton failed to suggest, either explicitly or implicitly, that the Spin Devices might be covered by his patent rights. Acclarent is informed and believes, and on that basis alleges that, Albritton's

silence misled Acclarent into believing that Albritton would not assert any patents against the Spin Devices. Acclarent relied on Albritton's misleading conduct due to the false sense of security Albritton created through his actions, position of trust, and silence. Acclarent will be materially prejudiced if Albritton is permitted to assert the '412 Patent against it now, particularly in view of the years of research and development Acclarent invested, and the myriad design decisions Acclarent made, for the Spin Devices.

**FOURTH CLAIM FOR RELIEF**

**(Declaratory Judgement that the '412 Patent is Invalid for Derivation)**

49. Acclarent restates and incorporates by reference the allegations in paragraphs 1 through 48 of this Complaint as if fully set forth herein.

50. Albritton claims to own all rights, title, and interest in the '412 Patent.

51. There is an actual, substantial, and continuing case or controversy between Acclarent and Albritton regarding whether at least claims 4-6, 11-13, and 17-19 of the '412 Patent are invalid for derivation. A judicial declaration is necessary to determine the parties' respective rights regarding the '412 Patent.

52. Claims 4-6, 11-13, and 17-19 of the '412 Patent are dependent claims that require the suction catheter system of their respective independent claims to have a "second opening" in the handle for controlling suction.

53. Acclarent is informed and believes, and on that basis alleges, that Albritton did not himself invent the subject matter of claims 4-6, 11-13 and 17-19 of the '412 Patent and that the subject matter of those claims was instead conceived by Acclarent and communicated to Albritton, who later claimed the subject matter as his own.

54. Acclarent employee John Morriss documented his idea and design for a guidewire catheter system with suction, a handle oriented in the same way as the '412 Patent's guide catheter systems, and a "second opening" in the handle for controlling suction, in 2006.

55. Albritton conceded in writing that the "practical use of suction" in a catheter system was "thought out," not by him, but by Acclarent engineers and IP staff. Albritton did not add to his patent applications any disclosure regarding a "second opening" in the handle for controlling suction

until he filed his non-provisional application in May 2009, after Acclarent communicated to him confidential information about its suction catheter designs and the idea of using a second opening ("thumb port") on the handle to control suction.

56. Claims 4-6, 11-13 and 17-19 of the '412 Patent are invalid for derivation under 35 U.S.C. §§ 102(f) or 102(f)/103.

**FIFTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Noninfringement)**

57. Acclarent restates and incorporates by reference the allegations in paragraphs 1 through 56 of this Complaint as if fully set forth herein.

58. Albritton claims to own all rights, title, and interest in the '412 Patent.

59. There is an actual, substantial, and continuing case or controversy between Acclarent and Albritton regarding whether the Spin Devices infringe or have infringed the '412 Patent. A judicial declaration is necessary to determine the parties' respective rights regarding the '412 Patent.

60. In 2015, Albritton accused Acclarent of infringing the '412 Patent by allegedly making, using, selling, and/or offering for sale Acclarent's Relieva Spin Balloon Sinuplasty System, and he more recently extended his infringement allegations to the Relieva® SpinPlus™ Sinus Balloon Sinuplasty System.

61. Acclarent does not directly or indirectly infringe the '412 Patent, either literally or under the doctrine of equivalents. For example, Albritton sent Acclarent an email in April 2009, explaining that he viewed "the handle and its consequent advantages/improvements" to be "the invention." As evidenced by its Figures 4 and 5, which are reproduced below, the '412 Patent discloses a catheter with handle that is held like a pistol, such that the thumb and index finger are freely movable while the handle is being held.

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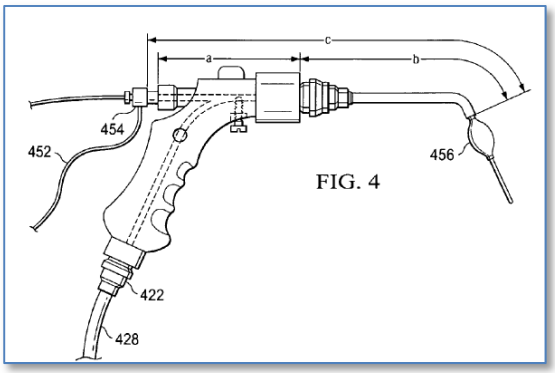

FIG. 4

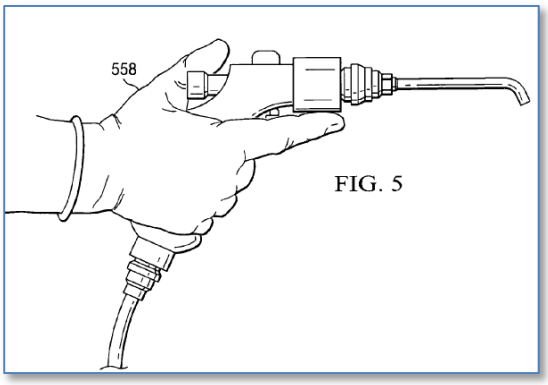

FIG. 5

62. The claims of the ’412 Patent require a handle adapted to permit the thumb and index finger of the hand holding the device to manipulate the working device immediately adjacent to the handle’s opening. For example, exemplary independent claim 1 recites a handle structure “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.” The ’412 Patent’s remaining independent claims contain similar limitations.

63. In contrast, the Spin Devices do not have (and are not used in a method that involves) a handle adapted to permit the thumb and index finger of the hand holding the device to manipulate the working device immediately adjacent to the handle’s opening. The Spin Devices do not have a pistol-type handle that leaves the thumb and forefinger free to manipulate a working device immediately adjacent to the handle’s opening; they instead have a pencil-type configuration in which the thumb only manipulates the working device via a slider remote from the handle’s opening.


64. Acclarent is entitled to a judicial declaration that the Spin Devices do not directly or indirectly infringe any claim of the ’412 Patent.

**SIXTH CLAIM FOR RELIEF**

**(Declaratory Judgment of Invalidity over the Prior Art)**

65. Acclarent restates and incorporates by reference the allegations in paragraphs 1

through 64 of this Complaint as if fully set forth herein.

66. Albritton claims to own all rights, title, and interest in the '412 Patent. A true and correct copy of the '412 Patent is attached hereto as Exhibit B.

67. There is an actual, substantial, and continuing case or controversy between Acclarent and Albritton regarding the validity of the claims of the '412 Patent.

68. In 2015, Albritton accused Acclarent of infringing the '412 Patent by allegedly making, using, selling, and/or offering for sale the Spin Devices, and Albritton continues to allege that the Spin Devices infringe claims of the '412 Patent.

69. The claims of the '412 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including 35 U.S.C. §§ 102 and 103, as well as other judicially created bases for invalidation.

70. For example, the '412 Patent is invalid as anticipated or rendered obvious under 35 U.S.C. §§ 102 and/or 103, in light of prior art including, for example, U.S. Patent No. 8,747,389 (Goldfarb), entitled "Systems for Treating Disorders of the Ear, Nose and Throat;" U.S. Patent No. 5,562,640 (McCabe), entitled "Endoscopic Surgical Instrument for Aspiration and Irrigation;" and U.S. Patent Pub. No. 2006/0063973 (Makower), entitled "Methods and Apparatus for Treating Disorders of the Ear, Nose and Throat," either alone or in combination with U.S. Patent No. 4,915,691 (Jones), entitled "Aspirator."

71. As shown in the exemplary figures below, Goldfarb discloses, *inter alia*, a guidewire catheter system with a handle that can be grasped in the same manner as the pistol-type device to which the claims of the '412 Patent are directed, leaving the thumb and index finger free to manipulate a working device. Goldfarb also discloses a hole in the handle for controlling suction.

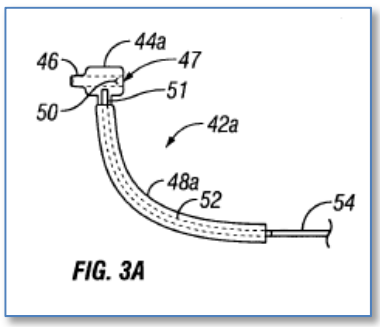

FIG. 3A

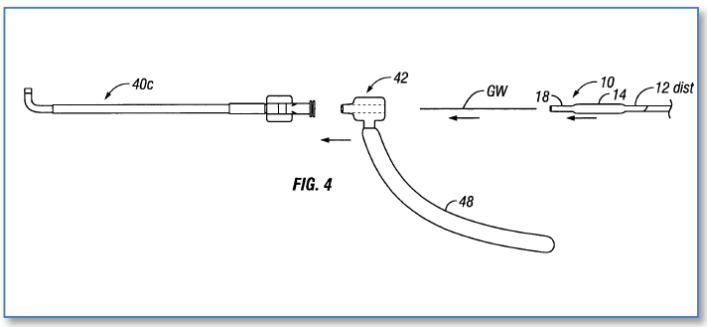

FIG. 4

72. As shown in the exemplary figure below, McCabe discloses, *inter alia*, a guide catheter system with a handle that can be grasped in the same manner as the pistol-type device to which the claims of the '412 Patent are directed, leaving the thumb and index finger free to manipulate a working device. McCabe further discloses a valve (hole) in the handle for controlling suction.

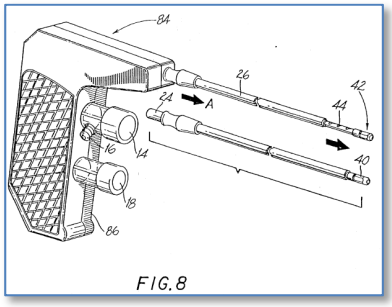

FIG. 8

73. As shown in the exemplary figure below, Makower discloses, *inter alia*, guide catheters with a handle that can be grasped such that the thumb and index finger are free to manipulate a working device.

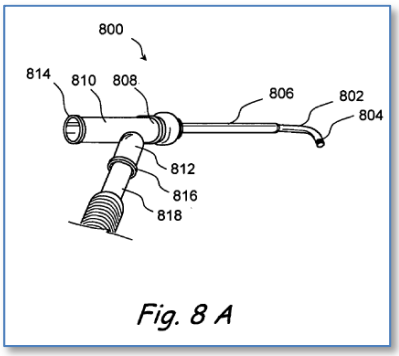

Fig. 8 A

74. Although McCabe does not expressly disclose a second opening in the handle to control suction, such a feature would have been obvious to a person of skill in the art. For example, 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" and further discloses, as illustrated in Figures 2 and 3 below, that 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."

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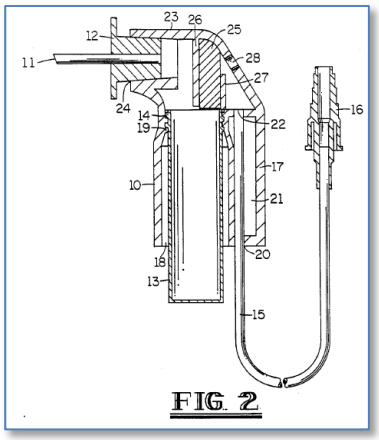


FIG. 2

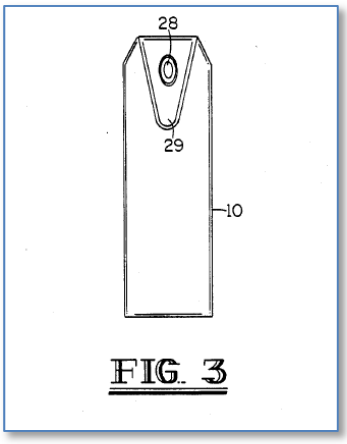


FIG. 3

75. Acclarent is entitled to a judicial declaration that the claims of '412 Patent are invalid in view of at least Goldfarb, McCabe, Makower, and Makower in view of Jones.

**PRAYER FOR RELIEF**

WHEREFORE, Acclarent prays for judgment and relief as follows:

A. Damages judgment in favor of Acclarent and against Albritton in an amount to be determined at trial;

B. Declaratory judgment in favor of Acclarent that it is the owner of the '412 Patent by assignment;

C. Declaratory judgment in favor of Acclarent that Albritton is equitably estopped from enforcing the '412 Patent against Acclarent;

D. Declaratory judgment in favor of Acclarent that claims 4-6, 11-13, and 17-19 of the '412 Patent are invalid for derivation under 35 U.S.C §§ 102(f) or 102(f)/103;

E. Declaratory judgment in favor of Acclarent that the Spin Devices do not infringe the '412 Patent;

F. Declaratory judgment in favor of Acclarent that the '412 Patent is invalid over prior art under 35 U.S.C. §§ 102 or 103;

G. Finding that this is an exceptional case under 35 U.S.C. § 285;

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H. Awarding Acclarent its costs and attorney fees in connection with this action; and

I. Such further and additional relief as the Court deems just and proper.

Dated: December 1, 2016

WILLIAM C. ROOKLIDGE
FRANK P. COTÉ
GIBSON, DUNN & CRUTCHER LLP

By: */s/ William C. Rooklidge*
William C. Rooklidge

Attorneys for Plaintiff ACCLARENT, INC.

102212774.2

# EXHIBIT A

**ACCLARENT, INC.**

**CONSULTING AGREEMENT**

This Consulting Agreement ("**Agreement**") is entered into as of June 6, 2008 by and between Acclarent, Inc. (the "**Company**") and Ford D. Albritton IV, MD, FACS ("**Consultant**"). The Company desires to retain Consultant as an independent contractor to perform consulting services for the Company, or its designee, and Consultant is willing to perform such services, on the terms described below. In consideration of the mutual promises contained herein, the parties agree as follows:

1. *Services and Compensation.* Consultant agrees to perform for the Company, or its designee, the services described in Exhibit A (the "**Services**"), and the Company agrees to pay Consultant the compensation described in Exhibit A for Consultant's performance of the Services.

2. *Confidentiality.*

A. *Definition.* "**Confidential Information**" means any non-public information that relates to the actual or anticipated business or research and development of the Company or of Consultant, technical data, trade secrets or know-how, including, but not limited to, research, product plans or other information regarding Company's products or services and markets therefore, customer lists and customers (including, but not limited to, customers of the Company on whom Consultant called or with whom Consultant became acquainted during the term of this Agreement), software, developments, inventions, processes, formulas, technology, designs, drawing, engineering, hardware configuration information, marketing, finances or other business information.

B. *Nonuse and Nondisclosure.* Consultant and the Company will not, during or subsequent to the term of this Agreement, (i) use the Confidential Information for any purpose whatsoever other than the performance of the Services on behalf of the Company, or its designee, or (ii) disclose the Confidential Information to any third party. Consultant agrees that all Confidential Information of the Company will remain the sole property of the Company, or its designee. The Company agrees that all Confidential Information of Consultant will remain the sole property of the Consultant, or its designee. Consultant and the Company also agree to take all reasonable precautions to prevent any unauthorized disclosure of such Confidential Information.

C. *Former Client Confidential Information.* Consultant agrees that Consultant will not, during the term of this Agreement, improperly use or disclose any proprietary information or trade secrets of any former or current employer of Consultant or other person or entity with which Consultant has an agreement or duty to keep in confidence information acquired by Consultant, if any. Consultant also agrees that Consultant will not bring onto the Company's premises any unpublished document or proprietary information belonging to any such employer, person or entity unless consented to in writing by such employer, person or entity.

D. *Third Party Confidential Information.* Consultant recognizes that the Company has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Consultant agrees that, during the term of this Agreement and thereafter, Consultant owes the Company and such third parties a duty to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person, firm or corporation or to use it except as necessary in carrying out the Services for the Company consistent with the Company's agreement with such third party.

E. *Return of Materials.* Upon the termination of this Agreement, or upon Company's earlier request, Consultant will deliver to the Company all of the Company's property, including but not limited to all electronically stored information and passwords to access such property, or Confidential Information that Consultant may have in Consultant's possession or control.

3. *Ownership.*

A. *Assignment.* Consultant agrees that all materials, notes, records, drawings, designs, inventions, improvements, developments, discoveries and trade secrets conceived, discovered, developed or reduced to practice by Consultant, solely or in collaboration with others, during the term of this Agreement that relate in any manner to the Company's Confidential Information or the business of the Company that Consultant may be directed to undertake, investigate or experiment with or that Consultant may become associated with in work, investigation or experimentation in the Company's line of business in performing the Services under this Agreement (collectively, "**Inventions**"), are the sole property of the Company. All Inventions are works made for hire to the extent allowed by law and, in addition, Consultant agrees to assign (or cause to be assigned) and hereby assigns fully to the Company, or its designee, all Inventions and any copyrights, patents, mask work rights or other intellectual property rights relating to all Inventions.

B. *Further Assurances.* Consultant agrees to assist Company, or its designee, at the Company's expense, in every proper way to further evidence, record, perfect and secure the Company's rights in Inventions and any copyrights, patents, mask work rights or other intellectual property rights relating to all Inventions in any and all countries, including the disclosure to the Company of all pertinent information and data with respect to all Inventions, the execution of all applications, specifications, oaths, assignments and all other instruments that the Company may deem necessary in order to apply for and obtain, perfect, record, evidence, maintain, enforce and defend such rights and in order to assign and convey to the Company, its successors, assigns and nominees the sole and exclusive right, title and interest in and to all Inventions, and any copyrights, patents, mask work rights or other intellectual property rights relating to all Inventions. Consultant also agrees that Consultant's obligation to execute or cause to be executed any such instrument or papers shall continue after the termination of this Agreement.

C. *Attorney-in-Fact.* Consultant agrees that, if the Company is unable because of Consultant's unavailability, dissolution, mental or physical incapacity, or for any other reason, to secure Consultant's signature for the purpose of applying for or pursuing any application for any United States or foreign patents or mask work or copyright registrations covering the Inventions assigned to the Company in **Section 3.A**, then Consultant hereby irrevocably designates and

appoints the Company and its duly authorized officers and agents as Consultant's agent and attorney-in-fact, to act for and on Consultant's behalf to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyright and mask work registrations with the same legal force and effect as if executed by Consultant.

4. *Conflicting Obligations*. Consultant represents and warrants that Consultant has no outstanding agreement or obligation that is in conflict with any of the provisions of this Agreement or that would preclude Consultant from complying with the provisions of this Agreement. Consultant will not enter into any such conflicting agreement during the term of this Agreement. Consultant's violation of this Section 4 will be considered a material breach under **Section 6.B**.

5. *Reports*. Consultant also agrees that Consultant will, from time to time during the term of this Agreement or any extension thereof, keep the Company advised as to Consultant's progress in performing the Services under this Agreement. Consultant further agrees that Consultant will, as requested by the Company, prepare written reports with respect to such progress. The Company and Consultant agree that the time required to prepare such written reports will be considered time devoted to the performance of the Services.

6. *Term and Termination*.

A. *Term*. The term of this Agreement will begin on the date of this Agreement and will continue until the earlier of (i) final completion of the Services or (ii) termination as provided in **Section 6.B**.

B. *Termination*. Either party may terminate this Agreement upon giving the other party 14 days' prior written notice of such termination pursuant to **Section 10.D** of this Agreement. The Company may terminate this Agreement immediately and without prior notice if Consultant refuses to or is unable to perform the Services or is in breach of any material provision of this Agreement.

C. *Survival*. Upon such termination, all rights and duties of the Company and Consultant toward each other shall cease except:

(1) The Company will pay, within 30 days after the effective date of termination, all amounts owing to Consultant for Services completed and accepted by the Company prior to the termination date and related expenses, if any, submitted in accordance with the Company's policies and in accordance with the provisions of Section 1 of this Agreement; and

(2) Section 2 (Confidentiality), Section 3 (Ownership), Section 4 (Conflicting Obligations), Section 7 (Independent Contractor; Benefits), Section 8 (Indemnification) and Section 9 (Nonsolicitation).

7. *Independent Contractor; Benefits*.

A. *Independent Contractor*. It is the express intention of the Company and Consultant that Consultant perform the Services as an independent contractor to the Company. Nothing in this Agreement shall in any way be construed to constitute Consultant as an agent, employee or representative of the Company. Without limiting the generality of the foregoing, Consultant is not

authorized to bind the Company to any liability or obligation or to represent that Consultant has any such authority. Consultant agrees to furnish (or reimburse the Company for) all tools and materials necessary to accomplish this Agreement and shall incur all expenses associated with performance, except as expressly provided in Exhibit A. Consultant acknowledges and agrees that Consultant is obligated to report as income all compensation received by Consultant pursuant to this Agreement. Consultant agrees to and acknowledges the obligation to pay all self-employment and other taxes on such income.

B. *Benefits.* The Company and Consultant agree that Consultant will receive no Company-sponsored benefits from the Company. If Consultant is reclassified by a state or federal agency or court as Company's employee, Consultant will become a reclassified employee and will receive no benefits from the Company, except those mandated by state or federal law, even if by the terms of the Company's benefit plans or programs of the Company in effect at the time of such reclassification, Consultant would otherwise be eligible for such benefits.

8. *Indemnification.* Company agrees to indemnify and hold harmless the Consultant from and against all taxes, losses, damages, liabilities, costs and expenses, including attorneys' fees and other legal expenses, arising directly or indirectly from or in connection with (i) any negligent, reckless or intentionally wrongful act of Company or Company's assistants, employees or agents, (ii) any breach by Company or Company's assistants, employees or agents of any of the covenants contained in this Agreement, (iii) any failure of Company to perform the Services in accordance with all applicable laws, rules and regulations, (iv) any violation or claimed violation of a third party's rights resulting in whole or in part from the Company's use of the work product of Consultant under this Agreement, or (v) any product liability associated with the sale of any company products.

9. *Nonsolicitation.* From the date of this Agreement until 12 months after the termination of this Agreement (the "**Restricted Period**"), Consultant will not, without the Company's prior written consent, directly or indirectly, solicit or encourage any employee or contractor of the Company or its affiliates to terminate employment with, or cease providing services to, the Company or its affiliates. During the Restricted Period, Consultant will not, whether for Consultant's own account or for the account of any other person, firm, corporation or other business organization, intentionally interfere with any person who is or during the period of Consultant's engagement by the Company was a partner, supplier, customer or client of the Company or its affiliates.

10. *Miscellaneous.*

A. *Governing Law.* This Agreement shall be governed by the laws of California without regard to California's conflicts of law rules.

B. *Assignability.* Except as otherwise provided in this Agreement, Consultant may not sell, assign or delegate any rights or obligations under this Agreement.

C. *Entire Agreement.* This Agreement constitutes the entire agreement between the parties with respect to the subject matter of this Agreement and supersedes all prior written and oral agreements between the parties regarding the subject matter of this Agreement.

D. *Notices*. Any notice or other communication required or permitted by this Agreement to be given to a party shall be in writing and shall be deemed given if delivered personally or by commercial messenger or courier service, or mailed by U.S. registered or certified mail (return receipt requested), or sent via facsimile (with receipt of confirmation of complete transmission) to the party at the party's address or facsimile number written below or at such other address or facsimile number as the party may have previously specified by like notice. If by mail, delivery shall be deemed effective 3 business days after mailing.

(1) If to the Company, to:
Acclarent, Inc.
1525-B O'Brien Drive
Menlo Park, CA 94025

Attention: Bill Facteau
Telephone: 650-687-5840
Facsimile: 650-687-5889

(2) If to Consultant, to the address for notice on the signature page to this Agreement or, if no such address is provided, to the last address of Consultant provided by Consultant to the Company.

E. *Severability*. If any provision of this Agreement is found to be illegal or unenforceable, the other provisions shall remain effective and enforceable to the greatest extent permitted by law.

*(Remainder of page intentionally left blank.)*

IN WITNESS WHEREOF, the parties hereto have executed this Consulting Agreement as of the date first written above.

**CONSULTANT**

By: _____

Name: Ford D. Albritton IV, MD, FACS

Title: Chairman

**ACCLARENT, INC.**

By: _____

Name: Greg Garfield

Title: Chief Operating Officer

Address for Notice:

Department Otolaryngology – Head & Neck Surgery

Presbyterian Hospital of Dallas

8440 Walnut Hill, Suite 500

Dallas, TX 75231

Ph: 214 345 5702 – Office

Fax: 214 345 5708

For year end tax reporting purposes, we are requesting your social security/taxpayer identification number should a payment transpire for the services you render to the Company.

SSN/TIN 454-77-8765

EXHIBIT A

Services and Compensation

1. *Contact*. Consultant's principal Company contact:

Name: Greg Garfield

Title: Chief Operating Officer

2. *Services*. The Services shall include the following:

Clinical and product development consulting and conceptualization assistance relating to modifications of and improvements to the Snorkel, Cyclops, Wiggle/Airway, Stubby 2 and Condor products.

3. *Compensation*.

A. The Company will pay Consultant $250.00 per hour, except that Consultant will not be paid for more than $2,000.00 per day.

B. The Company will reimburse Consultant for all reasonable expenses incurred by Consultant in performing the Services pursuant to this Agreement, if Consultant receives written consent from an authorized agent of the Company prior to incurring such expenses and submits receipts for such expenses to the Company in accordance with Company policy.

Every two weeks, Consultant shall submit to the Company a written invoice for Services and expenses, and such statement shall be subject to the approval of the contact person listed above or other designated agent of the Company.

# EXHIBIT B

US009011412B2

(12) **United States Patent**
**Albritton, IV et al.**

(10) **Patent No.: US 9,011,412 B2**
(45) **Date of Patent: Apr. 21, 2015**

(54) **APPARATUS, SYSTEM AND METHOD FOR MANIPULATING A SURGICAL CATHETER AND WORKING DEVICE WITH A SINGLE HAND**

(76) Inventors: **Ford Albritton, IV**, Dallas, TX (US); **Bryan Lunsford**, Arlington, TX (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1091 days.

(21) Appl. No.: **12/454,560**

(22) Filed: **May 18, 2009**

(65) **Prior Publication Data**

US 2010/0057045 A1 Mar. 4, 2010

**Related U.S. Application Data**

(60) Provisional application No. 61/127,848, filed on May 16, 2008.

(51) **Int. Cl.**

| | |
|---|---|
| ***A61M 25/00*** | (2006.01) |
| ***A61M 25/01*** | (2006.01) |
| ***A61B 17/00*** | (2006.01) |
| *A61B 17/34* | (2006.01) |
| *A61B 17/22* | (2006.01) |
| *A61M 1/00* | (2006.01) |

(52) **U.S. Cl.**

CPC ..... ***A61M 25/01*** (2013.01); ***A61B 17/00*** (2013.01); *A61B 17/00234* (2013.01); *A61B 17/3415* (2013.01); *A61B 2017/0042* (2013.01); *A61B 2017/00424* (2013.01); *A61B 2017/00469* (2013.01); *A61B 2017/22049* (2013.01); *A61B 2217/005* (2013.01); *A61M 1/008* (2013.01); ***A61M 25/0097*** (2013.01)

(58) **Field of Classification Search**

CPC ..... A61B 17/24; A61B 17/32053; A61B 17/320725; A61B 17/320758; A61B 17/320783; A61B 17/3478; A61B 2017/22061; A61F 2250/0039; A61F 2/18; A61F 2/82

USPC ..... 604/506, 96.01, 528; 600/114, 104, 600/146, 156

See application file for complete search history.

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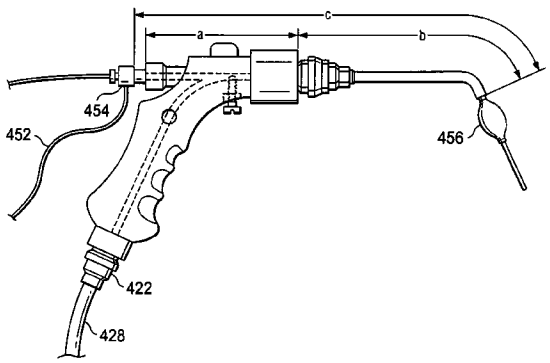
* cited by examiner

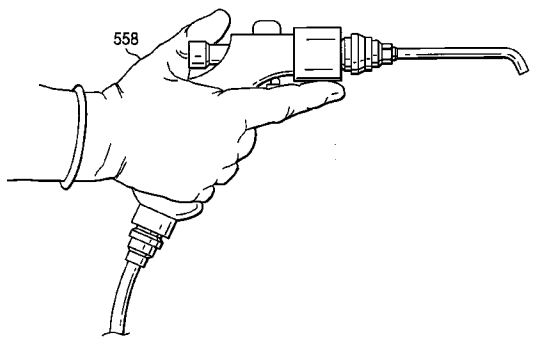
*Primary Examiner* — Kevin C Sirmons
*Assistant Examiner* — Deanna K Hall

(57) **ABSTRACT**

Systems and methods are disclosed that include a guide catheter apparatus insertable through a external body passage of a subject. The guide catheter apparatus includes a substantially rigid shaft and a handle. The shaft has a proximal opening, a distal opening, and a lumen extending between the proximal opening and the distal opening. 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.

**20 Claims, 3 Drawing Sheets**



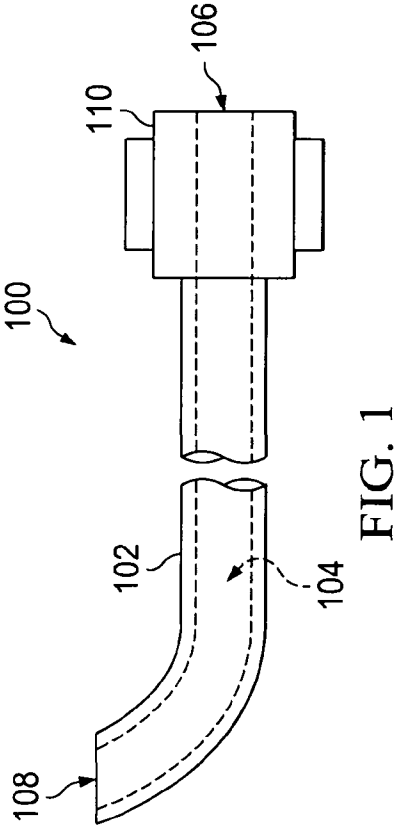

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FIG. 1

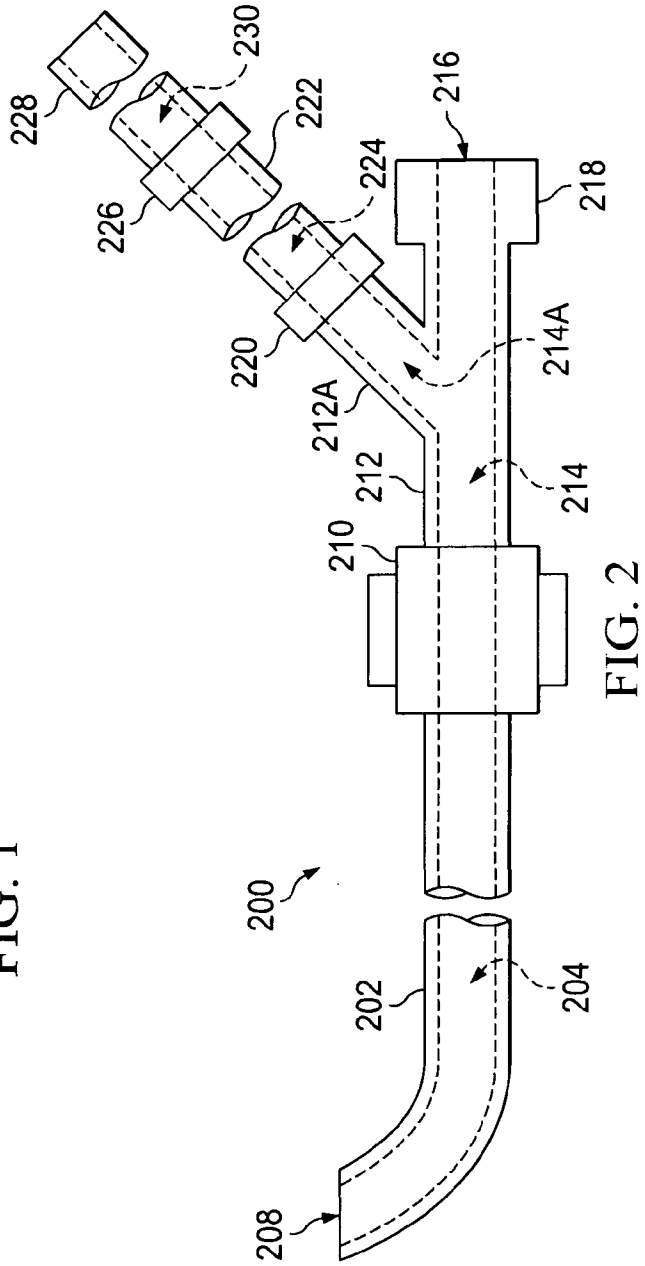
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FIG. 2

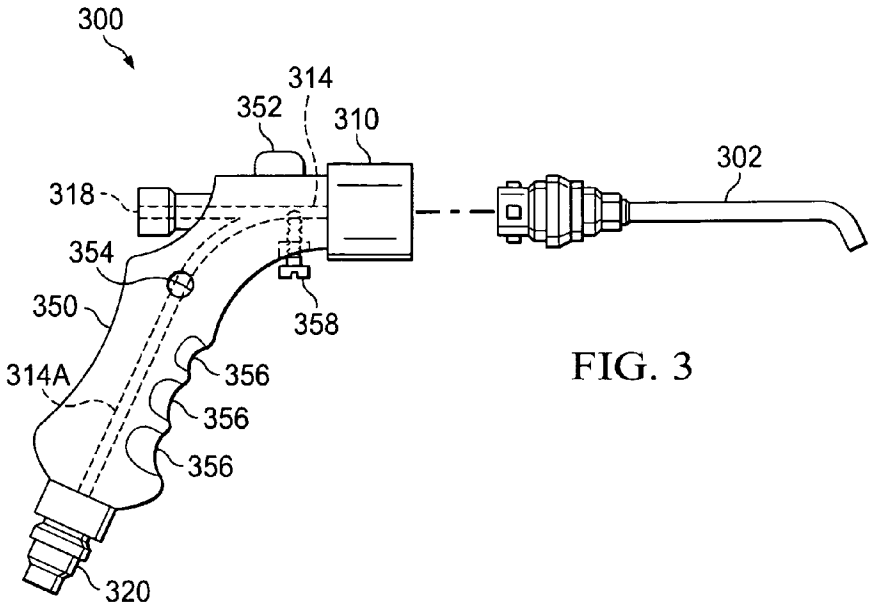
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FIG. 3

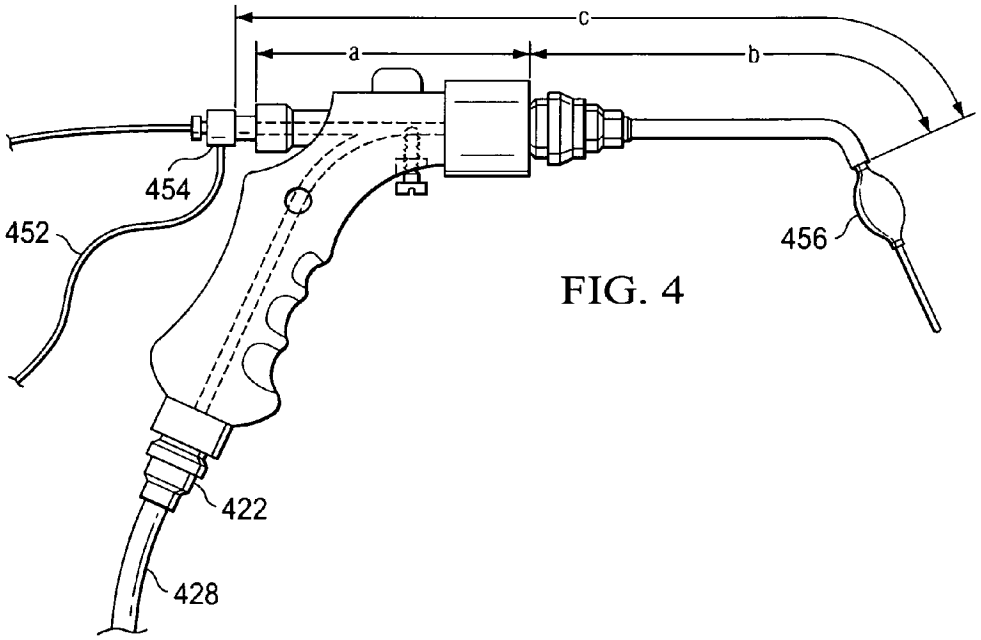
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FIG. 4

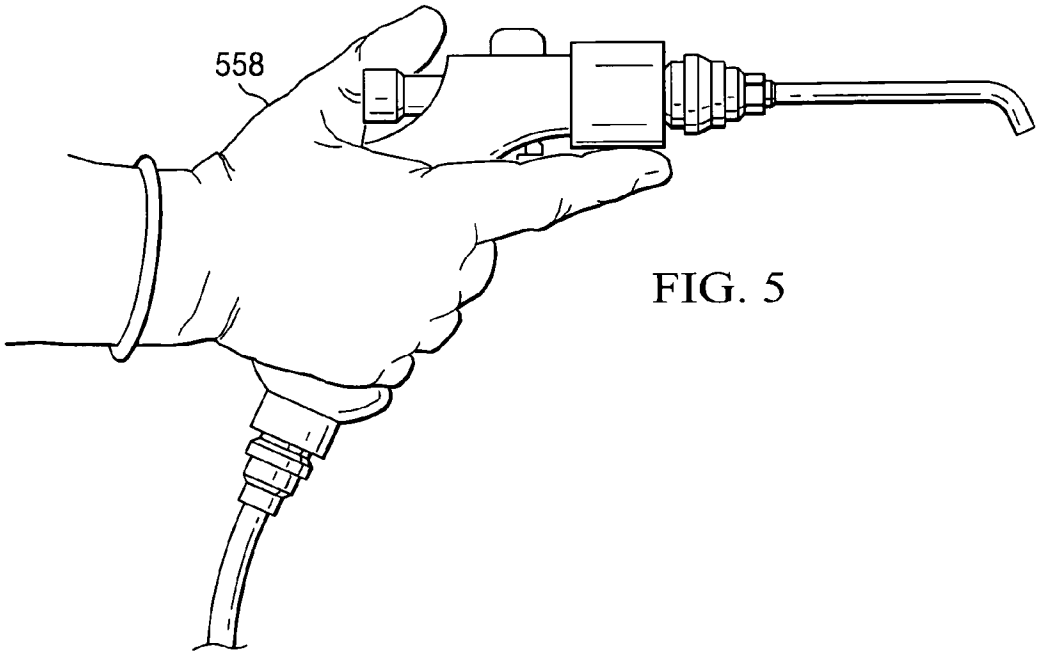


FIG. 5

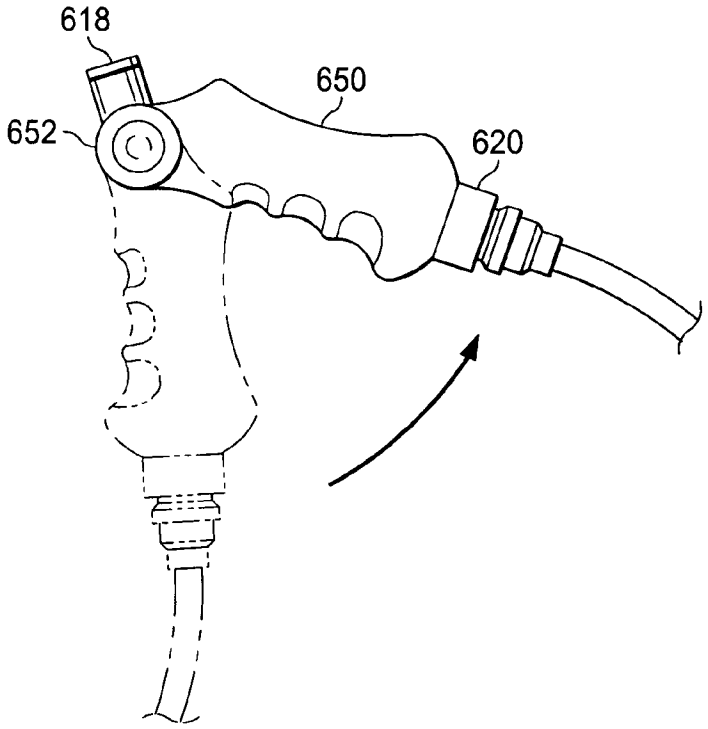


FIG. 6

# APPARATUS, SYSTEM AND METHOD FOR MANIPULATING A SURGICAL CATHETER AND WORKING DEVICE WITH A SINGLE HAND

## CROSS-REFERENCE TO RELATED APPLICATION(S) AND CLAIM OF PRIORITY

The present application is related to U.S. Provisional Patent Application Ser. No. 61/127,848, filed May 16, 2008, entitled "APPARATUS, SYSTEM AND METHOD FOR CONTROLLING THE POSITION OF AND PROVIDING SUCTION IN A SURGICAL CATHETER OR GUIDE". Provisional Patent Application Ser. No. 61/127,848 is assigned to the assignee of the present application and is hereby incorporated by reference into the present application as if fully set forth herein. The present application hereby claims priority under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 61/127,848.

## TECHNICAL FIELD

The present invention is generally directed to surgical devices and, in particular, to an apparatus, system and method for manipulating a surgical catheter and working device with a single hand.

## BACKGROUND

FIG. **1** presents a schematic diagram of a typical surgical catheter (or guide) **100** that may be used to perform a procedure in a nasal, sinonasal, or oral passage or other external body passage. The catheter **100** includes a tube **102** having therein a duct **104**. The tube **102** may be introduced into the body passage and a guidewire or other working device inserted into the duct **104** via an opening **106** at a proximal end of the catheter **100**. The duct **104** then operates to guide the working device to an opening **108** at a distal end of the tube **102**. A handle **110** may be formed into or attached to the proximal end of the tube **102** to permit positioning of the catheter **100** by movement of the catheter **100** into and out of the body passage and rotation of the catheter **100** around a longitudinal axis with a first hand. Once a desired position is obtained, the catheter **100** with fingers of a second hand that also grasps an endoscope and held in position. The first hand may then be used to manipulate the working device inserted into the duct **104**.

## SUMMARY

This disclosure provides an apparatus, system and method for manipulating a surgical catheter and working device with a single hand.

In one embodiment, a system includes a guide catheter, a working device and a handle coupled to the guide catheter. The guide catheter is insertable through an external body passage of a subject, and includes a substantially rigid shaft, a proximal opening, a distal opening and a lumen extending between the proximal opening and the distal opening. The working device is adapted to be insertable through the lumen of the guide catheter. 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.



In another embodiment, a method includes inserting a guide catheter through an external body passage of a subject, inserting a working device through the lumen of the guide catheter, and controlling a position of the guide catheter using a handle affixed to the guide catheter while substantially simultaneously manipulating the working device. The position of the guide catheter is controlled by some or all of three fingers of a hand and a thumb and index finger of the hand manipulate the working device via a portion of the working device immediately adjacent to the handle.

In still another embodiment, a guide catheter apparatus insertable through a external body passage of a subject includes a substantially rigid shaft and a handle. The shaft has a proximal opening, a distal opening, and a lumen extending between the proximal opening and the distal opening. 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.

## BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and its advantages, reference is now made to the following description taken in conjunction with the accompanying drawings, in which:

FIG. **1** presents a schematic diagram of a surgical catheter;

FIG. **2** presents a schematic diagram of a surgical catheter according to this disclosure;

FIG. **3** presents a schematic diagram of another surgical catheter according to this disclosure;

FIG. **4** presents a schematic diagram of a surgical catheter according to this disclosure with working devices inserted;

FIG. **5** presents a schematic diagram of a surgical catheter according to this disclosure held by a user; and

FIG. **6** presents a schematic diagram of still another surgical catheter according to this disclosure.

## DETAILED DESCRIPTION

FIG. **2** depicts a schematic diagram of a surgical catheter **200** according to the present disclosure. The catheter **200** includes a tube **202** having therein a duct **204** with an opening **208** at a distal end. A handle **210** may be formed into or attached to the proximal end of the tube **202**. A Y-shaped section **212** is coupled to a proximal end of the tube **202** at a distal end of the section **212**. The section **212** includes a second handle **218** and an opening **216** at a proximal end of the section **212**. The section **212** includes a duct **214** that mates with the duct **204** of the tube **202**. As described for the catheter **100**, working devices may be inserted in the opening **216** and guided to the opening **208** at the distal end of the tube **202** by the duct **214** and the duct **204**.

The section **212** further includes a branch section **212**A having a branch duct **214**A. Suction may be applied to the catheter **200** via the branch section **212**A. Where both the opening **216** and the opening **208** are left uncovered, the suction will be conducted to the opening **216** via the ducts **214**A and **214** and to the opening **208** via the ducts **214**A, **214** and **204**. Because the tube **202** is inserted into a body passage and, possibly, through a hole in a membrane of the body, the opening **208** may be sealed off from the ambient air pressure outside the catheter **200**. In such a situation, the suction

applied to the branch section **212**A will primarily result in air being drawn through the opening **216** and into the duct **214**A.

Partially or completely blocking the opening **216**, however, will result in the suction drawing blood, mucous, and other materials into the opening **208** and along the ducts **204**, **214** and **214**A, resulting in removal of the materials from the vicinity of the distal end of the tube **202**. An operator of the catheter **200** may vary the mount of blockage of the opening **216** with a finger or valve, in order to control the amount of suction delivered to the opening **208**. In this way, materials produced by the body in response to operation of the working devices (or freed from the body by the operation of the working devices) may be removed from vicinity of the distal end of the tube **202** by way of a controlled amount of suction. Such removal may provide a clearer view for an endoscope inserted into the catheter **200**, a clearer working area for a cutter, or other similar benefits.

A coupling **220** at a proximal end of the branch section **212**A couples a tube **222** having a duct **224** to the branch section **212**A and the duct **214**A, respectively. The tube **222** may conduct the suction to the section **212** from a suction canister or other suction source. Where the tube **222** is stiff, the coupling **220** may permit rotation of the branch section **212**A relative to the tube **222**, to reduce interference by the tube **222** with an operator's positioning of the catheter **200**.

In another embodiment, a coupling **226** at a proximal end of the tube **222** may couple a second tube **228** having a duct **230** to the tube **222** and the duct **224**, respectively. The coupling **220** does not permit rotation of the tube **222** relative to the branch section **214**A, nor does the coupling **226** permit rotation of the tube **228** relative to the tube **222**. However, where the tube **228** is stiff, a flexible tube **222** may be employed to reduce interference by the tube **228** with an operator's positioning of the catheter **200**.

While the section **212** is shown and described as separate from the tube **202**, it will be understood that in other embodiments, the section **212** may be formed integrally with the tube **202**. In still other embodiments, the coupling **220** may be mounted directly to a side of the section **212**, rather than to the branch section **212**A. While the section **212** is shown fixedly attached to the tube **202**, in other embodiments the section **212** may move relative to the tube **202**, in order to further free tethering and increase a user's free and unencumbered movements in space, while leaving the tube **202** in a substantially fixed position relative to the patient's body. In such embodiments, the section **212** may rotate freely or be moved to a desired position and then locked into place via a suitable locking mechanism.

FIG. **3** presents a schematic diagram of a second surgical catheter **300** according to the disclosure. The catheter **300** includes a body having a handle **350**. At a distal end of the catheter **300** is a guide coupling **310**, which may be a rotating 'female' luer lock. The guide coupling **310** accepts and locks a guide **302**. The coupling also operates to permit the guide **302** to be rotated to a desired position relative to the handle **350** and locked in that position for use. The guide coupling **310** may include detents to allow the guide **302** to be positioned only at predetermined positions relative to the handle **350**.

The handle **350** may include concavities **356** adapted to provide a secure grip on the handle **350** by some or all of the middle, ring and little fingers of a user's hand, as will be described in greater detail with reference to FIG. **5**. The handle **350** may include a protrusion **352** adapted to a secure grip on the handle **350** by a user when the upper portion of the handle **350** is positioned between the middle and ring fingers while grasping the lower portion of the handle **350** with the ring and little fingers.

The handle **350** includes a duct **314** that passes from the guide coupling **310** to an opening **318** at a distal end of the handle **350**. The duct **314** is aligned with a duct in the guide **302** when the guide **302** is mounted in the guide coupling **310**, so that an endoscope, guidewire or other working device may be inserted into the opening **318**, pass through the duct **314** and the guide **302** to emerge from a distal end of the guide **302**. A branch section **314***a* of the duct **314** extends through the handle **350** to a handle coupling **320**. A source of suction may be attached to the handle **350** at the handle coupling **320** to provide suction at the distal end of the guide **302**, as described with reference to FIG. **2**.

Where the opening **318** is provided with a one-way valve to prevent air being drawn into the opening **318** by suction in the branch section **314***a*, an opening **354** may be provided between the branch section **314***a* and the exterior of the handle **350** to allow the user to control the amount of suction present at the distal end of the guide **302**.

The handle **350** may be provided with a locking screw **358**. Once a user has inserted a guide catheter through the duct **314** to a desired position within the patient, the user may operate the locking screw **358** to hold the guide wire in position while inserting another working device, such as a balloon catheter, along the guide wire. Once the second working device reaches the position of the locking screw **358**, the locking screw **358** may be operated to withdraw it from the duct **314** and allow the second working device to continue along the duct **314**.

With reference to FIG. **4**, a balloon catheter **454** has been inserted into the opening **318** and through the guide **302**. The balloon catheter **454** includes a tube **452** coupled to an inflation device. Operation of the inflation device causes an inflation segment **456** of the balloon catheter **454** to inflate. The handle **350** may be designed so that the distance between the opening **318** and the guide coupling **310** (indicated by the letter a), when added to the length of the guide **302** (indicated by the letter b), totals less than the distance between the attachment of the tube **452** at a proximal end of the balloon catheter **454** and the inflation segment **456** (indicated by the letter c).

Furthermore, the distance between the opening **318** and the guide coupling **310** may be selected based upon a distance between a shoulder feature of the proximal end of the balloon catheter **454** and the inflation segment **456**. The distance may be selected to allow the shoulder feature to engage the opening **318** while the inflation segment **456** extends past the distal end of the guide **302** substantially only far enough to inflate without interference from the distal end of the guide **302**. In this way, motion of the inflation segment **456** towards or away from the guide **302** during inflation may be minimized to reduce the likelihood that the inflation segment **456** will slip out of position when inflated.

A suction tube **428** may be attached to the handle coupling **320** by a tube coupling **422**. Where the suction tube **428** is stiff, the tube coupling **422** (or the handle coupling **320**) may be flexible and/or rotate to reduce interference by the stiff tube **428** with positioning the surgical catheter **300**.

FIG. **5** illustrates the surgical catheter **300** in use. A surgeon or other user holds the handle **350** in a hand by some or all of the small finger, the ring finger and the middle finger. Gripped in this way, the surgeon may move the guide **302** in the direction of its longitudinal axis, may rotate the guide **302** about its longitudinal axis, or may rotate the guide **302** about an axis other than its longitudinal axis ('yaw'). 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**. As described with reference to FIG. **4**, flexibility and/or rotation of the couplings **320** and/or **422** may reduce the interference of a stiff suction tube **428** on such motion.

The lower portion of the handle **350**, which is grasped by the fingers, makes an angle with the upper portion of the handle, and with the guide **302**, that facilitates the user's manipulation of working devices with the thumb and forefinger of a hand while grasping the handle with some or all of the remaining fingers of the hand. That is, the 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**. As shown in the figures, that angle may be approximately sixty (60) degrees, although other angles that are less than ninety (90) degrees and more than zero (0) degrees may be employed.

Using the handle **350**, the user is enabled to control the position of the guide **302** by positioning the arm and wrist of the hand that is grasping the handle, while simultaneously controlling the position of a working device inserted into the guide **302** with the thumb and forefinger of the same hand. This leaves the user's other hand free for other activities, such as holding an endoscope in position to view the distal ends of the guide **302** and the working device. In this way, the user is able to simultaneously control the position of the distal end of the guide **302** adjacent to a desired region of the patient and manipulate the working device with one hand.

FIG. **6** illustrates a handle **650** according to the present disclosure wherein the upper portion of the handle **650** comprises a pivot **652**. The upper portion includes an opening **618** and a main duct and guide coupling (not shown, but similar to the duct **314** and the guide coupling **310**) are in a fixed position relative to each other and to the pivot **652**. The duct branch in the handle **650** (not shown, but similar to the branch duct **314***a*) is pivotally coupled to the main duct, to allow suction applied to a handle coupling **620** to be applied to the opening **318** and a guide attached to the guide coupling. The pivot **652** allows the handle **650** to be rotated to a desired angular position relative to the upper portion and locked into the desired position.

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.

What is claimed is:

**1**. A system, comprising:

a guide catheter insertable through an external body passage of a subject, said guide catheter having a substantially rigid shaft, a proximal opening, a distal opening and a lumen extending between the proximal opening and the distal opening;

a handle coupled to the guide catheter, the handle having a handle opening, a handle coupling and a structure, wherein 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, and wherein the handle coupling is configured to couple a source of suction to the lumen; and

a working device adapted to be insertable through the handle opening into the lumen of the guide catheter,

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 via a portion of the working device immediately adjacent to the handle opening and to control, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen.

**2**. The system of claim **1**, wherein 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.

**3**. The system of claim **1**, wherein the handle comprises a pivot configured to allow adjustment of an angle between a longitudinal axis of the handle and a longitudinal axis of the guide catheter to a desired value.

**4**. The system of claim **1**, wherein the opening is a first opening, wherein the handle further comprises a second opening adapted to permit control of the amount of suction coupled to the distal opening of the lumen.

**5**. The system of claim **4**, wherein 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.

**6**. The system of claim **4**, wherein the handle coupling is further adapted to allow movement of the source of suction relative to the handle.

**7**. The system of claim **1**, wherein the handle is removably coupled to the guide catheter.

**8**. A method comprising:

inserting a guide catheter through an external body passage of a subject, wherein the guide catheter comprises a substantially rigid shaft, a proximal opening, a distal opening and a lumen extending between the proximal opening and the distal opening;

coupling a source of suction to the lumen through the handle;

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

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

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.

**9**. The method of claim **8**, wherein 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.

**10**. The method of claim **8**, further comprising 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.

**11**. The method of claim **8**, wherein 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.

**12**. The method of claim **11**, wherein 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.

**13**. The method of claim **11**, further comprising coupling the handle to the guide catheter.

**14**. A guide catheter apparatus insertable through an external body passage of a subject, comprising:

a substantially rigid shaft with a proximal opening, a distal opening, and a lumen extending between the proximal opening and the distal opening; and

a handle coupled to the shaft, the handle having a handle opening, a handle coupling and a structure, wherein 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 handle coupling is configured to couple a source of suction to the lumen, 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 via a portion of the working device immediately adjacent to the handle opening when the working device is inserted through the handle opening into the lumen of the shaft, and wherein the structure of the handle is configured to permit the operator to control, by one of the thumb or index finger, an amount of suction coupled to the distal opening of the lumen.



**15**. The apparatus of claim **14**, wherein 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.

**16**. The apparatus of claim **14**, wherein the handle comprises a pivot configured to allow adjustment of an angle between a longitudinal axis of the handle and a longitudinal axis of the guide catheter to a desired value.

**17**. The apparatus of claim **14**, wherein the opening is a first opening, wherein the handle further comprises a second opening adapted to permit control of the amount of suction coupled to the distal opening of the lumen.

**18**. The apparatus of claim **17**, wherein 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.

**19**. The apparatus of claim **17**, wherein the handle coupling is further adapted to allow movement of the source of suction relative to the handle.

**20**. The apparatus of claim **14**, wherein the handle is removably coupled to the shaft.

* * * * *

# EXHIBIT C

**Tolling and Standstill Agreement**

This Tolling and Standstill Agreement is dated 1 | 19, 2016 ("Effective Date"), by and among Dr. Ford Albritton ("Dr. Albritton") and Acclarent, Inc. ("Acclarent").

WHEREAS, Dr. Albritton and Acclarent intend to engage in discussions relating to Acclarent's potential licensing of certain patents and patent applications owned by Dr. Albritton related to balloon dilation of the paranasal sinuses.

WHEREAS, Dr. Albritton and Acclarent each desire that the intended discussions take place without the threat of the filing of litigation or patent office action and desire to toll each party's right to file such litigation or patent office action as set forth herein.

NOW THEREFORE, the parties agree as follows:

1. The parties will cooperate in meeting to discuss potential licensing of Dr. Albritton's patents and patent applications in the area of balloon dilation of the paranasal sinuses and related technologies.

2. As of the Effective Date, Dr. Albritton agrees that he will not file any infringement lawsuit or similar action regarding any of his patents against Acclarent until after 11:00 AM California Time on December 1, 2016.

3. As of the Effective Date, Acclarent agrees that it will not file any Declaratory Judgment action in court or any proceeding or request in any patent office (referenced above as a "patent office action") regarding any patent(s) and/or patent application(s) of Dr. Albritton until after 11:00 AM California Time on December 1, 2016.

4. If the parties are still actively engaged in good faith discussions as the tolling deadline approaches and are making progress toward a license arrangement, the parties agree to cooperate in good faith to extend the tolling deadlines of Paragraphs 2 and 3.

5. If a tolling deadline or extension thereof expires without execution of a license agreement between the parties, and without written agreement to further extend such deadline, then the parties' tolling obligations shall terminate at the time of expiration of such deadline or extension without notice.

6. The parties further agree that Federal Rule of Evidence 408 also shall apply to these discussions, that the discussions are confidential and shall be treated as a compromise negotiation for the purpose of the Federal Rules of Evidence, and any state counterpart rules or doctrine, but the Agreement is broader than and in addition to any such evidentiary rule.

7. In addition, the parties and their counsel will not (a) disclose, or (b) use for any purpose whatsoever any information, including offers, promises, conduct, statements or settlement terms, whether oral or written, made in connection with or during the discussions by the parties, their agents, employees, experts and attorneys. If, pursuant to regulatory or accounting requirements or Patent Office disclosure requirements, either party is obligated to make a disclosure of materials received during the Discussions, the disclosure shall not be

a breach of the Agreement if the disclosure is no broader than necessary to achieve compliance.

**AGREED and ACCEPTED:**

**Dr. Ford Albritton**

Signature: _____

Name: FORD D. ALBRITTON, MD

Date: 1/14/16

**Acclarent, Inc.**

Signature: _____

Name: Paul DeLoSA

Title: VP R&D

Date: 1/19/16