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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U.S. Patent No. 9,011,412

Issue Date: April 21, 2015

Title: Apparatus, System and Method for Manipulating
a Surgical Catheter and Working Device
With a Single Hand

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Inter Partes Review No. 2017-00498

DECLARATION OF DR. HOWARD L. LEVINE, M.D. IN SUPPORT OF ACCLARENT'S REPLY

Neurent 1104
Neurent v. Foundry
IPR2024-00279

I, Howard L. Levine, M.D. declare as follows:

1. I have been asked to evaluate and assess certain facts in connection with the petition for *inter partes* review filed by Acclarent, Inc. and the Patent Owner Response filed by Ford Albritton IV ("Patent Owner") in this proceeding. More specifically, I have been asked to assess and respond to the opinions of Douglas K. Holmes (Ex.2020) regarding whether claims 1-7 and 14-20 of U.S. Patent No. 9,011,412 ("Albritton" or "the '412 Patent") are anticipated or rendered obvious by the cited prior art references, including U.S. Patent No. 8,747,389 ("Goldfarb"), U.S. Patent No. 5,562,640 ("McCabe"), U.S. Patent Publication No. 2006/0063973 ("Makower"), and U.S. Patent No. 4,915,691 ("Jones"). All of the opinions and conclusions found in this declaration are my own.

Compensation

2. I am being compensated for my work at my normal consulting rate of $600/hour for time spent in connection with this matter. My compensation is not contingent on the results of my work or the testimony I provide.

Qualifications

3. I received a Bachelor of Arts (BA) from the University of Pennsylvania in 1966 and a Doctor of Medicine (MD) from Northwestern University in 1970.

4. I subsequently completed two surgical residencies at the University

Materials Considered

15. In arriving at the opinions set forth in this declaration, I relied on the following materials as well as any other materials cited herein:

A. Patkin, M. (2001). A checklist for handle design. *Ergonomics Australia On-Line*, *15* (supplement) (Ex.A);

B. Mesire™ Balloon Sinus Dilatation System Brochure. Merrill Life Sciences Pvt. Ltd. (Ex.B);

C. Declaration Of Douglas K. Holmes in Support Of Patent Owner's Response to Acclarent's Petition For Inter Partes Review Of U.S. Patent No. 9,011,412 (Ex.2020);

D. Declaration Of Douglas K. Holmes in Support Of Patent Owner's Preliminary Response to Acclarent's Petition For Inter Partes Review Of U.S. Patent No. 9,011,412 (Ex.2006);

E. Jan. 12, 2018 Transcript of Deposition of Douglas K. Holmes, MD, FACS, ("Holmes Depo.") (Ex.1016) and related exhibits (Exs.1011-15);

F. U.S. Patent No. 9,011,412 to Albritton, IV *et al.* (the "'412 patent" or "Albritton") (Ex.1001);

G. Declaration of Randy Kesten In Support of Acclarent's Petition for *Inter Partes* Review Under 35 U.S.C. §§ 311-319 and 37

C.F.R. § 42.100 *et seq.* (Petition Ex.1004);

H. U.S. Patent No. 8,747,389 of Goldfarb et al. ("Goldfarb") (Petition Ex.1005);

I. U.S. Patent No. 5,562,640 of McCabe et al. ("McCabe") (Petition Ex.1006);

J. U.S. Patent No. 4,915,691 of Jones et al. ("Jones") (Petition Ex.1007);

K. U.S. Patent Publication No. 2006/0063973 of Makower et al. ("Makower") (Petition Ex.1009);

L. NEJM Article "Pounds, Kilograms, Newtons, and Units of Force" (Ex.1013);

M. NYT article "Get Along without a Pinkie? It's Tougher than You Might Think" (Ex.1014);

N. Can. J. Plastic Surgery Article "Contributions of the Ulnar Digits to Grip Strength" (Ex.1015);

O. Deposition Transcript of Dr. Douglas K. Holmes (Ex.1016);

P. Supplemental Declaration of Randy J. Kesten (Petition Ex.2019);

Q. The videos cited below as Exs.2022-27;

R. The medical dictionaries cited below (Exs.2028-29);

S. The Influence of Wrist Position on Individual Finger Forces During Forceful Grip, by Zong-Ming Li, PhD, The Journal of Hand Surgery (2002) (Ex.2030).

The Person of Skill in the Art

16. I have been informed and understand that a person of skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. I have been informed and understand that, in determining the level of skill in the art, one may consider: the type of problems encountered in the art, prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field.

17. I understand that in its institution decision in this proceeding, the Board determined that a person of ordinary skill versed in the technology of Albritton (hereinafter a "POSA") would have had "[a]t 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 (MD) and at least 2 years of experience with laparoscopic or endoscopic surgical procedures."

18. Based on my experience, I believe that this is an acceptable definition of a POSA[1], and it is therefore from the perspective of such a person that I offer my opinions with respect to the Albritton patent method claims.

Dr. Holmes' Criticisms of Randy Kesten and Mr. Kesten's Opinions

19. While discussing the POSA standard, Dr. Holmes offered opinions about Randy Kesten, a former colleague of mine at Acclarent. I have reviewed the opinions of Dr. Douglas Holmes MD about Mr. Kesten which I found to be quite remarkable. *See* e.g., Ex.2020, ¶19 ("Mr. Kesten also lacked the education, training, or experience required to understand the issues facing surgeons using laparoscopic or endoscopic surgical instruments at least as of the critical date of the '412 Patent."); Ex.2006, ¶16. Dr. Holmes opines that Mr. Kesten lacks experience with sinuplasty devices and therefore is not qualified to give opinions in this case. Ex.2020, ¶20. I am familiar with Mr. Kesten's industry experience and I worked with him for 4 years at Acclarent. In my opinion, the comments Dr. Holmes made about Mr. Kesten are extremely disingenuous.

20. Mr. Kesten brought a wealth of experience from decades of prior

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[1] While it would not change any of my opinions in this declaration, I would also include doctors of osteopathic medicine (DO) in addition to MDs.

work when he joined Acclarent. *See* e.g., Ex.1004, ¶¶5-9 and 11. Mr. Kesten knows the intimate relationship between engineers and physicians – i.e., he knows how closely engineers work with surgeons. Contrary to Dr. Holmes statements, Mr. Kesten worked with many relevant devices prior to joining Acclarent, including work with a variety of endoscopic devices and balloon catheters. It should be noted that the balloon sinuplasty technology was conceived from these other technologies and Mr. Kesten brought this rich experience to Acclarent and applied it to his work with balloon sinuplasty devices. *See* Ex.2019, ¶8; Ex.1004, ¶¶5, 7, and 8. This **was** relevant experience for a procedure that had only been in existence for about 4 years at the time when Mr. Kesten joined Acclarent. Ex.1004. I also understand from his supplemental declaration that Mr. Kesten was an inventor on more than ten patent and patent applications involving balloon catheters for medical use (Ex.1004, ¶16), and at Acclarent, Mr. Kesten largely focused on devices for use in balloon sinuplasties.

21. Dr. Holmes has never met or worked with Mr. Kesten and has no basis to comment about Mr. Kesten's experience and knowledge with devices used in balloon sinuplasties or other endoscopic procedures. Ex.1016 (Holmes Depo.) p. 31:7-19. And from a review of his transcript, Dr. Holmes does not himself have the industry perspective to question the role of an experienced biomechanical engineer in the research and development process. Dr. Holmes has never been

involved in the development or design of a medical device and holds no patents or patent applications in the ENT field, or otherwise. Ex.1016, pp. 23:14-25:2. Dr. Holmes has also never worked with medical devices that were not already FDA approved. *Id.*, p. 24:2-24.

22. I don't know Dr. Holmes and I take him for his word regarding his credentials and assume he is a fine ENT surgeon, but he is clearly undervaluing the role of engineers in a medical device company and the knowledge they possess. *See* e.g., Ex.2020, ¶19 (Dr. Holmes stating that bioengineers lack the "medical education or training in the specialized field of laparoscopic and endoscopic surgery required to understand the use of surgical guide catheters, working devices, or other surgical apparatus like those claimed in the '412 Patent."). While I agree with Dr. Holmes that it is the biomedical engineer who constructs medical devices such as guide catheters (Ex.1016, pp. 28:5-29:2) they understand more than just general concepts about how a surgeon will use the device. (*id.* pp. 27:9-28:4)

23. Contrary to Dr. Holmes' assertions, biomedical engineers do not need the expertise to perform surgery to understand how biomedical equipment works. Based on my experience, biomedical engineers are highly educated people who develop the skills of observing surgical procedures and hone their expertise in query of surgeons about the problems, the challenges, and the successes encountered while using various surgical tools. It is their job to understand the

pathology, the procedures, and the existing solutions. It is their job to take this information and create better tools. My extensive interaction with Mr. Kesten in the development of surgical tools demonstrated to me his high skill level in all of these areas, including how the devices are used. It is with these skills and understanding of the engineer's role that Mr. Kesten's predecessor, Eric Goldfarb, and his team developed one of the patented prior art devices cited in this case without any surgeon or physician co-inventors. *See* Ex.1005 (Inventors). As I stated in paragraph 7, the embodiment of the Goldfarb prior art patent is the widely-used Relieva Side-kick. *See also,* Ex.2020. To the extent that Dr. Holmes asserts that Mr. Kesten is not qualified to offer his opinions in this case about what a POSA would have known at the time of Albritton, I could not disagree more.

Comments on Dr. Holmes' Depiction of the State of the Art

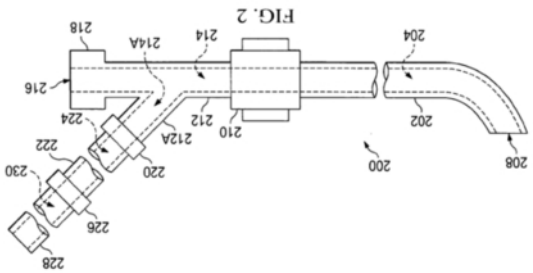
24. I have reviewed the Declaration of Douglas K. Holmes (Ex.2020) ("Holmes Declaration") and the documents cited within the Holmes Declaration.

25. Starting with paragraph 25, Dr. Holmes opined on the state of the art at the time of Albritton. Dr. Holmes states that prior to "a single-handed sinuplasty device" surgeons could either hold the endoscope in one hand, while holding the device in another and relying on an assistant to manipulate the guidewire, or the surgeon could hold the scope and the device in a single hand and use the other hand to manipulate the wire and/or working device. *Id.* I disagree with both the

Makower

59. I have reviewed Dr. Holmes' opinions regarding the Makower reference and Acclarent's asserted invalidity positions. Ex.2020, ¶¶75-95. I have also reviewed the reference cited within that part of Dr. Holmes' declaration. Ex.2030. For the reasons stated below, I disagree with Dr. Holmes' conclusions. In paragraph 76, Dr. Holmes states that he has "[n]ever heard of, seen, or considered as a possibility a device of the kind described in Makower. This is because the 'device' described in Makower would not be usable in actual sinuplasty." Ex.2020, ¶76. I find this statement to be remarkable for at least two reasons. First, the same could be said of the devices shown in the Albritton patent figures which neither Dr. Holmes nor I have ever seen in practice. Ex.2016, 1016, pp. 112:24-113:17.

60. Second, the cited Makower device looks remarkably similar if not identical to the Y-connector embodiment disclosed by Albritton. *Compare* Makower Fig. 8A with Albritton, Fig. 2 (inverted 180 degrees) below.



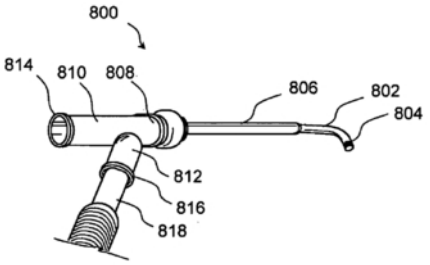


Fig. 8 A

Since Makower and Albritton are identical in structure, a POSA would have

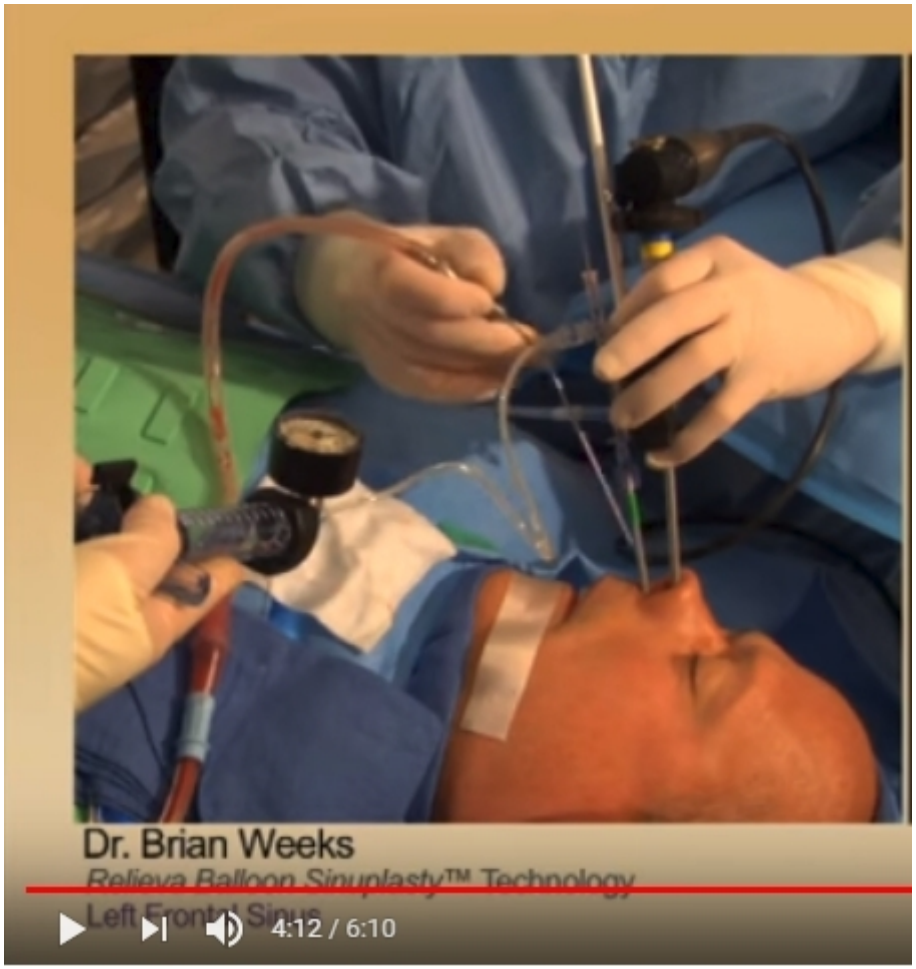
understood that Makower is capable of being held in the claimed manner.

61. In paragraphs 77-78, Dr. Holmes describes a "support device" disclosed by Makower and discusses it as though it is a required component of each Makower embodiment. Ex.2020, ¶¶77-78. I disagree. Makower states that "[o]ne or more devices disclosed herein *may* be supported by one or more support devices while performing diagnostic, therapeutic or access procedures on a patient." Makower, [0139] (emphasis added). Accordingly, Makower does not *require* use of the support device.

62. Dr. Holmes' discussion of the "locking mechanisms" disclosed in Makower are also not particularly relevant. Ex.2020, ¶79. Dr. Holmes is correct that forces "may" cause the position of the guidewire to change, however there are various ways to stabilize the devices. This is intuitive to any surgeon who learns over the years how to manage instruments in the most ideal way for the particular anatomy and pathology of his or her patients. As such, a POSA would not need a locking mechanism.

63. In paragraphs 80-81, Dr. Holmes' criticizes Makower's disclosure of controlling suction by using a luer hub or rotating hemostasis valves. Ex.2020, ¶¶ 80-81. Dr. Holmes ignores the fact that a user could release the handle and use the thumb and/or index finger to control suction, e.g., by rotating Makower's hub. I

saw this performed in one of the videos Dr. Holmes relies upon. *See* Ex.2023 (showing Dr. Weeks using suction at the 4:12 minute mark).



Dr. Holmes seems to assume that a user must control suction with the thumb or index finger *while* holding the Y-connector. I understand that this is not a requirement of the claims.

64. Dr. Holmes' opinion that a surgeon could not hold the Y-connector in such a way as to allow the guide catheter to positioned using three fingers is confusing. *See* Ex.2020, ¶82-83. This could be done and I have held instruments

like this and observed numerous surgeons do this in training sessions (i.e., cadaver labs and live surgery). In those situations, a surgeon is often able to hold the Y-connector in addition to the tubing. However, as demonstrated by the photo I took below which matches Mr. Kesten's hand drawing, it is very possible to simply hold the Y-connector with three fingers while the thumb and index finger remain free to manipulate a working device. I have demonstrated this below in a photo which I took with my digital camera on January 29, 2018. It shows me holding a Y-connector similar to the one shown by Mr. Kesten with my left hand while using my thumb and index finger of that same hand to manipulate a wire in the back. I did not edit this photograph in any way other than to crop the image. I also took a video of my left hand holding that same Y-connector while the thumb and index finger of my left hand manipulated the wire in the back. I understand that this same video which I created has been marked and filed as Exhibit 1020.

65. Moreover, Albritton discloses a Y-connector embodiment as discussed above, and a surgeon could have held the device in addition to the disclosed suction tube 818 which would have provided additional stability.

66. Dr. Holmes' statement that a grip like the one shown in the photo above "bears no resemblance to the grip actually used in surgery" is incorrect. Ex.2020, ¶83. Dr. Holmes only considers one grip style and patient position and as I discussed above, there are ***at least*** two grips used to accommodate differing patient positions.

67. Dr. Holmes has also relied on an impractically-sized Y-connector in his own photo while opining that these devices do not provide the required stability and range of motion for one-handed use. Ex.2020, ¶¶84-85. A larger exemplar would be more true to the teachings of Makower. Moreover, as Makower discloses (and as Mr. Kesten showed in his drawing), the Y-connector would have had a suction tube attached to it in effect increasing the length of the "Y" limb that would have assisted in stabilizing the device. *See* Makower, ¶[0167].

68. Additional statements by Dr. Holmes also require comments. Dr. Holmes states that "during a balloon sinuplasty procedure, the guide catheter must be inserted vertically and then rotated 90 to 120 degrees." Ex.2020, ¶85. This degree of rotation is only done upon initial insertion of the guide catheter. Following this initial placement, the tip is advanced and rotated minimally either

Conclusion

I declare under penalty of perjury under the laws of the United States of America and the State of Florida that the foregoing is true and correct.

Dated: January 29, 2018

Dr. Howard L. Levine

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