IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC, Plaintiffs, v. MINERVA SURGICAL, INC., Defendant.	C.A. No.: 15-1031-JFB-SRF REDACTED - PUBLIC VERSION

DECLARATION OF KARL R. LEINSING, MSME, PE, IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT AND PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY

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I, Karl R. Leinsing, declare as follows:

1. I have been asked by Hologic, Inc. ("Hologic") to provide expert opinions in the above captioned litigation regarding infringement and validity. Specifically, I have been asked to review U.S. Patent Nos. 6,872,183 ("the '183 patent"), 9,095,348 ("the '348 patent"), and 9,247,989 ("the '989 patent") (collectively, the "patents-in-suit") and Minerva's accused Endometrial Ablation System ("EAS") and determine what claims are infringed by the accused product and give a detailed technical analysis of the patents and the accused product.

I. BACKGROUND AND QUALIFICATIONS

2. I am President and founder of ATech Designs, Inc., a medical device product development and consulting company based in Dover, New Hampshire. I am an engineer with substantial experience in the design and development of a wide variety of medical instruments and devices since 1992 from conception through regulatory approval and manufacturing including sales and marketing.

3. I hold a Master's of Science Degree in Mechanical Engineering from North Carolina A&T State University and a Bachelor of Science Degree in Mechanical Engineering from the University of New Hampshire. I am a licensed professional engineer in New Hampshire (PE License No. 11437).

4. I have designed or developed several medical instruments and devices including a needle-scopic surgical fastener (US Patent Application: US2004/0073237) that uses a curved nitinol wire to fasten tissue together. I have also worked on a reusable laparoscopic suturing device (US Patent Application: US2005/0070922) for Onux Medical, Inc. and developed a disposable version of the same device. I have also done consulting work on speculums and knitted tension-free vaginal tape (TVT) devices used for urinary incontinence.

5. More closely related experience to this case is my experience with the function, design, and development of the NovaSure knitted endometrial ablation array that is made with eight (8) different yarns (both silver plated and non-plated). My company developed and patented the knitting machine that makes the NovaSure RF ablation array (US Patent No. 6,158,250) and we manufactured two machines for Novacept. It's my understanding that Hologic purchased the NovaSure technology from Novacept, but I have not done any consulting work for Hologic nor have we sold them any products or additional knitting machines.

6. I have been named as an inventor on over twenty-snine (29) U.S. patents (many others pending). I have received many awards for my designs with one design published on the cover of LIFE Magazine and I was recognized as one of the top 100 medical device professionals in the country by MD&DI Magazine.

7. My curriculum vitae (Ex. 38)[1] includes a list of publications that I have authored in the last 10 years, a list of the patents granted to me, and the cases in which I have testified as an expert at trial or deposition in the last 5 years.

II. COMPENSATION

8. I am being compensated for the time spent on this litigation at my customary rate of $450 per hour. My compensation does not depend in any way upon the outcome of this litigation.

III. SUMMARY OF OPINIONS

9. The Minerva EAS infringes at least claims 1, 2, 5, 6, 7, 9, 11, 13, 14, and 15 of the '183 patent, claims 1, 3, and 12 of the '348 patent, and claims 1 and 7 of the '989 patent.

10. Use of the Minerva EAS infringes the asserted '183 patent claims because it

[1] The Exhibits ("Ex.") herein refer to the Exhibits to the Declaration of Marc Cohn.

performs the claimed step of "monitoring for the presence of a perforation in the uterus using a pressure sensor" — the only disputed limitation. The Minerva EAS's flow sensor in combination with its fixed orifice satisfies the pressure sensor limitation as construed by the Court because its input detects indirectly a force per unit area and outputs a corresponding electrical signal. The flow rate of gas through the flow sensor and orifice plate is proportional to the pressure differential between the CO_2 source and the uterus. Because the source pressure is fixed, the flow sensor indirectly detects a force per unit area in the uterus and delivers an electrical signal corresponding to that pressure. The principle of indirectly sensing a force per unit area by using a flow sensor and orifice plate is known by a POSITA as Bernoulli's Principal and is confirmed in Minerva's core technical documents, through its direct testing and comparisons with Hologic's patented NovaSure device, as well as in Minerva's representations to the FDA and others.

11. The Minerva EAS infringes the asserted '348 patent claims because it includes "an indicator mechanism . . . configured to indicate a dimension of the uterus" — the only disputed limitation. The Minerva EAS's disposable handpiece includes a "PFA Width Indicator" that includes a Red/Green area, rows of dots, and a black indicator line. When the Minerva EAS's applicator is deployed in a uterus, the PFA Width Indicator indicates uterine width. As confirmed by Minerva's core technical documents, its representations to the FDA, clinicians, and investors, and by my own testing, the boundary between the Red and Green areas indicates a uterine width of approximately 2.5 cm and the rows of three, four, and five dots indicate uterine widths of 3 cm, 4 cm, and 5 cm, respectively. Accordingly, the Minerva EAS's width indicator is configured to indicate the width of the uterus.

12. Use of the Minerva EAS infringes the asserted '989 patent claims because it

performs the claimed actuating step wherein actuating the handle includes "translating the inner sleeve relative to the proximal grip" — the only disputed limitation. The Minerva EAS's applicator is configured to be limited by the width of the uterus. Once the applicator is constrained by the walls of the uterus, there is no further distal movement of the inner sleeve. A force limiting spring, however, allows continued distal movement of the proximal grip. Thus, continued distal movement of the proximal grip results in translating the inner sleeve relative to the proximal grip when the applicator is constrained by the uterine width.

13. Dr. Tucker's enablement and written description opinions are focused on a narrow set of claim limitations, i.e., "applicator head," "an energy applicator," "one or more electrodes," "pressure sensor," and "thermal ablation device." Dr. Tucker has not opined that the asserted claims are invalid with respect to any other claim limitations.

14. With respect to "applicator head," "an energy applicator," "one or more electrodes," "pressure sensor," and "thermal ablation device," in my view, each of those limitations is enabled and has sufficient written description under 35 U.S.C. § 112. Therefore, in my view, the asserted claims — claims 1, 2, 5, 6, 7, 9, 11, 13, 14, and 15 of the '183 patent, claims 1, 3, and 12 of the '348 patent, and claims 1 and 7 of the '989 patent — are not invalid.

15. The '183 patent's specification provides a detailed disclosure and figures specifying the components of exemplary perforation detection systems, schematics of an exemplary perforation detection system and an exemplary pneumatic subsystem, and a simplified state diagram illustrating an exemplary mode of operation. Further, pressure sensors that directly and indirectly detect a force per unit area are well-known in the art and the relationship between flow rate and pressure is a well-known, basic principle of fluid dynamics. Thus, the asserted claims of the '183 patent are not invalid for lack of written description or enablement.

16. The '183 patent specification clearly discloses that the described perforation detection system can be used in combination with thermal ablation devices. Further, it is readily apparent to one of skill in the art how to combine the disclosed perforation detection system and components with a thermal ablation device. Accordingly, claim 15 of the '183 patent is not invalid for lack of written description or enablement.

17. The common specification of the '348 and '989 patents provides a detailed disclosure and 47 figures of exemplary applicators and electrodes. The specification teaches electrical conductors both on the surface of the applicator and inside the applicator. Further, non-permeable applicators and capacitive coupling were well-known in the art. Thus, the asserted claims of the '348 and '989 patents are not invalid for lack of written description or enablement.

18. In my opinion, Dr. Tucker's invalidity opinions regarding enablement and written description are irrelevant and unreliable because Dr. Tucker ignored the Court's claim constructions and did not apply the applicable legal standards for enablement and written description as I understand them.

IV. APPLICABLE LEGAL PRINCIPLES

19. I understand that I am obliged to apply any pertinent legal principles in providing my opinions. I will not offer opinions of law as I am not an attorney. However, I have been informed of several principles concerning patent infringement, non-infringement, validity, and invalidity, which I used in arriving at my conclusions. The legal principles that I have been asked to apply are set forth below.

A. Patent Infringement

20. I have been instructed by counsel that a determination of patent infringement

involves a two-step process: (1) the Court determines the meaning of the claim terms according to a person of skill in the art; and (2) the properly construed claims are compared to the accused product to determine whether all of the elements of the claims are present.

21. I understand that, in order for a patent claim to be directly infringed, an accused method must perform each step of the claimed method, or an accused product or instrumentality must embody each element of a claimed apparatus, structure, or compound.

22. I understand from counsel that a single element or step of the accused product or method may satisfy more than one element of a claim. I further understand that multiple components together may satisfy a claim limitation so long as the claim does not require a single-component structure.

23. Further, I understand that a party can be liable as an infringer if that party contributes to or induces others to infringe the patents-in-suit by aiding and abetting others to practice the patented invention.

24. I understand that there are two types of claims: independent claims and dependent claims. I further understand that independent claims do not refer to any other claims and infringement is established when all the limitations of the independent claim have been met. I also understand that dependent claims add additional requirements to the independent claim. Therefore, in order to infringe a dependent claim, the allegedly infringing device or method must meet all limitations of that dependent claim as well as any other claims to which it refers.

25. Whoever, without authority, makes, uses, offers to sell, or sells any patented invention during the term of the patent(s) is found to infringe the patent(s).

26. It is my understanding that the patentee has the burden of proving infringement by a preponderance of the evidence. I understand this standard to require that the patentee present

evidence that as a whole shows that the fact sought to be proved is more probable than not.

B. Patent Validity

27. I understand that the patents-in-suit are presumed valid and Minerva has the burden to prove by clear and convincing evidence that the patents-in-suit are invalid.

28. The first paragraph of 35 U.S.C. § 112[2] provides that the "specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.]" I understand that these requirements are referred to as the enablement and written description requirements.

1. The Law Of Enablement

29. I understand that the patent specification must enable a person of ordinary skill in the art at the time of the invention to make and use the claimed invention without undue experimentation. Because enablement pertains to the claimed invention, I understand that the enablement inquiry depends on the claims as construed by the Court. Accordingly, my opinions below are based on the scope of the claimed inventions as construed by the Court.

30. I have been informed that the enablement requirement is assessed from the perspective of a person of ordinary skill in the art ("POSITA") at the time of the invention, which in this case is May 8, 1998 for the asserted claims of the '348 and '989 patents and November 10, 1999 for the asserted claims of the '183 patent. A POSITA would assess the claims of the asserted patents in light of the patent specification together with the knowledge in the art as of the earliest effective filing date, to determine whether the enablement requirement is

[2] I understand that, because the patents-in-suit have an effective filing date before September 16, 2012, the Pre-America Invents Act version of 35 U.S.C. § 112 applies.

satisfied. I have been advised by counsel that the enablement requirement is satisfied when the specification provides enough information for a POSITA to make and use the claimed invention without undue experimentation. I have been instructed to consider the following factors to determine whether undue experimentation is required: (1) the quantity of experimentation needed to make or use the invention based on the content of the disclosure; (2) the amount of direction provided by the inventor; (3) the existence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the level of one of ordinary skill; (7) the level of predictability in the art; and (8) the breadth of the claims. I understand that these factors are known as the *Wands* factors.

31. I have also been informed that a patent disclosure need not convey information that is already within the knowledge of a POSITA. In addition, I understand a patent applicant is not required to test all the embodiments of his invention. Moreover, neither the time nor the money that may be required to complete testing necessitates a finding of undue experimentation. I understand that the fact that experimentation may be complex does not necessarily make it undue if the art typically engages in such experimentation. The test of enablement is not whether any experimentation is necessary, but whether the necessary experimentation is undue.

32. I understand that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied. Failure to disclose other methods by which the claimed invention may be made or used does not render a claim invalid. Since enablement pertains to the scope of the claimed inventions, a patent specification does not have to enable unclaimed aspects present in an accused product. As such, I understand that it is generally irrelevant if the patent specification does not enable the making or using of the accused

product if it enables another mode of the practicing the invention. Similarly, I understand that in general a patent need not enable unclaimed features of the embodiments described in the specification.

33. I understand that whether the inventor believes or does not believe that the patent specification sufficiently enables the full scope of the claims is usually irrelevant to the enablement conclusion because this inquiry must focus objectively on whether or not one of skill in the art would find the claims to be enabled. I understand that the subjective beliefs of an inventor may be subject to bias and need not always be considered. My opinions below are from the perspective of a POSITA at the time of the invention.

2. The Law of Written Description

34. I am informed that the test for sufficiency of the written description is whether the disclosure of the application relied upon reasonably conveys to a POSITA that the inventor(s) had possession of the claimed subject matter as of the filing date. I understand that "possession" is shown by the disclosure and that the specification must describe an invention understandable to a POSITA and show that the inventor actually invented the claimed invention. I am informed that the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. I understand that applicable factors include the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue.

35. As with enablement law, written description pertains to the ***claimed*** invention. Accordingly, my opinions below are based on the claims as construed by the Court.

36. I have been informed that the written description requirement is assessed from the

point of view of a POSITA at the time of the invention. A POSITA would assess the claims in light of the patent specification together with the knowledge in the art as of the earliest effective filing date to determine whether the written description requirement is satisfied. I have also been informed that a patentee does not need to include that which is already known to and available to a POSITA. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. The written description requirement must be applied in the context of the particular invention and the state of the knowledge. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the written description requirement is met.

37. I understand that to meet this requirement, the patentee is not required to describe in the specification every conceivable and possible future embodiment of the claimed invention. A specification may contain a written description of a broadly claimed invention without describing all species that the claim encompasses. I also understand that unclaimed aspects of the inventions or unclaimed aspects of the accused products do not need to be described.

V. ONE OF ORDINARY SKILL IN THE ART

38. I have approached my analysis of the Hologic patents from the perspective of a POSITA, which means the level of skill of a POSITA at the time of the filing of each patent (or the effective filing date of the applications that led to each of the patents) analyzed.

39. The patented technology relates to methods and systems for ablating the endometrial lining of uterine tissue in order to treat abnormal uterine bleeding, in addition to a method of checking for holes in the uterine cavity as a safety procedure before any ablation

occurs. To determine who a POSITA would be for purposes of my declaration, I considered the problems encountered in working in the field, the nature of the prior art relating to the field, and the complexity and speed of the development of the technology. Based on these factors, it is my opinion that a POSITA would have, through education and/or professional experience, the equivalent of a bachelor's degree in biomedical engineering, mechanical engineering, or a related technical field, and at least two years' experience designing or working with devices for use in the uterus.[3] Under this definition I would be considered a POSITA since 1998.

40. I understand that Minerva has proposed its own definition of a POSITA. I have considered this definition and although I disagree with it, my opinions in this declaration would not change if I applied either definition of a POSITA.

VI. BACKGROUND OF THE RELEVANT TECHNOLOGY

A. Endometrial Ablation

41. The technology of the asserted claims relates to the treatment of chronic bleeding of the endometrial layer of the uterus, i.e., "menorrhagia." Ex. 2 at 1:28-31. One treatment for this condition is a surgical technique known as "endometrial ablation," in which the lining of the uterus is destroyed and/or coagulated by heat or electrical energy. *Id.* at 1:25:28; Ex. 1 at 1:22-28.

42. Prior art ablation techniques (such as the "heated fluid techniques" and then-existing RF ablation techniques) posed great risks. Ex. 2 at 1:65-2:24; discussions with Dr. Jamieson and Dr. Johns. For example, the heated fluid method "is a very passive and ineffective

[3] [redacted] In my view, my opinions in this declaration would not change if I applied Dr. Tucker's definition of a POSITA.

heating process" because the "process does not account for variations in factors such as the amount of contact between the balloon and the underlying tissue, or cooling effects such as those of blood circulating through the organ." *Id.* at 1:54-59. Likewise, prior art RF ablation techniques provided no feedback as to actual ablation depth. *Id.* at 1:59-64. Accordingly, these prior art techniques required great care to prevent over ablation. *Id.* at 1:65-2:24.

43. In the early-1990s, physicians used endometrial ablation instruments such as a "roller ball" or wire loop under visualization to burn tissue away inside the uterus. D.I. 29, ¶ 4. These first-generation procedures often took 30 to 50 minutes because the physician had to move the instrument carefully over the entire inner surface of the uterus to ensure complete removal of the endometrial layer. *Id.*, ¶¶ 5-6, 12.

44. Another risk associated with endometrial ablation is the presence of an undetected perforation in the uterus. If a perforation is present and undetected, the ablation device could pass through the perforation and cause injury. Ex. 1 at 1:35-38. Prior to the inventions here, physicians would sometimes visually inspected the uterus for perforations (e.g., holes in the uterine wall) using hysteroscopy. *Id.* Additionally, a perforation could allow hot fluids generated during ablation to escape the uterus and cause serious injury to other organs. D.I. 29, ¶ 7. Physicians were not always able to see small perforations, thus increasing patient risk during an ablation.

B. The Patents-In-Suit

45. The patents-in-suit relate to devices and methods for use in endometrial ablation. The asserted claims relate specifically to endometrial ablation of the uterus.

46. The '183 patent, entitled "System and Method for Detecting Perforations in a Body Cavity," was filed on May 24, 2004 and relates to a provisional application filed

November 10, 1999. The effective filing date of the '183 patent is thus November 10, 1999. I understand that Hologic holds the rights to the '183 patent.

47. Generally, the '183 patent's asserted claims are directed to monitoring perforations in the uterus prior to endometrial ablation. Ex. 1 at Abstract, 1:42-50. If no perforations are found, endometrial ablation can begin.

48. Claim 1 recites:

> A method of ablating a uterus, comprising the steps of:
>
> inserting an ablation device into a uterus;
>
> flowing an inflation medium into the uterus;
>
> monitoring for the presence of a perforation in the uterus using a pressure sensor; and
>
> treating the interior of the uterus using the ablation device.

Ex. 1 at 8:10-15.

49. The '989 patent, entitled "Moisture Transport System for Contact Electrocoagulation," was filed on March 2, 2015 and relates to a provisional application filed May 8, 1998. The effective filing date of the '989 patent is thus May 8, 1998. I understand that Hologic holds the rights to the '989 patent.

50. The '989 patent is directed to methods of performing endometrial ablation that involve transcervically inserting into a uterus the energy applicator at the distal end of an ablation device. Ex. 3 at 18:29-31, 19:15-17. Claim 1 recites:

> A method for performing endometrial ablation comprising:
>
> transcervically positioning a distal portion of an ablation device into a uterus, the distal portion comprising an energy applicator, the

energy applicator comprising a tissue contacting surface and an expandable-contractible carrying member, the expandable-contractible carrying member including first and second inner flexures and first and second outer flexures, the first and second outer flexures being coupled to an outer sleeve and the first and second inner flexures being coupled to an inner sleeve, the inner sleeve being slidably and coaxially disposed within the outer sleeve;

actuating a handle coupled to a proximal portion of the ablation device to cause the carrying member to expand the energy applicator in the uterus, the handle comprising a proximal grip and a distal grip pivotally attached to one another at a pivot point, and wherein actuating the handle includes moving the proximal grip and the distal grip closer together while translating the inner sleeve relative to the proximal grip;

actuating an inflation source to further expand the energy applicator in the uterus; and

delivering energy through the energy applicator to thereby deliver energy to endometrial lining tissue of the uterus.

51. The '348 patent, entitled "Moisture Transport System for Contact Electrocoagulation," was filed on August 8, 2013 and relates to a provisional application filed May 8, 1998. The effective filing date of the '348 patent is thus May 8, 1998. I understand that Hologic holds the rights to the '348 patent.

52. The '348 patent is directed to an endometrial ablation device. Ex. 2 at 11:51-52, 19:14-21. Claim 1 recites:

A device for treating a uterus comprising:

an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner

sleeve slidably and coaxially disposed within the outer sleeve;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;

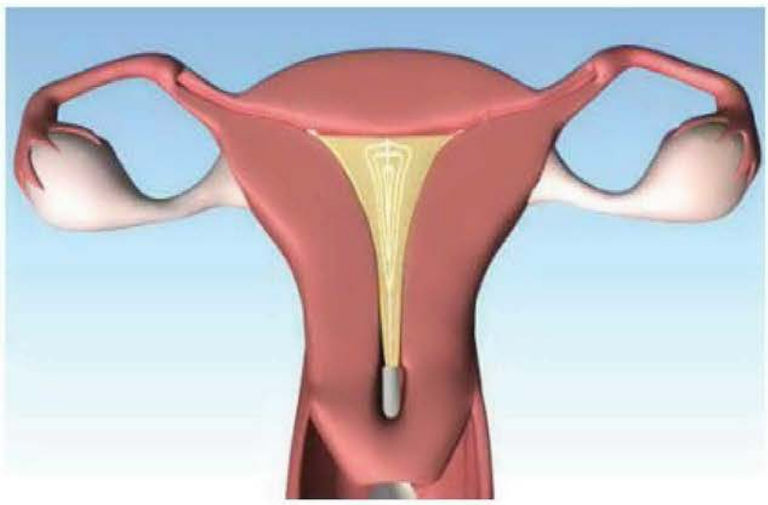
a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

53. There are numerous other aspects of the inventions claimed in each of these patents. They are discussed below in the context of the infringement analysis.

C. Hologic's NovaSure System

54. Hologic's NovaSure system was approved by the FDA in 2002. D.I. 28, ¶ 13. Notably, in contrast to prior art roller ball or wire loop ablation techniques, NovaSure employed an applicator head that conformed to the shape of the uterus. D.I. 29, ¶¶ 7, 12. NovaSure allowed for ablation of the endometrial lining throughout the cavity in two minutes or less.



Id., ¶ 7.

55. The NovaSure system substantially reduced the time required for the procedure and made it possible for the procedure to be performed at a physician's office. *Id.*, ¶ 12. The NovaSure procedure also detects perforations in the uterus prior to an ablation procedure using computerized monitoring. If a perforation is detected, the NovaSure system prevents the ablation procedure from proceeding. The NovaSure procedure has treated over two million patients. *Id.*, ¶ 14.

56. The NovaSure RF Controller (Version 10) with instruction manual, power cord and footswitch are pictured below:

57. I understand that the NovaSure system was developed originally by Novacept. D.I. 28, ¶ 13. In 2004, Cytyc Corporation acquired Novacept. *Id.* In 2007, Hologic acquired Cytyc. *Id.*

D. Minerva's Endometrial Ablation System

58. I understand that one of the founders of Novacept, Mr. Csaba Truckai, is a named inventor on all of the patents-in-suit. *Id.*, ¶ 15. Mr. Truckai is also a founder of Minerva. D.I. 12, Ex. 3 at 52-53. Minerva's EAS directly competes with NovaSure. D.I. 28, ¶ 4. As noted in Section VIII *infra*, it is my opinion that Minerva's EAS infringes the patents-in-suit.

59. The front of the Minerva RF controller is pictured below.

60. The Minerva instructions, power cord, footswitch, argon and CO_2 canisters, and RF Controller are pictured together below:

61. The Minerva EAS is very similar to the NovaSure system in that it also uses a bipolar Radio Frequency ("RF") system that uses high voltage RF electrical current to heat and ablate the endometrial layer of the uterus.

62. [redacted] The Minerva EAS uses a bipolar design to deliver RF energy. *See* Ex. 62 at 279371 ("[A] small amount of bipolar RF current travelling through the target tissue (and resultant head), results in the ablation of endometrial tissue."). [redacted]

63. A majority of the features and design elements between the Hologic NovaSure and the Minerva EAS are identical or similar. A picture of each device is shown below showing both the side and top views of the devices. In a brief summary, they both have an expandable and contractible flat triangular energy applicator with an inner frame with at least two sets of flexures and an inner and outer sleeve. They both use RF energy to create tissue ablating heat. Bi-polar electrodes are placed inside the array or energy applicator of both devices to create the RF energy. The two devices also both have a long introducer sheath. Both devices also have an applicator head that collapses for insertion into the uterus. The introducer sheath also controls the depth or length that the array can expand into the uterus to account for differences in uterus size. The length dimension is controlled by an adjustable locking mechanism to set the length

from 4.0 to 6.5 cm on both devices. The width of the array is tensioned by the frame in both devices, which has sliding sleeves and flexural elements to open the array against the uterus. The tension is set by a spring in the handle that pushes on the inner sleeve that pushes out on the array. The position of the inner sleeve relative to the outer sleeve corresponds to the width of the array, so it is connected to an indicator mechanism present on both devices to display the width to the user. The sleeves that control the tension and width of the array are also coupled to the grips on the handles. The grips are also pivotally attached to each other and move closer and apart from each other to control the width on the array. These similarities are apparent in the pictures below and will be discussed in more detail in this declaration.

[redacted]

64. [redacted]

[redacted]

VII. CLAIM CONSTRUCTION

65. I understand that the Court has construed the claims in this case. D.I. 227. In formulating my opinions, I understand that I must apply the Court's construction of the disputed claim terms. The Court's constructions of the disputed terms of the asserted claims are included below. To the extent that the Court has not construed a particular term, I am relying on my own understanding of the plain and ordinary meaning of the term as one of ordinary skill in the art would have understood it at the time of the inventions.

Claims	Term	Court's Construction
'183 Patent Claims 1, 9	"pressure sensor"	"a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal"
'183 Patent Claims 1, 5-7, 9, 11	"monitoring"	"monitoring"
'348 Patent Claims 1, 12	"applicator head"	"a distal end portion of an ablation device that applies energy to the uterine tissue"

Claims	Term	Court's Construction
'989 Patent Claim 1	"an energy applicator"	"an applicator of an ablation device that delivers energy to the uterine tissue"
'348 Patent Claim 1	"an indicator mechanism"	"a mechanism configured to indicate a dimension"
'348 Patent Claim 1	"one or more electrodes"	"one or more electrical conductors"

D.I. 227.

66. I understand that the parties have agreed to the following constructions:

Claims	Term	Agreed Construction
'183 Patent Claims 1, 6, 9, 11	"a perforation in the uterus"	"an abnormal hole in the wall of the uterus"
'348 Patent Claim 1; '989 Patent Claim 1	"pivot point"	"a point of attachment between two members about which the members hinge or rotate"

D.I. 155 at 3.

VIII. INFRINGEMENT ANALYSIS

67. As an initial matter, I understand that the Aurora Endometrial Ablation System — also referred to as the Gen. 1 Minerva EAS — was used in clinical studies. This iteration was subsequently modified and became known as the Minerva EAS. I [redacted]

A. The Asserted Claims

68. I understand that Hologic is presently asserting the following claims in this litigation: claims 1, 2, 5, 6, 7, 9, 11, 13, 14, and 15 of the '183 patent, claims 1, 3,and 12 of the '348 patent, and claims 1 and 7 of the '989 patent. In my opinion, Minerva's EAS infringes each of these claims. Minerva infringes each apparatus claim by making, using, and selling the Minerva EAS. Minerva infringes each method claim by performing each step of the claims and by inducing or contributing to the infringement of others.

B. US Patent No. 6,872,183

1. Claim 1

69. I address the limitations of claim 1 in order, but I understand that Minerva's non-infringement argument for this claim pertains to only whether Minerva's Uterine Integrity Test ("UIT") "monitor[s] for the presence of a perforation in the uterus using a pressure sensor," analyzed in Section VIII.B.1.d below.

a. "*A method of ablating a uterus, comprising the steps of*"

70. To the extent the preamble is limiting, the use of the Minerva EAS involves "a method of ablating a uterus." Minerva's EAS " is designed to ***treat abnormal uterine*** bleeding due to benign causes in pre-menopausal women for whom childbearing is complete" and is indicated by the FDA "for ablation of the endometrial lining ***of the uterus*** in pre-menopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete." Ex. 62 at 279367, item 2.0 (emphasis added); Ex. 74 at 2290.

b. "*inserting an ablation device into a uterus*"

71. Use of the Minerva EAS includes inserting an ablation device into a uterus. The Operator's Manual states that the handpiece is "inserted and positioned at the fundus of the uterine cavity." Ex. 62 at 279371, item 3.0.

c. "*flowing an inflation medium into the uterus*"

72. Use of the Minerva EAS includes flowing an inflation medium, namely CO_2, into the uterus. The Operator's Manual instructs users that "the Minerva RF Controller has a uterine integrity test (UIT) feature designed to assess possible defects of the uterus or the PFA ***using the introduction of CO_2 gas***." *Id.* at 279369, item 2.2 (emphasis added).

d. "*monitoring for the presence of a perforation in the uterus using a pressure sensor*"

(i) The Minerva Uterine Integrity Test

73. Prior to delivering ablation energy, the Minerva EAS performs a UIT that is, according to Minerva's documentation, "DESIGNED TO DETECT A PERFORATION OF THE UTERINE WALL." *Id.* at 279373, item 6.1.

74. During the UIT, the Minerva EAS passes CO_2 gas through the handpiece and into the uterus to inflate the uterus. *Id.* at 279374, item 6.3; *see also* Ex. 63 at 52910, 52921-22; Ex. 66 at 2337-38. [redacted] Because the pressure in the uterus is low and because the pressure applied by the Minerva EAS is high, CO_2 gas will flow into the uterus according to the magnitude of this pressure differential.

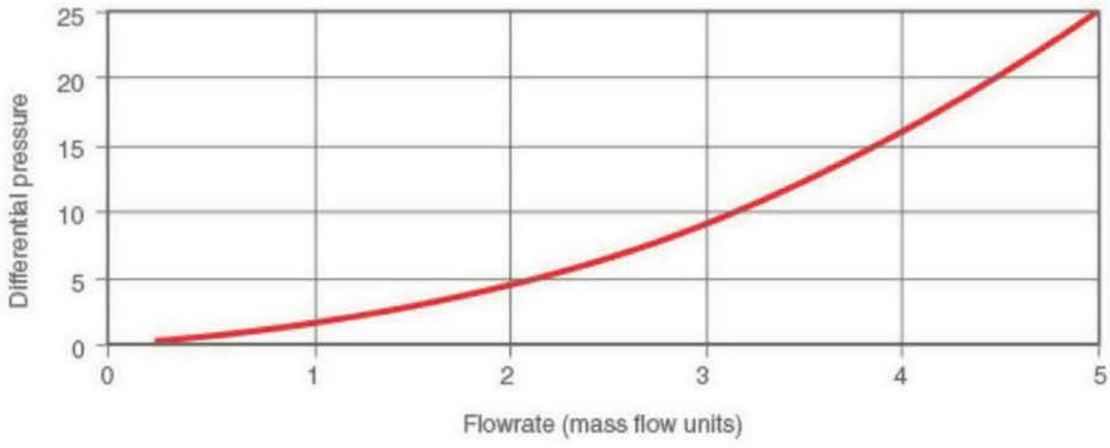
75. The Minerva EAS uses a flow sensor to measure the flow rate of CO_2 gas into the uterus. According to a well-known law of physics governed by Bernoulli's Equation (simplified below), the flow rate of the CO_2 gas will be proportional to the square root of the pressure drop:

[4] [redacted]

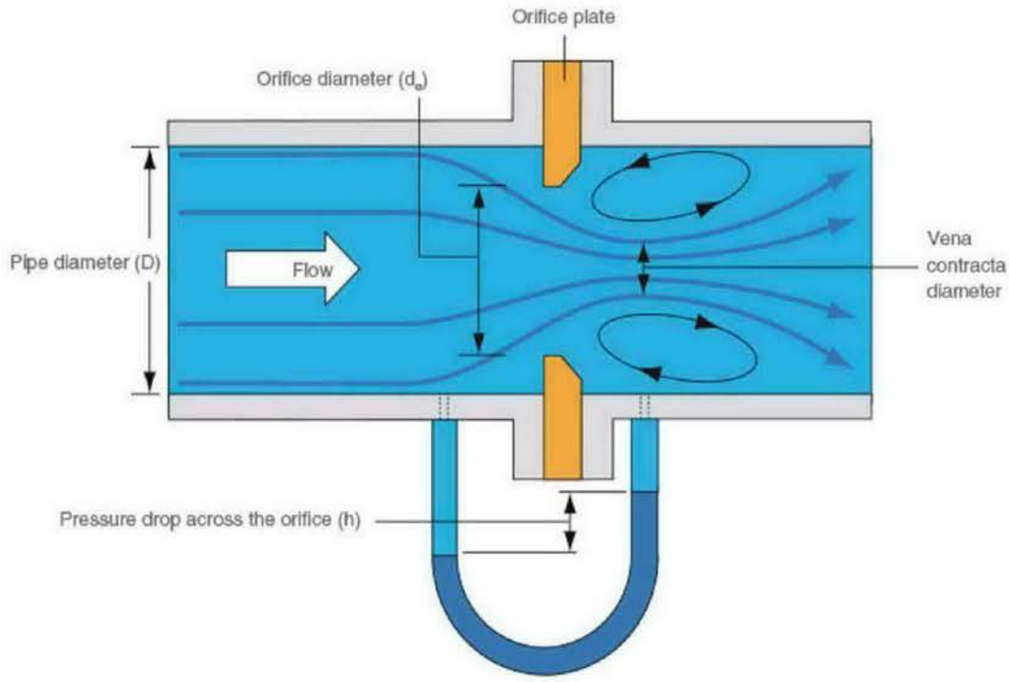
$$q_v \propto \sqrt{\Delta p}$$

In the equation above, q_v is the volumetric flow rate and Δp is the pressure drop. *See* Ex. 45 at 536.

76. The Minerva RF Controller uses the flow sensor in conjunction with a fixed orifice to monitor for the presence of perforations. As CO_2 gas flows into the uterus, the uterine pressure will rise, in much the same way that the pressure inside a balloon rises when gas flows into it. This rising uterine pressure means that the pressure differential between the CO_2 gas in the Minerva EAS (at 50 mmHg) and the uterus is reduced, and this will in turn reduce the flow rate of the CO_2 gas. If there is no perforation, and if the uterus is perfectly sealed, eventually the pressure will rise to match the input pressure (about 50 mmHg) and the flow rate will fall to zero, as there will no longer be a pressure difference between the pressurized CO_2 gas in the Minerva EAS and in the uterus. This relationship between flow and pressure during the UIT can be shown schematically below:



See id. at 534 ("The square-root relationship of an orifice plate flowmeter").



See id. at 535 ("An orifice plate with vena contracta").

77. The Minerva EAS determines that no perforation is present by checking to see that the flow rate of CO_2 gas falls below a certain threshold for a certain amount of time. In this manner and using the equation above, the Minerva EAS checks to see if the uterine pressure will stay above a certain threshold for a certain amount of time, which is exactly how the preferred embodiment of the '183 patent monitors for perforations.

78. Minerva was able to go one step further in the relationship between pressure and flow rate. Minerva knew the pressure, accuracy of pressure regulators, flow rate, and pressure and flow rate thresholds to detect a perforation with the NovaSure system. [redacted]

[redacted]

79. [redacted]

(ii) Infringement Analysis

80. Use of the Minerva EAS includes monitoring for the presence of a perforation in the uterus using a pressure sensor.

81. [redacted]

[redacted] "Be aware of the appropriate sequence of actions detailed in this Operator's Manual and the troubleshooting section in the event the system detects a high CO_2 flow rate during the Uterine Integrity test, ***which may be indicative of a uterine perforation***." Ex. 62 at 279367, item 1.0 (emphasis added).

82. I understand that the parties agreed on the construction of a "perforation" as an "abnormal hole in the wall of the uterus." [redacted]

83. The Minerva EAS relies on the principle that the pressure of the uterus will rise above a threshold and remain there for a certain amount of time if there is no perforation, and that the pressure will not do so if there is a perforation. The flow rate of the CO_2 gas senses this rise in uterine pressure — as the uterine pressure rises, the flow rate goes down according to the relationship I described above in Section VIII.B.1.d(i). Thus, Minerva's documents explain that "[t]he position of the CO_2 arrow icon along the red-green scale near the bottom of the touch screen display indicates the likelihood of passing or failing the subsequent Uterine Integrity Test (UIT). If the CO_2 arrow icon is in the green zone, ***the CO_2 flow rate is sufficiently low*** that initiation of the UIT test is appropriate. If the CO_2 arrow icon is in the red zone, however, the ***CO_2 flow rate remains sufficiently high*** that the UIT test will not likely pass if initiated." Ex. 62 at 279395, item 13.11 (emphasis added).

84. The Court has defined a "pressure sensor" as "a device whose input detects,

directly or indirectly, a force per unit area and outputs a corresponding electrical signal."

85. The Minerva EAS uses a Honeywell Zephyr flow sensor (Ex. 75) and a Bird Precision 0.006" diameter precise orifice (Ex. 76) to indirectly detect a force per unit area:

[redacted]

86. The input of the flow sensor in the Minerva EAS indirectly detects the force per unit area (pressure) in the uterus because the flow of the CO_2 gas through the sensor is directly proportional to the force per unit area (pressure), as discussed above in Section VIII.B.1.d(i).

[redacted]

[redacted]

87. The flow sensor in the Minerva EAS delivers an electrical signal representing the flow rate of CO_2 gas into the uterus — which corresponds to the force per unit area — according to the following equation:

$$V_o = V_s\left\{0.5 + 0.4\frac{F_A}{F_{FS}}\right\}$$

$$F_A = \frac{F_{FS}\left(V_o/V_s - 0.5\right)}{0.4}$$

Where:
V_O= output voltage of the device
V_S= supply voltage measured at the device
F_A = flow applied across the device
F_{FS} = full scale flow specified for the device

Ex. 75 at 2262. [redacted]

88. Minerva's design documents and regulatory submissions corroborate the

[5] If it is determined that the "input" of the flow sensor in conjunction with the fixed orifice is not directly or indirectly detecting the force per unit area in the uterus, which I believe would be unreasonable, then it would be my opinion that the flow sensor in the Minerva EAS in combination with the orifice and tubing that connects the flow sensor to the uterus is, together, also a "pressure sensor" within the meaning of claim 1. The "input" of this combined structure directly connects to the uterine cavity and detects uterine pressure directly. The flow rate through this combined structure would follow the same laws of physics that I outlined above (*see supra* Section VIII.B.1.d(i)) and would be directly proportional to the pressure differential across it.

relationship between pressure and flow rate:

- [redacted]

e. "*treating the interior of the uterus using the ablation device*"

89. Use of the Minerva EAS includes treating the interior of the uterus using the ablation device, *i.e.*, the Minerva Disposable Handpiece. According to the Operator's Manual: "Upon successful completion of the UIT, the ablation cycle is initiated and plasma energy is delivered." Ex. 62 at 279371, item 3.0.

2. Claim 2

90. Claim 2 recites: "The method of claim 1, wherein the treating step includes delivering electrical energy to the tissue."

91. Minerva's Operator's Manual explains that, during the treating step, the Minerva EAS delivers electrical energy, in the form of bi-polar RF energy, to the uterine tissue to ablate the endometrium: "The Minerva Endometrial Ablation System is a bipolar RF system that uses high voltage radio frequency (RF) ***electrical current*** at a frequency of 480 kHz to ionize argon gas that is fully contained and circulated within a sealed silicone membrane of the Plasma Formation Array (PFA)." *Id.* at 279367, item 2.0 (emphasis added).

3. Claim 5

a. "*The method of claim 1, wherein the flowing step includes: passing an inflation medium through the ablation device and into the uterus*"

92. Use of the Minerva EAS also includes passing an inflation medium through the ablation device and into the uterus as part of the flowing step. As noted above in Section VIII.B.1.c, the flowing step of the Minerva EAS's UIT includes passing CO_2, which is an inflation medium. [redacted] The flow path of CO_2 through the Handpiece is shown in red below:

[redacted]

b. "*the monitoring step includes monitoring a pressure within the uterus for a predetermined amount of time*"

93. The Minerva EAS monitors the pressure in the uterus for reasons discussed above in Section VIII.B.1.d.

94. [redacted]

4. Claim 6

95. Claim 6 recites: "The method of claim 1, further including the step of: if a

perforation is detected in the monitoring step, providing feedback alerting a user to the presence of a perforation in the uterus."

96. Use of the Minerva EAS includes providing feedback, such as by providing an animation and/or an audible tone, alerting a user to the presence of a perforation in the uterus if a perforation is detected in the monitoring step. According to the Operator's Manual: "***If the UIT fails, then the display on the Minerva RF Controller will indicate UIT Failure (Figure 23), and a rapid audible tone will sound.***" Ex. 62 at 279396, item 13.13 (emphasis added). A figure in the Operator's Manual illustrates the animation displayed by the Minerva RF Controller, activated when the Minerva EAS detects a perforation during the UIT:

Figure 23: Failed Uterine Integrity Test

Id. at 279396, Figure 23.

5. Claim 7

97. Claim 7 recites: "The method of claim 1, further including the step of preventing performance of the treating step until after the monitoring step has been carried out."

98. Use of the Minerva EAS also includes the step of preventing performance of the treating step until after the monitoring step of the UIT has been carried out. According to the Operator's Manual: "NOTE: ***Power will not be applied to the Minerva Disposable Handpiece until the UIT passes***." *Id.* at 279396 (emphasis added); *id.* at 279396, item 13.13. [redacted]

[redacted]

6. Claim 9

99. Minerva's EAS performs each step of claim 9 of the '183 patent.

a. "*A method of detecting a perforation in a uterus, comprising the steps of*"

100. To the extent that the preamble of this claim is a requirement, use of the Minerva EAS includes a method of detecting a perforation in a uterus. *See* Section VIII.B.1 *supra*.

b. "*passing an inflation medium into the uterus*"

101. The Minerva EAS includes a step of passing an inflation medium into the uterus. *See* Section VIII.B.1.c *supra*.

c. "*monitoring for the presence of a perforation in the uterus using a pressure sensor*"

102. The Minerva EAS includes a step of monitoring for the presence of a perforation in the uterus using a pressure sensor. *See* Section VIII.B.1.d *supra*

d. "*if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device*"

103. The Operator's Manual instructs users that the ablation will start automatically upon successful completion of the UIT and the Minerva RF Controller will display the image below:

13.13 Upon successful completion of the UIT, the screen will switch (**Figure 22**) and the ablation procedure will start automatically.

Figure 22: Successful Uterine Integrity Test

Ex. 62 at 279395-96, items 13.12, 13.13; *see also id.* at 279371, item 3.0.

e. "*if a perforation is detected during the monitoring step, preventing ablation of the uterus*"

104. Use of the Minerva EAS includes preventing ablation of the uterus if a perforation is detected during the UIT's monitoring step. According to the Operator's Manual: "NOTE: ***Power will not be applied to the Minerva Disposable Handpiece until the UIT passes***. If the UIT fails, then the display on the Minerva RF Controller will indicate UIT Failure (Figure 23), and a rapid audible tone will sound. Consult the Troubleshooting section for more information." *Id.* at 279396, item 13.13 (emphasis added).

7. Claim 11

105. Claim 11 recites: "The method of claim 9, further including the step of: if a perforation is detected during the monitoring step, activating a notification signal alerting the user to the presence of a perforation in the uterus."

106. Use of the Minerva EAS includes a step of activating a notification signal alerting the user to the presence of a perforation in the uterus if a perforation is detected during the monitoring step. *See* Section VIII.B.4 *supra.*

8. Claim 13

107. Claim 13 recites: "The method of claim 9, wherein the inflation medium is introduced using the ablation device."

108. Use of the Minerva EAS includes wherein the inflation medium is introduced using the ablation device. *See* Section VIII.B.3 *supra*.

9. Claim 14

109. Claim 14 recites: "The method of claim 9, wherein the ablation device is an RF ablation device."

110. Use of the Minerva EAS also includes wherein the ablation device of a Minerva Disposable Handpiece is an RF ablation device. *See* Section VIII.B.2 *supra*. [redacted] According to the Operator's Manual, "***The Minerva Endometrial Ablation System is a bipolar RF system*** that uses high voltage radio frequency (RF) electrical current at a frequency of 480 kHz to ionize argon gas that is fully contained and circulated within a sealed silicone membrane of the Plasma Formation Array (PFA)." Ex. 62 at 279367, item 2.0 (emphasis added).

10. Claim 15

111. Claim 15 recites: "The method of claim 9, wherein the ablation device is a thermal ablation device."

112. The Operator's Manual instructs users that "energy, ***in the form of heat***, is conducted through the silicone membrane and to the tissue in contact with the membrane," thereby ablating uterine tissue. *Id.* at 279371, item 3.0 (emphasis added); *see also id.* at 279367-

69, items 2.0-2.2. [redacted]

C. US Patent No. 9,095,348

1. Claim 1

113. Claim 1 of the '348 patent recites:

> A device for treating a uterus comprising:
>
> an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;
>
> an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;
>
> a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;
>
> a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and

second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

114. The Minerva EAS comprises the device of claim 1 of the '348 patent. I address the limitations of claim 1 in order, but I understand that Minerva's non-infringement argument for this claim pertains only to whether Minerva's EAS includes "an indicator mechanism . . . configured to indicate a dimension of the uterus," which is analyzed in Section VIII.C.1.f below.

a. *"A device for treating a uterus comprising"*

115. To the extent the preamble is limiting, the Minerva EAS is "a device for treating a uterus." *See* Section VIII.B.1.a *supra*.

b. *"an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve"*

116. The Minerva EAS includes an elongate member having a proximal portion and a distal portion:

[redacted]

Ex. 99 (emphasis added). The Operator's Manual similarly refers to the "distal tip" as the portion of the hand piece that is "inserted transcervically into the uterine cavity . . . until the distal tip of the PFA touches the fundus." Ex. 62 at 279393, item 13.6.

117. The Minerva EAS's elongate member comprises an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve. [redacted] To more clearly show the outer and inner sleeves, the pictures below do not include the silicone membrane that sits on top of the frame:

Ex. 98 (emphasis added). The photographs below show the inner and outer sleeves when the applicator head frame is in a contracted and expanded state:

118. The Minerva EAS comprises an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve.

c. *"an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus"*

119. The Minerva EAS includes an applicator head because it is a distal end portion of Minerva's ablation device that applies energy to the uterine tissue.

Ex. 99 (emphasis added). Minerva refers to its applicator head as a "Plasma Formation Array (PFA)." Ex. 62 at 279368, item 2.1. The applicator head applies energy to the uterine tissue using a bipolar RF system. *See* Sections VIII.B.2, VIII.B.9 *supra*. The Minerva EAS's applicator head defines an interior volume. Minerva's PFA consists of an interior volume, "an expandable metal frame covered by a stretchable silicone membrane." Ex. 62 at 279368, item 2.1. The argon gas "is fully contained and circulated within a sealed silicone membrane of the Plasma Formation Array (PFA)." *Id.* at 279367, item 2.0. The interior volume is pictured

below:

LEINSING_000063 (emphasis added).

120. The Minerva EAS's applicator head has a contracted state and an expanded state:

LEINSING_000059 (emphasis added); LEINSING_000060 (emphasis added); *see also* Ex. 63 at 52912-13 (Figures 5 and 6).

121. The Minerva EAS's applicator head's contracted state is configured for transcervical insertion and the expanded state is configured to conform to the shape of the uterus.

[redacted]

122. The Minerva EAS's applicator head includes one or more electrodes for ablating endometrial lining tissue of the uterus. [redacted]:

[redacted]

Ex. 64 at 4511; *see also* Ex. 63 at 52905, 52912-13, 52927 (Figures 6 and 14). The "electrodes" in the Minerva EAS are electrical conductors. Ex. 62 at 279368-69, item 2.1. [redacted]

d. *"a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state"*

123. The Minerva EAS comprises a handle coupled to the proximal portion of the elongate member. [redacted]

[redacted]

[redacted]

[redacted]:

[redacted]

Ex. 99 (emphasis added).

124. [redacted]

[redacted]

[redacted]:

Ex. 96 (emphasis added); Ex. 97 (emphasis added).

125.

LEINSING_000120 (emphasis added); LEINSING_000129 (emphasis added).

e. *"a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state"*

126. The Minerva EAS comprises a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve. The deflecting mechanism, outer and inner sleeves, and internal and external flexures are annotated below:

127. The Minerva EAS's deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state. "

f. "*an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus*"

128. The Minerva EAS comprises an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus. The

Minerva EAS indicator mechanism is pictured below:

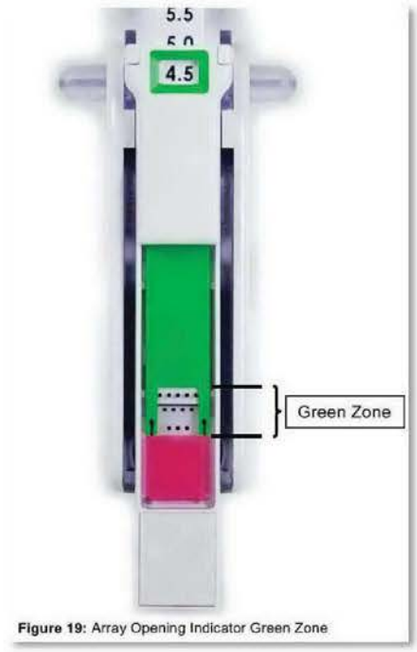


Figure 19: Array Opening Indicator Green Zone

Ex. 62 at 279394 (Figure 19); *see also* Ex. 63 at 52915-17 (Figures 8, 9, and 10). [redacted] The Court has previously found that "Minerva EAS' manufacturing specification refers to the indicator on the handpiece as a 'width indicator.'" D.I. 257 at 11-12 (citing Ex. 90). [redacted]

129. Minerva's indicator mechanism is operably coupled to the inner sleeve. The

Minerva EAS's indicator mechanism provides a Red/Green area upon which a black indicator line moves in conjunction with the expansion and contraction of the array head. Ex. 62 at 279394 (Figure 19). [redacted] The annotated photographs below depict Minerva's indicator mechanism in various states of disassembly:

LEINSING_000002 at 0:09; LEINSING_000022 at 0:55, 1:08, 2:00.

130. The Minerva EAS's indicator mechanism is configured to indicate a dimension of

the uterus. The Court has previously found that "Minerva's medical director testified that Minerva's clinical data excludes women with uteri that are smaller than 2.5 cm and the width indicator on Minerva EAS' handpiece indicates when a patient's uterus is smaller than 2.5 cm." D.I. 127 at 12 (citing D.I. 115, Ex. 7 at 164:22-165:5);

131. Because Minerva's clinical data excludes women with uteri smaller than 2.5 cm, Minerva's Operator's Manual instructs users: "Do not treat a patient if Array Opening Indicator is in the Red Zone following deployment of the Minerva Disposable Handpiece." Ex. 62 at 279394; *see also* Ex. 22 at 102:25-105:15.

132.

133.

[redacted]

D.I. 27 at 23. This is consistent with my measurements, shown below. I set a pair of calibrated calipers at 25.00 mm (2.5 cm) and locked them in place. I then expanded the array until the major width just touched the inside measurement surfaces of the calipers and took a picture of the position of the black line in the red/green window. [redacted]

[redacted]

LEINSING_000177 (emphasis added); *see also* LEINSING_000018 (Video). [redacted]

[redacted]

[redacted]

134. In addition, the Minerva EAS also provides an overlay of three rows of dots on the indicator mechanism, a row with three dots, a row with four dots and a row with five dots. The Court has previously found that the "dot scale on the width indicator shows widths of about 3, 4, and 5 cm, respectively, via the rows of 3, 4, and 5 dots." D.I. 127 at 12. [redacted] Cornu refers to where the uterus meets the fallopian tube, so a cornu to cornu measurement indicates a dimension of the uterus. [redacted]

Ex. 92 at 90339.

135. During my tests, I measured the width of the array to be approximately 3 cm when the black indicator line was at the row of three dots, approximately 4 cm when the black indicator line was at the row of four dots, and approximately 5 cm when the black indicator line was at the row of five dots. The Minerva EAS indicator mechanism is a mechanism configured to indicate several dimensions of the uterus.

[redacted]

LEINSING_000457; LEINSING_000458; LEINSING_000459; LEINSING_000017 (Video); LEINSING_000016 (Video); and LEINSING_000015 (Video).

136. [redacted]

[redacted] I am not aware of any Minerva documents that reflect such a manufacturing tolerance. I tested all of the Minerva devices provided to me and the width of the applicator head was approximately 3 cm, 4 cm, and 5 cm when the black indicator line was aligned with the rows of three, four, and five dots, respectively. *See supra* Paragraph 137; *see also* Ex. 72 at 299536-38.

137. [redacted] this would not change my opinion that the Minerva EAS comprises the claimed indicator mechanism. The asserted claims of the '348 patent do not recite any manufacturing tolerances. [redacted]

138. [redacted] First, the Court previously rejected Minerva's construction of "indicator mechanism" as "a measuring device used to display a value in units of measure." *See* D.I. 227, ¶ 6 n.10. Second, a POSITA reading the specification would not understand the claimed indicator mechanism to be limited to a gauge that displays numerical values. In fact, figure 32B depicts an embodiment of the claimed indicator mechanism in which there are no numerical values on the face of the indicator mechanism:

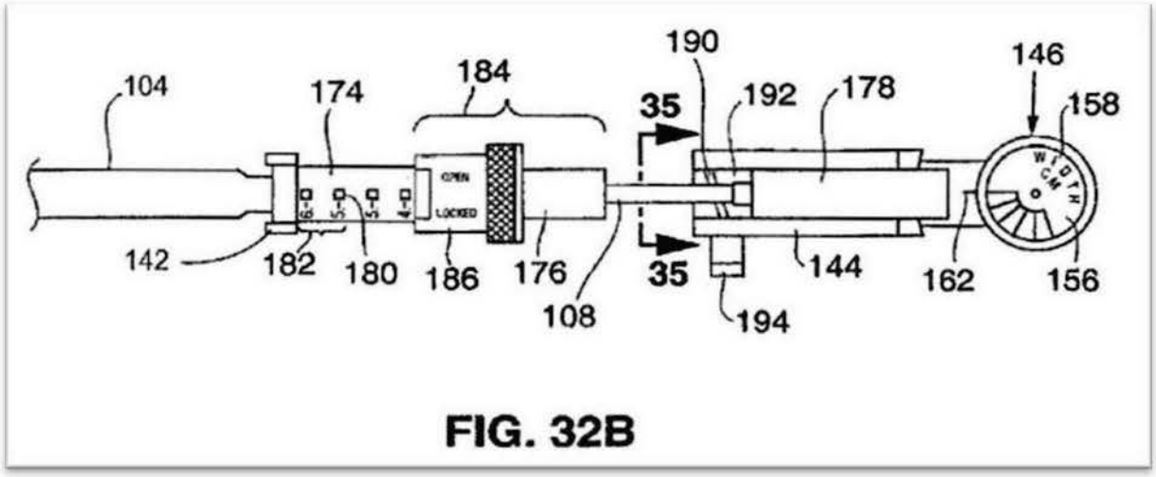
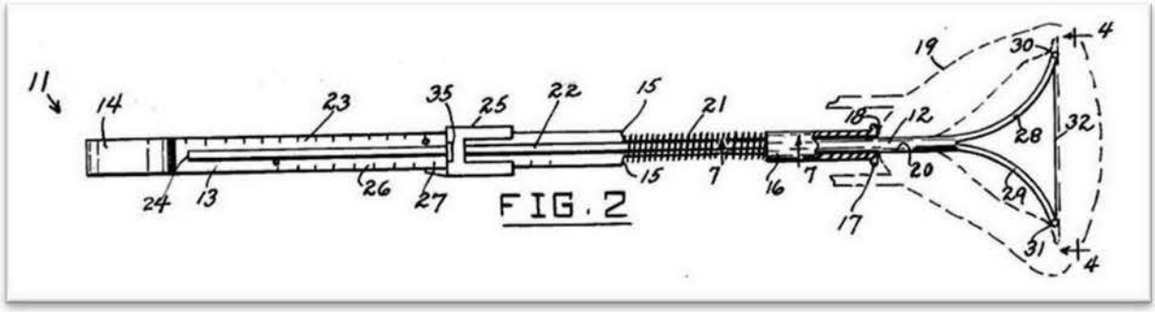


FIG. 32B

Ex. 2 at FIG. 32B. Third, U.S. Patent No. 4,016,867 to King et al., [redacted]

[redacted] does not display numerical values on "width scale 26":



Ex. 116 at FIG. 2.

139. [redacted] I disagree. Assuming Dr. Tucker's premise that [redacted] the patent highlights the correlation between the red/green indicator (i.e., Minerva's AOI) and uterine dimensions. *See, e.g.*, Ex. 115 at 15:30-37, 15:58-65, 16:2-12.

140. To the extent Minerva asserts that it does not directly infringe, the evidence above shows that Minerva's System infringe under the DOE. Specifically, the difference between the claimed "indicator mechanism" and Minerva's "width indicator" is insubstantial. Minerva's "width indicator" performs substantially the same function (indicating a dimension) in substantially the same way (a black indicator line that moves along a Red/Green spectrum and a dot scale, said black indicator line moving in conjunction with the expansion and contraction of the array head), leading to substantially the same result (indicating a dimension of the uterus).

141. [redacted] This is irrelevant because the Court construed "indicator mechanism" as "a mechanism configured to indicate a dimension." I understand that the Court has already rejected Minerva's proposed construction of this term as requiring "a measuring device used to display a value in units of measure" because, according to the Court, "[n]othing in the specification suggests that applicant intended to limit 'an indicator mechanism' to devices that solely display uterine widths in 'units of measure.'" D.I. 227 at 4-5 n.10.

2. Claim 3

142. Claim 3 recites: "The device of claim 1 wherein the first internal flexure includes a plurality of longitudinally spaced apertures."

143. The first internal flexure ("Nanoflex") includes a plurality of longitudinally spaced apertures, which are shown below with the silicone membrane removed:

LEINSING_000077 (emphasis added).

3. Claim 12

144. Claim 12 recites: "The device of claim 1 wherein the applicator head is configured to expand until limited by the dimension of the uterus."

145.

D. US Patent No. 9,247,989

1. Claim 1

146. Claim 1 recites:

> A method for performing endometrial ablation comprising:

transcervically positioning a distal portion of an ablation device into a uterus, the distal portion comprising an energy applicator, the energy applicator comprising a tissue contacting surface and an expandable-contractible carrying member, the expandable-contractible carrying member including first and second inner flexures and first and second outer flexures, the first and second outer flexures being coupled to an outer sleeve and the first and second inner flexures being coupled to an inner sleeve, the inner sleeve being slidably and coaxially disposed within the outer sleeve;

actuating a handle coupled to a proximal portion of the ablation device to cause the carrying member to expand the energy applicator in the uterus, the handle comprising a proximal grip and a distal grip pivotally attached to one another at a pivot point, and wherein actuating the handle includes moving the proximal grip and the distal grip closer together while translating the inner sleeve relative to the proximal grip;

actuating an inflation source to further expand the energy applicator in the uterus; and

delivering energy through the energy applicator to thereby deliver energy to endometrial lining tissue of the uterus.

147. Use of Minerva's EAS practices each step of claim 1 of the '989 patent. I address the limitations of claim 1 in order, but I understand that Minerva's non-infringement argument for this claim pertains to only whether "actuating the handle includes moving the proximal grip and the distal grip closer together ***while translating the inner sleeve relative to the proximal grip***."

a. "*A method for performing endometrial ablation comprising*"

148. To the extent the preamble is limiting, use of Minerva's EAS practices "a method

for performing endometrial ablation," using the Minerva EAS. *See* Section VIII.B.1.a *supra*.

b. "*transcervically positioning a distal portion of an ablation device into a uterus, the distal portion comprising an energy applicator, the energy applicator comprising a tissue contacting surface and an expandable-contractible carrying member, the expandable-contractible carrying member including first and second inner flexures and first and second outer flexures, the first and second outer flexures being coupled to an outer sleeve and the first and second inner flexures being coupled to an inner sleeve, the inner sleeve being slidably and coaxially disposed within the outer sleeve*"

149. Use of Minerva's EAS comprises "transcervically positioning a distal portion of an ablation device into a uterus." *See* Sections VIII.B.1.b, VIII.C.1.c *supra*. The distal portion of the Minerva EAS is shown below:

Ex. 99 (emphasis added).

150. Minerva refers to the energy applicator, a distal end portion of the ablation device that applies energy to the uterine tissue, as a PFA. As noted in Section VIII.C.1.c, Minerva's

energy applicator applies energy to the uterine tissue.

151. The Minerva EAS energy applicator comprises a stretchable silicone membrane that is a tissue contacting surface: [redacted] The tissue contacting surface and the expandable-contractible carrying member are pictured below:

[redacted]

LEINSING_000063 (emphasis added). The Minerva EAS's energy applicator has a contracted state and an expanded state. *See* Section VIII.C.1.c *supra*.

152. "The expandable-contractible carrying member include[es] first and second inner flexures and first and second outer flexures, the first and second outer flexures being coupled to an outer sleeve and the first and second inner flexures being coupled to an inner sleeve." The first and second inner flexures, first and second outer flexures, outer sleeve, and inner sleeve are notated below:

LEINSING_000063 (emphasis added).

153. The Minerva EAS's "inner sleeve [is] slidably and coaxially disposed within the outer sleeve." *See* Section VIII.C.1.b *supra*.

c. "*actuating a handle coupled to a proximal portion of the ablation device to cause the carrying member to expand the energy applicator in the uterus, the handle comprising a proximal grip and a distal grip pivotally attached to one another at a pivot point, and wherein actuating the handle includes moving the proximal grip and the distal grip closer together while translating the inner sleeve relative to the proximal grip*"

154. Use of Minerva's EAS comprises "actuating a handle coupled to a proximal portion of the ablation device to cause the carrying member to expand the energy applicator in the uterus." As noted in Section VIII.C.1.d, when the proximal grip and the distal grip are moved closer together, the energy applicator transitions from the contracted state to the expanded state.

155. The proximal grip, distal grip, and energy applicator are pictured below:

Ex. 99 (emphasis added).

156. The handle comprises "a proximal grip and a distal grip pivotally attached to one another at a pivot point." *See* Section VIII.C.1.d *supra*.

157. Ex. 62 at 279393, item 13.8 ("[s]lowly squeeze the Minerva Disposable Handpiece handle together while gently moving the Minerva Disposable Handpiece approximately 0.5 cm to and from the fundus until the Minerva Disposable Handpiece handle locks"); Ex. 63 at 52913; Ex. 121 (Video); Ex. 122 (Video) at 0:29-0:33.

158. For ease of reference, Minerva's inner sleeve — — is pictured below with Minerva's silicone membrane removed:

Ex. 98 (emphasis added).

159. [redacted]

Moving the proximal grip distally causes distal movement of the inner sleeve, which causes the frame to expand until limited by the walls of the uterus. At this point, continued distal movement of the proximal grip causes little to no distal movement of the inner sleeve and, instead of expanding the array, the movement increases tension between the lateral sides of the PFA and the uterine wall. The force developed between the lateral sides of the PFA and the uterine wall is limited by the force limiting spring. Because the inner sleeve does not move in unison with the proximal grip when the PFA is restricted, the inner sleeve is translating relative

to the proximal grip.

160. [redacted]

d. "*actuating an inflation source to further expand the energy applicator in the uterus*"

161. Use of Minerva's EAS comprises "actuating an inflation source to further expand the energy applicator in the uterus." [redacted]

e. "*delivering energy through the energy applicator to thereby deliver energy to endometrial lining tissue of the uterus*"

162. Use of Minerva's EAS comprises "delivering energy through the energy applicator to thereby deliver energy to endometrial lining tissue of the uterus." *See* Section VIII.C.1.c *supra*.

2. Claim 7

163. Claim 7 recites: "A method as in claim 1, wherein the tissue contacting surface circumscribes the expandable-contractible carrying member."

164. Use of Minerva's EAS comprises each step of claim 7 of the '989 patent. The expandable-contractible carrying member and tissue contacting surface are pictured below:

LEINSING_000063 (emphasis added). The tissue contacting surface is a "stretchable silicone membrane" that circumscribes the "expandable metal frame" shown above. Ex. 62 at 279367-68, items 2.0-2.1

IX. INVALIDITY ANALYSIS

A. DR. TUCKER'S OPINIONS REGARDING ENABLEMENT AND WRITTEN DESCRIPTION ARE IRRELEVANT AND UNRELIABLE

165. In my view, Dr. Tucker, Minerva's expert, arrived at the wrong conclusions by not using the Court's claim constructions and applying the wrong legal standards.

166. ***Claim Construction:*** Dr. Tucker's analysis bears no relationship to the Court's claim constructions.

167. I understand that Minerva proposed to construe "applicator head" as "an applicator having a permeable or absorbent tissue contacting surface into which moisture is drawn." D.I. 184 at 9. The Court rejected Minerva's proposal and agreed with Hologic, construing "applicator head" as "a distal end portion of an ablation device that applies energy to

the uterine tissue." D.I. 227, ¶ 3. Similarly, the Court construed "an energy applicator" as "an applicator of an ablation device that delivers energy to the uterine tissue."[6] *Id.*, ¶ 4.

168. ***Applicator Head:*** Despite the Court's construction, Dr. Tucker on numerous occasions replaces the Court's constructions with Minerva's proposed constructions:

[redacted]

[6] Because "applicator head" and "an energy applicator" have similar constructions, I will use the term "applicator head" or "applicator" to refer to this element.

[redacted]

169. ***Electrode:*** I understand that Minerva proposed to construe "one or more electrodes" and "at least one electrode" as "each electrode has a polarity and ***contacts the tissue surface*** during ablation." D.I. 184 at 16 (emphasis added). The Court rejected Minerva's proposal and agreed with Hologic, construing "one or more electrodes" as "one or more electrical conductors." D.I. 227, ¶ 7.

170. Despite the Court's construction, Dr. Tucker on numerous occasions replaces the Court's constructions with Minerva's proposed constructions:

[redacted]

171. ***Pressure Sensor:*** I understand that Minerva proposed to construe "a pressure sensor" as "a device whose input detects a force per unit area and that outputs a corresponding electrical signal." D.I. 184 at 2. I understand that Minerva attempted unsuccessfully to convince the Court that "a pressure sensor" must directly measure and quantify pressure. The Court rejected Minerva's proposal and construed the term as "a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal." D.I. 227, ¶ 1. The Court explained that "defendant's proposed construction (limiting the term to 'direct' measurement) would exclude commercially-available pressure sensors from the scope of the term 'pressure sensor.'" *Id.*, ¶ 1 n.2. This is because commercially-available pressure sensors often do not directly detect a force per unit area.

172. Despite the Court's construction, Dr. Tucker on numerous occasions replaces the Court's construction with Minerva's proposed construction:

[redacted]

173. ***Monitoring:*** I understand that the Court rejected Minerva's proposed construction of the term "monitoring" as "measuring a condition in a system." D.I. 227, ¶ 2 n.4. [redacted]

174. ***Balloon:*** [redacted] During claim construction, Minerva's proposed construction of "balloon" — "an inflatable member inside the energy applicator / working end and not in contact with the tissue" — was silent as to permeability. D.I. 155 at 2-3. Notably, the Court found that a balloon in the second embodiment "may contact uterine tissue." D.I. 227, ¶ 11. [redacted]

175. Because Dr. Tucker's invalidity opinions regarding enablement and written description are not based on the asserted claims as construed by the Court, they are irrelevant and unreliable. [redacted] The claimed inventions do not require an applicator head with an internal electrode that does not contact the tissue. Instead, the relevant inquiry is whether the inventors were in possession of an applicator head with one or more electrical conductors. *B*[redacted]

176. ***Unsupported, Exceedingly Narrow Characterizations of "The Invention" and the Prior Art*:** As described in more detail below, Dr. Tucker provides numerous characterizations of the scope of "the invention" — characterizations the Court has already considered and rejected.

177. [redacted] Dr. Tucker does not provide any support from the specification or prosecution history where the applicants

distinguished this art from the asserted claims on the basis that the claimed applicator head was permeable or absorbent.

178. [redacted] *See* Ex. 2 at 19:4-7 ("It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims."). I understand that the Court already rejected Minerva's arguments that the asserted claims include limitations as to permeability or absorbency. In this regard, it is my view that Dr. Tucker's analysis of these prior art references is incomplete, inaccurate, and irrelevant.

179. [redacted] This is inconsistent with Minerva's statements to the USPTO during prosecution of its own pending U.S. Application No. 14/657,684, during which Minerva stated that Stern '470 has "electrode segments 40 which may be formed on the ***interior or exterior surface*** of the balloon." *See* 1/18/2017 Applicant Remarks at 5. The examiner too stated that Stern '470 does not require electrodes in contact with the tissue because it "provide[s] for capacitive coupling RF current to the tissue which would use a fluid contained within the expandable structure ***rather than direct contact of electrodes with the tissue***." *See* 4/18/2017 Final Rejection at 3 (emphasis added). Further, a POSITA would be familiar with the teachings of Stern '470, which is prior art of record, including capacitive coupling of electrodes located inside an applicator to the uterine tissue. *See* Ex. 117 at 4:23-25,

5:35-46, 5:57-61. In my view, a POSITA at the time of the claimed inventions at issue in this case would have known from at least Stern '470 that direct contact between the electrodes and tissue is not required nor would they infer any such requirement from the specifications.

180. ***Requiring Enablement and Written Description of All Features of the Accused Product:*** [redacted] This is incorrect. I understand that the disclosure must enable and describe the claimed inventions as construed by the Court. [redacted] With respect to enablement, the relevant inquiry is whether it would require undue experimentation for a POSITA to practice a distal end portion (or an applicator) of an ablation device that applies energy to the uterine tissue. D.I. 227, ¶ 3. Dr. Tucker nowhere performs this analysis in his report.

181. [redacted] The relevant inquiry is whether the disclosure would reasonably convey to a POSITA that the inventors had possession of the claimed inventions. The combination of one or more

mechanisms of action is not a limitation of the claimed inventions.[7]

182. Similarly, the amount of experimentation required for a POSITA to make Minerva's EAS is not the relevant enablement analysis. A plasma formation array is not a claimed aspect of the inventions. [redacted] In my view, only routine experimentation would be needed to choose the material for the applicator head and the positioning of the electrodes.

183. [redacted] The relevant enablement analysis is whether the specification teaches how to make and use a system that performs the step of monitoring for the presence of a perforation in the uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal.

184. Dr. Tucker's misplaced attention on Minerva's accused product is apparent elsewhere. [redacted] "Balloon" is not a claimed element of the asserted claims and the Court did not construe "applicator head" or "energy applicator" as reciting a non-permeable external balloon. This is another example of Dr. Tucker's flawed analysis.

[7] In any event, the specification teaches that, even when removing moisture from the ablation site, some degree of thermal ablation occurs. *See* Ex. 2 at 11:16-17 ("RF ablation thereby stops and thermal ablation does not occur in significant amounts.").

185. ***Minerva's Patents:*** [redacted]

[redacted] Here again, Dr. Tucker's focus on Minerva's accused device and its patents is irrelevant to whether the asserted claims of the '348 and '989 patents are enabled and have sufficient written description. This is because a patent does not have to enable or describe all features of the accused product, just enable and describe the claimed inventions. Put another way, I understand that Minerva's EAS can infringe an asserted claim (A+B) as long as it practices the claimed elements (A+B). That the accused product might include other, un-claimed features (A+B+**C**) does not mean the accused product avoids infringement. In the same way, I am unaware of any requirement that the inventors must enable or describe A+B+**C** if their claim, as construed by the Court, recites only A+B. [redacted] I understand that a product may infringe regardless of whether it has additional improvements or is separately patentable.

186. In my view, Minerva's patents have no bearing on whether Hologic's asserted claims are enabled or sufficiently described. [redacted] Dr. Tucker does not cite any portion of the

prosecution history of the Minerva patents where the applicants distinguished their claimed inventions on those bases.

B. THE ASSERTED CLAIMS OF THE '348 AND '989 PATENTS HAVE SUFFICIENT WRITTEN DESCRIPTION AND ARE ENABLED

187. Dr. Tucker's enablement and written description analyses focus on a narrow set of claim limitations, i.e., "applicator head," "an energy applicator," and "one or more electrodes." Dr. Tucker has not challenged the validity of the claimed inventions with respect to any other claim limitations. Therefore, my analysis addresses the claim limitations upon which Dr. Tucker has opined.

1. Dr. Tucker's Characterization Of The Teachings And Disclosures Of The '348 And '989 Patents Is Incomplete and Inaccurate

188. [redacted] As noted above, Dr. Tucker disregards the Court's claim construction order and adopts Minerva's construction of several claim terms.

189. The inventions of the '348 patent family relate to an ablation apparatus and methods of use. *See* Ex. 2 at 2:34-36, 4:51. One aspect of the inventions includes a moisture transport system, but these patents are not just about moisture removal. In fact, neither the asserted claims of the '348 patent nor the asserted claims of the '989 patent recite a moisture transport system.

a. The Common Specification

190. [redacted]

[redacted] In my view, a POSITA reading the specification would not focus on the applicator head component to the exclusion of other claimed elements of the asserted claims.

191. The specification describes at least two exemplary embodiments of the inventions. The specification explains, however, that these two exemplary "embodiments have been shown for illustrative purposes only [and] . . . the invention is not intended to be limited to the specifics of the illustrated embodiments." Ex. 2 at 19:1-7. In my view, a POSITA reading this disclosure would not narrowly read the claims to be limited solely to these exemplary embodiments nor would a POSITA understand the presence of working examples to automatically teach away from all other embodiments.

192. [redacted] The specification clearly states that "an array of electrodes 14 [is] formed on the surface of the electrode carrying means 12." Ex. 2 at 4:60-61.

193. As discussed in more detail below (*see infra* ¶¶ 201-210), [redacted] Instead, the specification describes several limitations of the prior art methods as well as several solutions to address those limitations.

b. **Titles, Abstracts, And Figures Of The Patents**

194. [redacted] A POSITA would understand that a patent's

title, abstract, and figures do not always describe or limit the full scope of the claimed inventions. I understand Minerva and Dr. Tucker made virtually identical arguments during claim construction, which the Court rejected.

195. A POSITA would not have understood the titles of the '348 and '989 patents (Moisture Transport System For Contact Eletrocoagulation) to require contact between the electrodes and the uterine tissue. In fact, there is nothing in the titles that requires the electrodes to contact the uterine tissue. Further, there is nothing in the titles that requires a "permeable (or absorbent) array." *See id.*, ¶ 69.

196. Similarly, a POSITA would understand that a patent's abstract does not always describe the full scope of or limit the scope of the claimed inventions. Accordingly, a POSITA would understand the abstract to be describing an exemplary embodiment of the invention rather than limiting the scope of the invention or its disclosure.

197. Likewise, a POSITA would have understood the specification's figures as depicting certain exemplary embodiments of the inventions, and would not have understood the figures to limit the invention to those figures. Indeed, a POSITA would find that the specification supports this understanding because its states that the exemplary "embodiments have been shown for illustrative purposes only [and] . . . the invention is not intended to be limited to the specifics of the illustrated embodiments." Ex. 2 at 19:1-7.

198. [redacted] The abstract provides that "[f]ollowing placement of the ***ablation device*** into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated." The abstract teaches putting the ***ablation device*** into contact

with the tissue; the abstract does not say that direct contact between the ***electrodes*** and the tissue is necessary, however. A POSITA would not understand this disclosure to require that the electrodes contact the tissue.

c. **The Background Of The Invention**

199. [redacted]

200. [redacted] I disagree. Regarding both the prior art heated fluid method and RF ablation technique, the specification notes that "because no data or feedback is available to guide the physician as to how deep the tissue ablation has progressed, controlling the ablation depth and ablation profile with such devices can only be done by assumption." Ex. 2 at 1:49-53. The specification continues, "For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue." *Id.* at 1:54-56. The specification also notes that "RF ablation techniques can achieve more effective ablation since it relies on active heating of the tissue using RF energy, but presently the depth of ablation using RF techniques can only be estimated." *Id.* at 1:59-63. [redacted] As such, a POSITA would not understand this section as disparaging thermal

ablation techniques. This is confirmed by the specification, which states that these prior art ablation devices "are satisfactory for carrying out ablation procedures." *Id.* at 1:48-49.

201. [redacted] I disagree. The background section describes several limitations of these prior art methods that are not limited to the issue of drawing moisture away from the surface of the applicator head:

- That "controlling ablation depth and ablation profiles with such devices can only be done by assumption" because "no data or feedback is available to guide the physician as to how deep the tissue ablation has progressed." Ex. 2 at 1:49-53.
- "Both the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation." *Id.* at 1:65-67.
- "Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried out to a desired depth within the tissue," resulting in over or under ablation. *Id.* at 2:20-24.

The specification never attributes these limitations to the fact that the prior art devices had non-permeable applicator heads. Further, the specification never identifies the inability to draw moisture away from the surface of the applicator head as a problem associated with the heated fluid method.

202. With regard to preventing over ablation, the specification warns that, when using either prior art technique, "[i]f the temperature exceeds 100°C, the fluid ***within the tissue*** begins to boil and to thereby produce steam." *Id.* at 2:2-6 (emphasis added). A POSITA reading the

specification would understand that this is not describing a problem involving moisture between the applicator head and the uterine tissue, but instead a problem with temperature control and fluid within the tissue.

203. The background section identifies the problem of moisture released by the tissue only with respect to prior art RF devices. For example, the specification notes that "***in prior art RF devices*** the water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow." *Id.* at 2:9-11 (emphasis added). However, the specification notes only that "this ***can*** prevent the current from traveling into the tissue to be ablated." *Id.* at 2:11-12 (emphasis added). But, again, a POSITA reading the specification would not attribute this problem to the prior art device's non-permeable applicator head.

204. [redacted] The only support Dr. Tucker cites for this assertion is Mr. Truckai's declaration. However, the proper inquiry is from the perspective of a POSITA and is not based on Mr. Truckai's subjective beliefs. [redacted]

205. [redacted] The specification identifies this thermal ablation as a drawback only to the extent that it "causes thermal ablation to continue well beyond the desired ablation depths." Ex. 2 at 2:16-19; *see also*

id. at 11:16-17. A POSITA reading the specification would understand that the problem is not that thermal ablation occurs at all — the specification acknowledges that thermal ablation will occur to some extent — but only when thermal ablation occurs in significant amounts such that it causes ablation to continue well beyond the desired depth.

206. [redacted] In my view, this is inaccurate. That paragraph in the specification does not mention non-permeable applicator heads, heated liquids retained in the cavity, or the lack of a "mechanism to control the extent to which that heated liquid would ablate the tissue." This paragraph describes "another problem" — distinct from the problem described in the preceding paragraphs — "that it is difficult for a physician to find out when ablation has been carried out ***to a desired depth***" (i.e., when to terminate ablation). Ex. 2 at 2:20-22 (emphasis added). This is in contrast with the prior paragraph where the problem was that the ablation could "continue well ***beyond the desired ablation depths***" (i.e., ablation continues after it is terminated). *Id.* at 2:16-19 (emphasis added).

207. [redacted] The background section identifies more than one goal of the inventions: 1) "[i]t is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site," and 2) "[i]t is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically discontinues ablation once the desired depth has been reached." Ex. 2 at 2:25-30. Therefore, by ignoring that the patents identify multiple

problems and set forth multiple goals, Dr. Tucker ignores the full breadth of the disclosure.

208. In my opinion, a POSITA would have understood the "Background of the Invention" section of the specification as identifying several limitations of the prior art heated fluid techniques and RF ablation techniques. In light of the rest of the specification, a POSITA would understand that multiple aspects of the inventions could be implemented to address the identified limitations and that not every solution required a permeable or absorbent applicator head with electrodes that directly contact the tissue to be ablated. Further, a POSITA would understand that the inventors were not "teaching away from" or "disparaging" the prior art methods in general, but instead identifying aspects of these methods that can be improved.[8]

d. **The Summary Of The Invention**

209. A POSITA reading the "Summary of the Invention" would see that "[t]he present invention is an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ." *Id.* at 2:34-36. A POSITA would then see that the summary goes on to describe "[a]n ablation device." *Id.* at 2:36. In my view, a POSITA would read this as merely describing "an ablation device" according to the invention, not defining the metes and bounds of the invention. As discussed below, this is confirmed by the remainder of the specification.

e. **The Detailed Description**

210. In my opinion, a POSITA reading the detailed description of the invention would not understand the applicator head to be limited to an applicator head with a permeable or absorbent tissue contacting surface.

211. A POSITA reading the detailed description section would see that "[t]he ablation apparatus according to the present invention will be described with respect to two exemplary

[8] The Court found that the statements in the specification "d[id] not rise to the level of disclaimer." *See* D.I. 227, ¶ 3 n.6.

embodiments." *Id.* at 4:51-53. A POSITA would understand that these are examples of the invention and do not limit the scope of the claims. This understanding is later confirmed by the detailed description:

> Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

Id. at 19:1-7.

212. [redacted] Instead, the specification provides that the first exemplary embodiment's electrode carrying means is "***preferably*** a sack formed of a material which is non-conductive, which is ***permeable to moisture*** and/or which has a tendency to absorb moisture . . . . Examples of ***preferred*** materials for the electrode carrying means include open cell sponge, foam, cotton, fabric, or cotton-like material, or any other material having the desired characteristics." Ex. 2 at 5:52-60 (emphasis added). The specification also describes a "flow pathway 36" through which "gas [or] fluid ***may*** be introduced into, or withdrawn from" the uterus. *Id.* at 8:19-24 (emphasis added); *see also id.* at 8:24-32 (noting that "suction ***may*** be applied" or "insufflation gas . . . ***may*** be introduced") (emphasis added). In my view, a POSITA would not read this language as requiring permeability or absorbency of an applicator head nor would it necessarily teach away from using a non-permeable material.

213. The first exemplary embodiment similarly teaches that the electrodes "are ***preferably*** attached to the outer surface of the electrode carrying means," *id.* at 5:66-67 (emphasis added), and that "it is ***most desirable*** for the electrodes . . . to be held in contact with"

the tissue to be ablated, *id.* at 8:47-49 (emphasis added). In my view, a POSITA would not read this language as requiring external electrodes in contact with the tissue nor would it necessarily teach away from using an electrode that does not contact the tissue directly.

214. [redacted]

215. [redacted] As stated above, this is not a claimed element. In addition, the patent teaches alternative embodiments in which moisture removal is not necessarily required. For example, the patent teaches that the applicator head "may be provided to have additional components inside it that add structural integrity." Ex. 2 at 8:50-52.

> ***For example***, referring to FIG. 11, alternative spring members 15*a*, 19*a* may be attached to the shaft 10 and biased such that, when in a resting state, the spring members are positioned in the fully resting condition shown in FIG. 11. . . .
>
> ***Alternatively***, a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in FIG. 20 and connected to a tube (not shown) extending through the shaft 10 and into the balloons 52. . . .
>
> Structural integrity ***may also be added*** to the electrode carrying means through the application of suction to the proximal end 22*a* of the suction/insufflation tube 17.

Id. at 8:53-9:3 (emphasis added). In my view, a POSITA would understand this section to be describing three optional means of adding structural integrity — alternative spring members 15*a*, 19*a*, balloons 52, and suction. In my view, one skilled in the art also would understand that, in an embodiment using balloons 52, more efficient ablation due to increased surface area due to the balloons pressing against the tissue could render active removal of moisture unnecessary. Thus, a POSITA would understand from the patent's teachings that not all of the solutions proposed by the named inventors require moisture removal.

216. [redacted] The specification, however, teaches an alternate ablation device "in which the electrode carrying means includes inflatable balloons." Ex. 2 at 3:42-45, 8:59-9:5. This disclosure does not include a limitation that the embodiment must remove moisture or that the applicator head must be permeable or absorbent. In fact, a POSITA would understand the opposite because areas between the balloon(s) and tissue would trap moisture during the ablation process — there would also be some potential thermal ablation in these areas as a result. The option of using a balloon(s) is clearly described in the specification. Notably, the Court found that a balloon in the second embodiment "may contact uterine tissue." D.I. 227, ¶ 11. [redacted] Likewise, when construing "sack" in claim 3 of the '898 patent, the Court again rejected Minerva's argument that the electrode carrying-member had to be permeable or absorbent because "nothing in the intrinsic record suggests that applicant intended the term to implicitly include the limitations proposed by defendant." D.I. 227, ¶ 10. [redacted]

[redacted]

217. Rather than monitoring impedance, the specification provides that "[o]ther means for monitoring and terminating ablation may also be provided." Ex. 2 at 11:29-30. For example, the specification provides that a thermocouple or other temperature sensor may be used to monitor tissue temperature and terminate ablation when the desired temperature is reached. This would address the problem of steam (identified in the background section). By monitoring tissue temperature, a physician could determine when the proper depth of ablation has been reached while also ensuring the temperature does not exceed 100°C — the point at which fluid within the tissue begins to boil and produce steam and the potential adverse consequences warned about in the background section.

218. [redacted] Dr. Tucker ignores the specification's description of the differences between the two exemplary embodiments:

> The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array. Naturally, aspects of the first and second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.

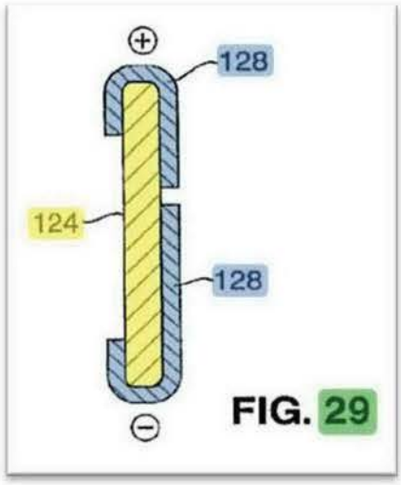
Ex. 2 at 11:53-58. A POSITA reading this disclosure would know the inventors contemplated it was possible to combine various aspects of the exemplary embodiments.

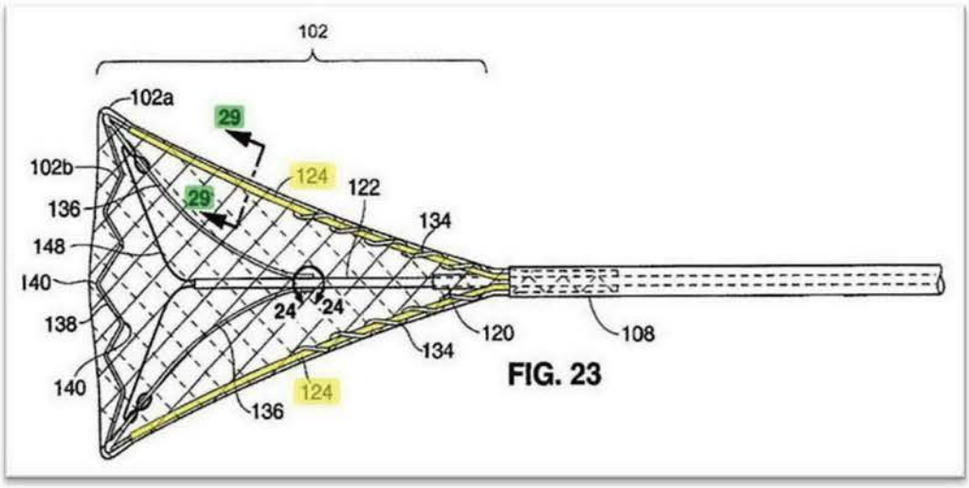
219. [redacted] However, a POSITA reading the specification would understand

from its plain words that these features were optional. Indeed, when describing these features, the specification provides that "gas fluid ***may*** be introduced into, or withdrawn from the suction/insufflation tube 17," "suction ***may*** be applied [to suction/insufflation tube 17]," and "insufflation gas, such as carbon dioxide, ***may*** be introduced into the suction/insufflation tube 17." *See* Ex. 2 at 8:20-35. Reading this disclosure, a POSITA would understand these features to be optional and would not require the applicator head to be permeable.

220. [redacted]

221. [redacted] The specification states only that the electrodes "are ***preferably*** attached to the outer surface of the electrode carrying means." Ex. 2 at 5:66-67 (emphasis added). The specification teaches electrical conductors located inside the applicator head: "Each flexure 124 preferably includes conductive regions that are electrically coupled to the array 102*a* for delivery of RF energy to the body tissue. Referring to FIG. 29, strips 128 of copper tape or other conductive material extend along opposite surfaces of each flexure 124." *Id.* at 13:19-23.





Id. at FIGS. 23, 29 (emphasis added). The specification also discloses that RF energy can travel through an intermediate conductive medium, including moisture or, as in the example above, a metallized fabric mesh. *See id.* at 2:9-11, 11:2-8. The specification describes adding "1-5 cc of saline . . . via suction/insufflation tube 17 to initially wet the electrodes and to improve electrode electrical contact with the tissue." *Id.* at 10:9-12. [redacted] A POSITA reading the specification would understand that the inventors taught ways to improve delivering energy to

the tissue by not directly contacting the electrodes to the tissue. As noted earlier, Stern '470, which is prior art of record of which a POSITA would have been aware, teaches capacitive coupling of electrodes located inside an applicator to the uterine tissue. *See* Ex. 117 at 4:23-25, 5:42-46.

222. [redacted]

This is incorrect for the same reasons stated above, primarily that even the embodiments described do not have electrodes formed on the surface, but instead are electrodes covered with a mesh. By design, there are open areas of the mesh and there are non-conductive or insulating regions 110 that ***prevent*** the inner electrodes from contacting the tissue. Further, the specification discloses "an ablation device ***according to*** the present invention." A POSITA would understand this language to be describing an exemplary embodiment of the invention rather than as language limiting the scope of the invention to applicator heads with external, tissue-contacting electrodes. Further, the specification indicates that the invention is not limited to those two embodiments:

> Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

Ex. 2 at 19:1-7.

223. I understand that when the Court construed "one or more electrodes," the Court rejected the same arguments from Minerva and Dr. Tucker. Specifically, the Court found that "[n]othing in the specification suggests applicant intended to limit the claim term to having a polarity or to contacting the tissue surface during ablation." D.I. 227, ¶ 7 n.12. Based on my review of the disclosure and for the reasons stated above, I agree.

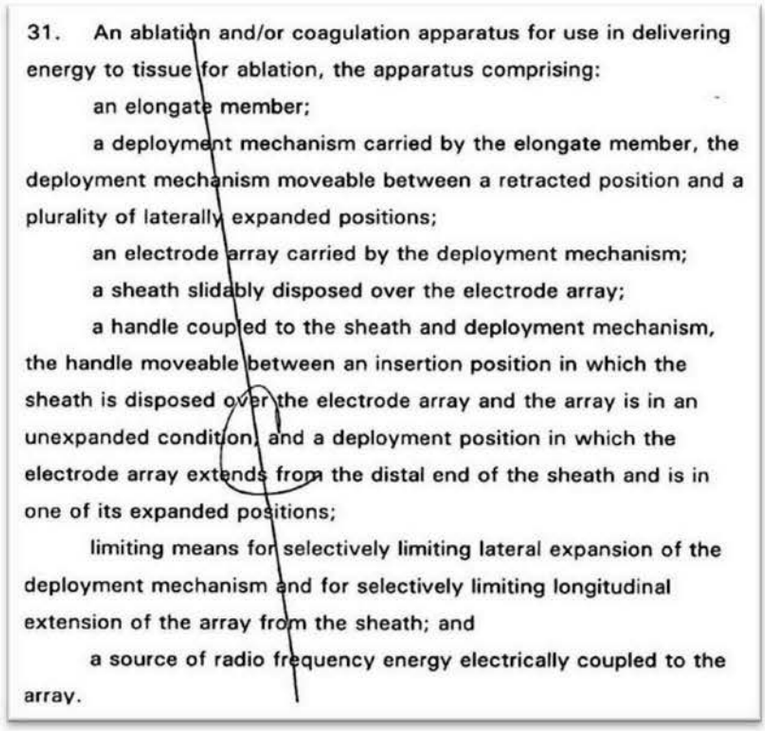
f. **The Prosecution History**

224. [redacted]

Dr. Tucker does not offer any support for this assertion and there is no support in the prosecution history where the applicants differentiated the claimed inventions on this basis.

225. [redacted] I understand that courts consider the claims as filed in the original application to be part of the relevant disclosure.

226. [redacted] Originally filed claim 31 of U.S. Application No. 09/103,072 reads:



31. An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

an elongate member;

a deployment mechanism carried by the elongate member, the deployment mechanism moveable between a retracted position and a plurality of laterally expanded positions;

an electrode array carried by the deployment mechanism;

a sheath slidably disposed over the electrode array;

a handle coupled to the sheath and deployment mechanism, the handle moveable between an insertion position in which the sheath is disposed over the electrode array and the array is in an unexpanded condition, and a deployment position in which the electrode array extends from the distal end of the sheath and is in one of its expanded positions;

limiting means for selectively limiting lateral expansion of the deployment mechanism and for selectively limiting longitudinal extension of the array from the sheath; and

a source of radio frequency energy electrically coupled to the array.

Ex. 114 at 146893. Original claim 31 does not recite any limitations about the permeability of the array or the need for moisture removal. That the claim did not "issue" (it was allowed, but cancelled due to a later restriction requirement) does not mean claim 31 is not part of the inventors' disclosure.

227. In my view, a POSITA reading original claim 31 would not understand that the inventors considered their invention [redacted] This is supported by the subsequent prosecution history of claim 31, during which neither the examiner nor the applicants stated that claim 31 was so limited. Nor did the applicants attempt to distinguish any prior art on the basis of permeability of the applicator head or the need for suction. *See, e.g., id.* at 146915-16, 146928-31.

2. Dr. Tucker's Characterization Of The Minerva EAS

228. In my view, Dr. Tucker's analysis is largely misplaced. Again, I understand that

the proper analysis with respect to written description and enablement focuses on the claimed inventions as construed by the Court, not on whether the disclosure enables or describes all features of the accused product.

229. Additionally, Dr. Tucker's characterization of the Minerva EAS is inaccurate and incomplete. [redacted] This is not accurate. [redacted]

230. [redacted] Regardless of Dr. Tucker's inaccurate characterization of the Minerva EAS, this does not speak to whether the claimed inventions are enabled or are supported with sufficient written description.

231. As I noted previously, "The Minerva EAS is very similar to the NovaSure system

in that it also uses a bipolar Radio Frequency (RF) system that uses high voltage RF electrical current to heat and ablate the endometrial layer of the uterus." *See supra* Paragraph 63. I further noted that "[a] majority of the features and design elements between the [NovaSure system] and the Minerva EAS are identical or similar." *See supra* Paragraph 65.

232. [redacted]

233. [redacted] The asserted claims of the '348 and '989 patents, as construed by the Court, do not claim a plasma formation mechanism.

234. [redacted] The asserted claims of the '348 and '989 patents, as construed by the Court, do not claim a specific power output.

235. [redacted] As noted above, this is irrelevant because the claimed inventions do not include these limitations.

3. The Asserted Claims Of The '348 And '989 Patents Have Sufficient Written Description

236. [redacted]

[redacted] I disagree. In my opinion, these elements of the asserted claims of the '348 and '989 patents have sufficient written description.

237. For the reasons stated above and elaborated further below, in my opinion, the specification provides sufficient written description support for the claimed "one or more electrodes," i.e., one or more electrical conductors. The disclosure would reasonably convey to a POSITA that the inventors had possession of one or more electrical conductors.

238. For example, in the second exemplary embodiment, the specification states that "[a]pplicator head 102 includes an external electrode array 102*a*." Ex. 2 at 12:5-6. The specification further provides that "[a]blation power is supplied to the electrode array 102*a* by the RF generator system 250" and that the "tissue is heated as the RF energy passes from electrodes 118*a-d* to the tissue." *Id.* at 18:44-47.

239. During claim construction, the Court found that "[n]othing in the specification suggests applicant intended to limit the claim term . . . to contacting the tissue surface during ablation." D.I. 227, ¶ 7 n.12. I agree. The specification teaches electrical conductors located within the applicator head: "Each flexure 124 preferably includes conductive regions that are electrically coupled to the array 102*a* for delivery of RF energy to the body tissue. Referring to FIG. 29, strips 128 of copper tape or other conductive material extend along opposite surfaces of each flexure 124." Ex. 2 at 13:19-23.

240. [redacted]

[redacted]

241. For the reasons stated above and elaborated further below, in my opinion, the specification provides sufficient written description support for the claimed "applicator head" and "energy applicator." The disclosure would reasonably convey to a POSITA that the inventors had possession of an ablation device having an applicator that delivers energy to the uterine tissue. The specification includes voluminous disclosure of ablation devices with an applicator head or energy applicator that delivers energy to the uterine tissue. For example, the specification discloses that "applicator head 102 extends from the distal end of a length of tubing 108 [and] includes an external electrode array 102*a* and an internal deflecting mechanism 102*b*." Ex. 2 at 12:3-6. The specification also provides that "the applicator head 102 is slidably disposed within the sheath 104 during insertion of the device into the uterine cavity, and the handle 106 is subsequently manipulated to cause the applicator head 102 to . . . expand into contact with body tissue." *Id.* at 11:61-66; *see also id.* at 14:19 ("conform to the shape of the uterus").

242. [redacted]

243. In my view, the level of detail provided in the disclosure of the patents is consistent with the nature and scope of the claims. This includes detailed disclosure and 47 accompanying figures specifying the components of exemplary applicator heads and electrodes, schematic representations showing the device positioned in and ablating the uterus, and cross-

sectional views of the applicator head. The types of figures and results provided in the specification are consistent with what a POSITA would expect given their background knowledge and the complexity and predictability of the relevant technology.

4. The Asserted Claims Of The '348 And '989 Patents Are Enabled

244. [redacted] I disagree. In my opinion, for the same reasons as discussed above, the '348 patent's specification would have enabled a POSITA to make and use without undue experimentation an ablation device having a distal end portion that applies energy to the uterine tissue and including one or more electrical conductors. In my opinion, the '989 patent's specification would have enabled a POSITA to make and use an ablation device having an applicator that delivers energy to the uterine tissue without undue experimentation.

245. As discussed above (*see supra* Paragraph 245), the '348 and '989 patents provide a detailed disclosure and 47 accompanying figures specifying the components of exemplary applicator heads and electrodes, preferred shapes and materials of the applicators, instructions for how to make a metallized fabric mesh, schematic representations showing the device positioned in and ablating the uterus, and cross-sectional views of the applicator head. The specification discloses the use of electrical conductors inside the applicator head. The specification also indicates that aspects of the first and second embodiments may be combined. This detailed disclosure provides sufficient guidance to make and use an ablation device with a distal end portion that applies energy to the uterine tissue and includes one or more electrical conductors. [redacted] The disclosure of two embodiments in the

specification suggests that a POSITA would need to undertake minimal, routine experimentation to make and use a distal end portion of an ablation device that applies energy to the uterine tissue and includes one or more electrical conductors, choose the material for the applicator head, and determine the positioning of the electrodes. This also is evident from the similarity between Figure 23 and the current commercial embodiment of the NovaSure devices, as shown below:

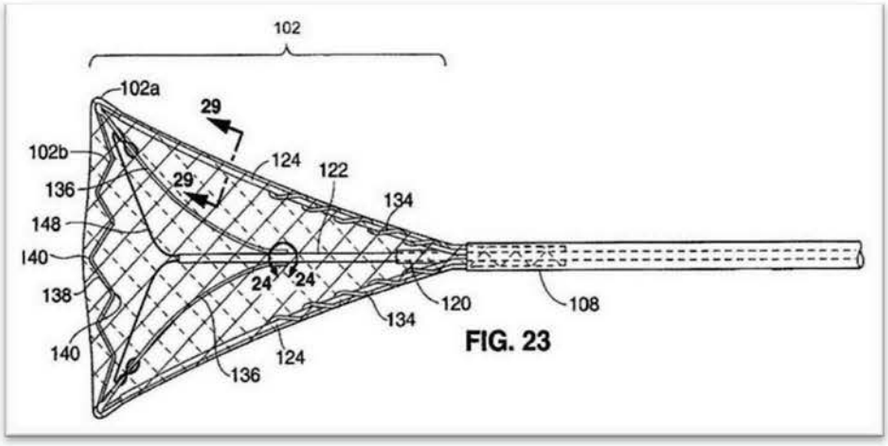


FIG. 23

[redacted]

Ex. 2 at FIG. 23; LEINSING_000323 (NovaSure Gen. 3); LEINSING_000245 (NovaSure Gen. 4.1). The similarity between Figure 23 and the commercial NovaSure devices reinforces my opinion that the specification would enable a POSITA to make and use the claimed device with little to no experimentation — and certainly without undue experimentation.

246. The level of skill in the art is relatively high. A POSITA would have knowledge of engineering principles and experience designing or working with devices for use in the uterus.

A POSITA would be familiar with prior art thermal and RF ablation techniques using devices with inflatable applicators. A POSITA would be able to draw upon this knowledge and experience to implement the devices of the '348 patent and the methods of the '989 patent.

247. In my view, the specification provides a sufficiently detailed explanation of how to make and use the claimed inventions that is commensurate in scope with the type of technology here, which relates to devices and methods for ablating or coagulating uterine tissue. The degree of disclosure here is also consistent with that in the prior art reviewed by the examiner and which would be available to a POSITA. This prior art included examples of ablation devices with inflatable applicators using thermal and RF ablation techniques.

248. [redacted] The claims of the '348 patent recite ablation devices with, among other things, a distal end portion that applies energy to uterine tissue that includes one or more electrical conductors. The '989 patent recites methods for performing endometrial ablation including, among other things, the step of positioning into a uterus an applicator of an ablation device that delivers energy to the uterine tissue. In my opinion, the claims of the '348 and '989 patents are fairly narrow and would not require a POSITA to perform undue experimentation to make and use the claimed inventions.

C. THE ASSERTED CLAIMS OF THE '183 PATENT HAVE SUFFICIENT WRITTEN DESCRIPTION AND ARE ENABLED

1. Dr. Tucker's Characterization Of The Teachings And Disclosures Of The '183 Patent Is Incomplete And Inaccurate

249. [redacted]

[redacted] The purpose of the inventions was to provide systems and methods for detecting the presence of a perforation in a body cavity.

250. In my opinion, the specification provides sufficient written description of and enables a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal. [redacted]

a. **State Of The Art**

251. ***Bernoulli's Equation***. A POSITA would be aware of and understand the well-known law of physics governed by Bernoulli's Equation — which was first published in 1738 — that the flow rate of the CO_2 gas in a system will be proportional to the square root of the pressure drop between two points in that system. *See* Ex. 45 at 536. This equation and its principle are basic aspects of fluid dynamics that were well-known to POSITAs at the time of the invention.

252. Similarly, a POSITA would be aware that fluid flows from an area of high pressure to an area of low pressure, in much the same way that wind is the result of bulk movement of air from an area of high pressure to an area of low pressure. When the pressure on both sides of a system are equal, there will be no net flow of fluid. The relationship between flow rate and pressure, known to a POSITA at the time of the invention, was also disclosed in prior art. *See, e.g.*, Ex. 118 at 3:8-12, 5:8-16, claim 1. This relationship also is a basic aspect of fluid flow that was well known to POSITAs at the time of the invention.

253. [redacted] I would not have expected that the inventors would include such information because it reflects basic laws of physics such as the Bernoulli Effect that would be apparent to a POSITA reading the patents.

b. **The Common Specification**

254. In describing one embodiment of the claimed inventions, the specification states: "Downstream of the medical device 12 is a pressure sensor 84, ***such as*** the Sensym ACSX05DN." Ex. 1 at 5:21-22 (emphasis added). A POSITA would understand that the identified pressure sensor is merely an exemplary pressure sensor that may be used with the exemplary embodiment. This understanding is reinforced by the specification:

> [A]lthough the system is described with reference to ***a particular embodiment***, many other configurations are suitable for implementing the teachings of the invention. Those having ordinary skill in the art will certainly understand from the embodiment disclosed herein that ***many modifications are possible without departing from the teachings hereof***. All such modifications are intended to be encompassed within the following claims.

Id. at 8:1-8 (emphasis added).

255. A POSITA would also understand that the exemplary pressure sensor indirectly detects as its input the force per unit area. The sensor contains a diaphragm. Physical deflection of the diaphragm (in response to a change in pressure) results in a change in resistance of a resistive element in the sensor. This change in resistance in turn causes a corresponding change in the sensor's output voltage. Thus, a POSITA reading this disclosure would know that the disclosed sensor's output voltage corresponds to the force per unit area but that the disclosed sensor does not directly detect a force per unit area.

256. [redacted] As noted above, a POSITA would know that a flow

meter can also provide a signal proportional to the uterine pressure, because the flow rate is proportional to the pressure according to Bernoulli's equation, discussed above.

257. [redacted] I disagree. The specification provides only that the pressure sensor "delivers the signal to microprocessor 34." Ex. 1 at 5:22-25. A POSITA would understand that outputting an electrical signal ***corresponding to*** the force per unit area does not necessarily require an "actual quantified value of pressure" or "a corresponding value of that pressure."

258. [redacted] A POSITA reading the specification would understand that the pressure sensor detects, directly or indirectly, the force per unit area at this location within the system. As depicted in Figure 3, the pressure sensor is located "[d]ownstream of the medical device 12," *i.e.*, along the return line after the CO_2 flows through the medical device, which is positioned within the uterine cavity:

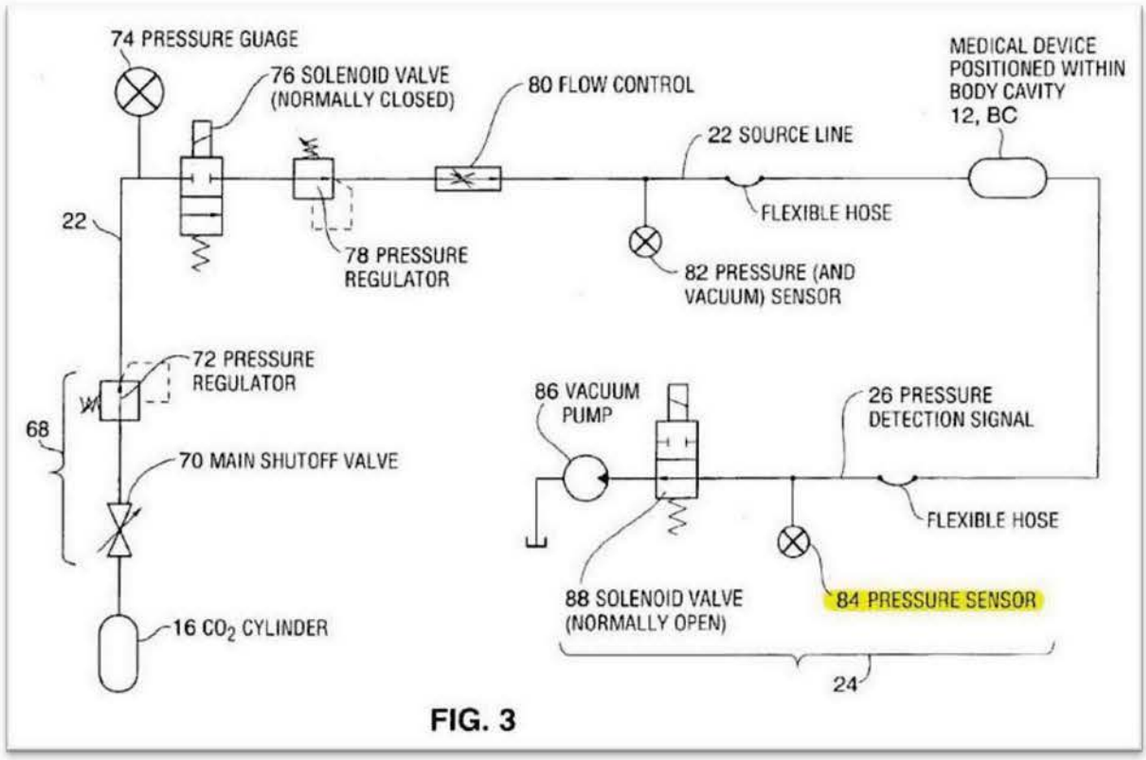


FIG. 3

A POSITA would not understand this to mean that "the ***pressure*** is [directly] detected at the input of pressure sensor 84." *See id.*

259. [redacted] First, a POSITA would understand that the specification is describing a single embodiment of the inventions. Second, a POSITA would not understand the specification's single use of the term "gauge" as it relates to pressure sensor 84 to limit the sensor to a gauge. This would be in contrast to the specification's consistent identification of element 74 as "pressure gauge 74" or "gauge 74."

260. [redacted]

[redacted] In one embodiment, the test begins with the uterus in an unpressurized state, and the test is passed when the ***pressure rises and remains*** above a predetermined threshold for a predetermined time period. In this embodiment, the test fails if either the pressure does not rise above the predetermined threshold or the pressure does not remain above the predetermined threshold for the predetermined time period. The specification states that in this first exemplary embodiment, the perforation detection test is performed while CO_2 is flowing into the uterus. Ex. 1 at 5:25-31, 6:44-46.

261. In another embodiment, the test begins with the uterus in a pressurized state and the test is passed if the pressure does not fall below a predetermined threshold within a predetermined time period. *Id.* at 6:47-51; *see also id.* at 2:37-43 ("Pressure sensing system 24 monitors the pressure within the body cavity BC while fluid/gas is being (or after it has been) delivered to the body cavity, and detects whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time.").

262. [redacted] However, a POSITA would know that '183 patent claim 1, for example, is not limited to sensing whether pressure fails to rise and remain above a predetermined threshold or rises and remains above a predetermined threshold for a predetermined amount of time. Those types of limitations are present in related claims to which the '183 patent claims priority. For example, claim 17 of U.S. Patent No. 6,554,780 includes limitations (in highlight) directed to threshold levels not present in the '183 patent:

> **17**. A method of detecting a perforation in a body cavity, comprising the steps of:
>
> (a) inserting a medical device into a body cavity;
>
> (b) passing an inflation medium through the medical device and into the body cavity;
>
> (c) monitoring a pressure within the body cavity; and
>
> (d) if the pressure monitored in step (c) rises and remains above a predetermined threshold level within a predetermined amount of time, providing feedback to a user that the body cavity is intact, and if the pressure monitored in step (c) fails to rise and remain above a predetermined threshold level within the predetermined amount of time, providing feedback alerting the user to the presence of a perforation in the body cavity.

263. [redacted] However, the specification only explains that the microprocessor "determines if pressure in the body cavity BC has failed to achieve a predetermined threshold . . . or if it has and maintained the threshold for a predetermined time period." Ex. 1 at 5:25-31. A POSITA would not understand this to mean that the microprocessor must compare an "actual quantified value of pressure" output by the sensor to a "predetermined threshold value of pressure." A POSITA would understand that the system could use another parameter as a replacement for pressure, which correlates to pressure, such as flow rate, or is representative of pressure change, such as a voltage signal or resistance change.

264. A POSITA reading the specification would not understand the inventions to be limited to a microprocessor (or other logic device) that must compare the sensor's output to a predetermined threshold pressure (i.e., make a pressure-to-pressure comparison). Accordingly, a POSITA would understand that the microprocessor can compare the sensor's output to a

predetermined threshold that corresponds to a pressure threshold.

265. The use of the ISO symbol of a pressure sensor for "pressure sensor 84" in Figure 3 is irrelevant. First, the ISO symbol does not require direct detection of a force per unit area. Second, even if it did, Figure 3 illustrates a single, exemplary embodiment of the inventions.

266. A POSITA reading the specification would understand that the disclosed perforation detection system is a closed system — assuming there is no perforation of the uterus. There are several disclosures in the specification indicating that it is a closed system:

- "Because the exhaust line of the vacuum pump may not be air-tight when it is not operating (including during the cavity assessment procedure) the valve 88 is provided to close the pressure signal line against leaks through the vacuum pump." Ex. 1 at 5:45-50;
- "Valve 88 is energized to close off the vacuum pump 86 to avoid loss of pressure through it." *Id.* at 6:40-42; and
- "Finally, the system includes a collar assembly 63 in FIG. 2*a* which is capable of sealing the entry into the body cavity BC if leaks are determined to exist, thus reducing the likelihood of a false test failure." *Id.* at 7:58-62.

267. [redacted] With respect to the first exemplary embodiment of the perforation detection algorithm, the specification provides:

> If it was not already opened, valve 76 is opened, allowing CO_2 to flow into the body cavity via medical device 12. When the pressure at gauge 84 rises and remains above 50 mmHg for 4 seconds, the test has passed and the system moves to a "PASSTHROUGH" state.

Id. at 6:42-46. [redacted] However, a POSITA reading the specification would understand that the CO_2 must be flowing during the perforation detection step. As the specification indicates, the pressure must

rise and remain above 50 mmHg. *See* Ex. 1 at 6:44-46; *see also id.* at 2:37-43 ("Pressure sensing system 24 monitors the pressure within the body cavity BC ***while fluid/gas is being*** (or after it has been) ***delivered*** to the body cavity . . . .") (emphasis added), 6:56-57 ("In the 'PASSTHROUGH' condition the CO_2 is turned off and the vacuum pump is re-enabled by re-opening valve 88."). With all else remaining equal, the pressure will not rise above the threshold without a flow of CO_2. Accordingly, a POSITA would understand that intrauterine pressure increases as CO_2 flows into the uterus.

2. Minerva's UIT

268. As previously discussed (*see supra* Paragraphs 77-78), Minerva's UIT functions according to the principles disclosed in the '183 patent. In a closed system — as is the case when the Minerva EAS is positioned in the uterus and the cervical seal is deployed — as gas fills the uterus, the pressure in the uterus increases. As the pressure increases, there is a proportional decrease in CO_2 flow rate. *See supra* Paragraphs 77-78; D.I. 127, ¶ 22 (citing Ex. 9 (Tucker) at 64:17-20). Accordingly, dropping below a flow rate threshold is equivalent to raising above a proportional pressure threshold. *See supra* Paragraph 79.

269. The length of time and the amount of experimentation it took Minerva to develop its UIT is irrelevant to the enablement analysis. [redacted]

[redacted]

270. [redacted]

[redacted]

3. The Asserted Claims Of The '183 Patent Have Sufficient Written Description

271. [redacted] I disagree. In my opinion, "pressure sensor" has sufficient written description. [redacted]

272. For the reasons stated above and elaborated further below, in my opinion, the

[redacted]

disclosure would reasonably convey to a POSITA that the inventors had possession of a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal. As detailed above, a POSITA would not have understood the description in the specification to be limited to monitoring for the presence of a perforation in the uterus using a device whose input ***directly*** detects a force per unit area and outputs a corresponding electrical signal.

273. I understand the Court found that "[n]othing in the specification requires the pressure sensor to measure pressure 'directly' so long as the pressure sensor can 'detect whether elevated pressure can be maintained in the uterus over a predetermined period of time.'" D.I. 227, ¶ 1. I agree. In my view, a POSITA reading this disclosure would not conclude that the inventors to be excluding or teaching away from indirectly detecting a force per unit area. This is supported by the fact that a POSITA would already know that pressure and flow rate are proportional.

274. The specification includes working examples of systems that monitor for the presence of a perforation in the uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal. The specification does not require that the microprocessor perform the disclosed algorithms "in units of pressure." In fact, the specification never mentions that the test is performed using a pressure-to-pressure comparison. A POSITA would understand that in the exemplary embodiments, as intrauterine pressure increases, the flow rate of CO_2 decreases. One way to determine that the pressure rises above a given threshold pressure is to measure whether the flow rate has fallen below a corresponding threshold flow rate.

275. [redacted]

[redacted] I agree that a flow meter can indirectly detect a pressure, especially when used in conjunction with a fixed orifice. A POSITA would understand that if the other variables in the equation are known, a pressure can be converted to a flow rate and vice versa. A POSITA could also, without undue experimentation, determine the requirements for pressure and make a direct correlation of pressure to flow rate to indirectly detect a drop in force per unit area. [redacted]

276. [redacted]

[redacted]

Ex. 68 at 293293. [redacted]

[redacted]

[redacted]

Ex. 70 at 299558; *see also* Ex. 69 at 299044-46, 299055; Ex. 70 at 299553-54, 299558-61, 299573, 299577-78. In my view, this experimentation is routine to a POSITA.

277. The priority application for the '183 patent (Provisional Application No. 60/164,482) notes that the delivery of fluid into the cavity can be "automatic, with known flow

rate and pressure" and that "[i]f a perforation or other leak were present, pressure would not build, or would build at a different rate or characteristic signal." A POSITA reviewing this disclosure would understand that if a perforation is present in the cavity, the pressure profile would change at a different rate, e.g., pressure increasing at a lower rate. Likewise, a POSITA would understand that a change in "characteristic signal" would include any linear or non-linear profile. A POSITA reading this disclosure would not understand that evaluating a different rate or characteristic signal of pressure would require directly detecting a force per unit area. A POSITA would know that pressure and flow worked together and that the POSITA could use pressure, rate of pressure change, flow rate, etc. to detect a leak or act as a "pressure sensor" in the system.

278. In addition, it was well known in the art that, in a closed system, pressure and flow rate are proportional. The specification discloses that, in one exemplary embodiment, the perforation detection test is performed while CO_2 is flowing into the uterus. This flow of CO_2 in turn causes the intrauterine pressure to increase. It was equally well known in the art that, in a closed system, a fluid will flow from an area of high pressure to an area of low pressure until the pressure on both sides of the system are equal, at which point the flow rate will approach zero. If the area of high pressure was a 50 mmHg CO_2 constant pressure source and the area of low pressure was a uterus, then the CO_2 would flow into the uterus until the intrauterine pressure approached 50 mmHg, at which point the flow rate would approach zero.

279. In my view, the level of detail provided in the disclosure of the patent is consistent with the nature and scope of the claims. This includes a detailed disclosure and accompanying figures specifying the components of exemplary perforation detection systems, schematics of an exemplary perforation detection system and an exemplary pneumatic

subsystem, and a simplified state diagram illustrating an exemplary mode of operation.

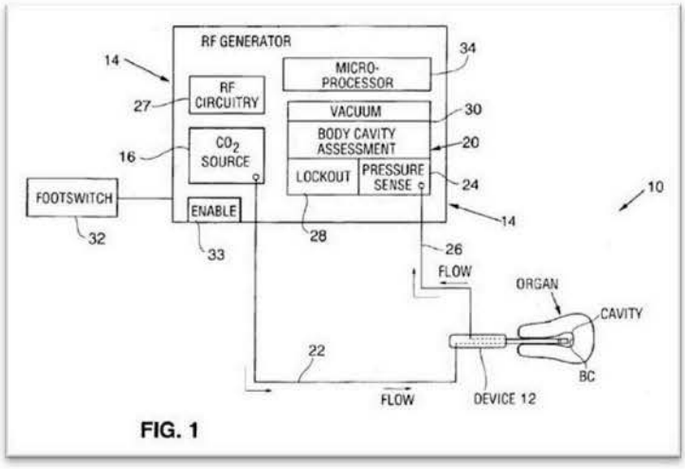


FIG. 1

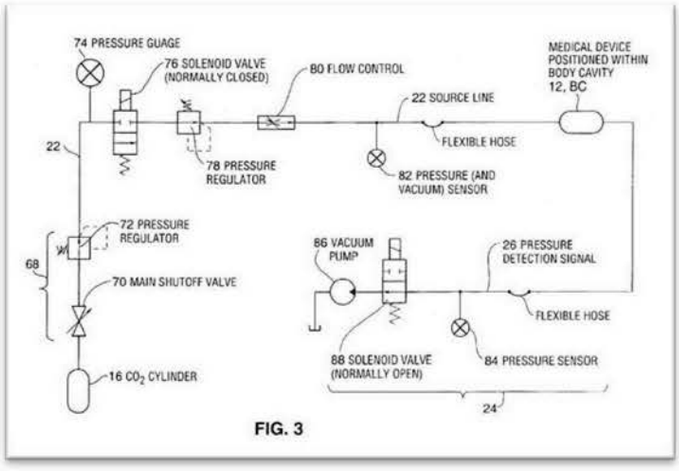


FIG. 3

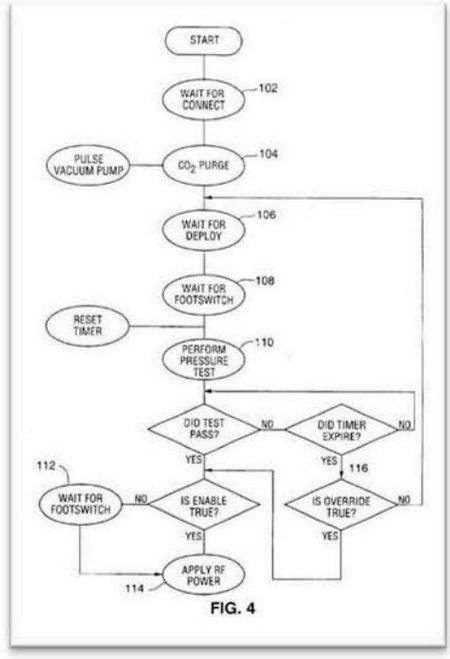


FIG. 4

Ex. 1 at FIG. 1 (schematic of exemplary perforation detection system), FIG. 3 (schematic of exemplary pneumatic subsystem), FIG. 4 (simplified state diagram); *see also id.* at 4:31-5:50 (describing the components of the pneumatic subsystem), 5:51-7:62 (describing the operation of an exemplary perforation detection system). The types of figures and results provided in the specification are consistent with what a POSITA would expect given their background knowledge and the complexity and predictability of the relevant technology.

280. In my opinion, as discussed above, a POSITA would conclude that the inventors had possession of monitoring for the presence of a perforation in the uterus using a device whose

input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal. Further, as discussed below, in my opinion a POSITA would conclude that the inventors had possession of a method of detecting a perforation in a uterus in conjunction with a thermal ablation device. Because Dr. Tucker does not identify any other terms or limitations lacking written description support, the asserted claims of the '183 patent are sufficiently described in the patent.

4. The Asserted Claims Of The '183 Patent Are Enabled

281. [redacted] I disagree. In my opinion, for the same reasons as discussed above, the '183 patent's specification would have enabled a POSITA to make and use without undue experimentation a system that monitors for the presence of a perforation in a uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal.

282. As discussed above (*see supra* Paragraph 282), the '183 patent provides a detailed disclosure and accompanying figures specifying the components of exemplary perforation detection systems, schematics of an exemplary perforation detection system and an exemplary pneumatic subsystem, and a simplified state diagram illustrating an exemplary mode of operation. The specification also teaches that "many other configurations are suitable for implementing the teachings of the invention" and that a POSITA would "certainly understand . . . that many modifications are possible without departing from the teachings [of the invention]." Ex. 1 at 8:1-8. The detailed disclosure and figures provide sufficient guidance to make and use a system that monitors for the presence of a perforation in a uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal.

283. In my view, a POSITA reading the disclosure of the '183 patent would not need to perform undue experimentation to develop a system that indirectly detects a force per unit area, such as by using a flow sensor. [redacted] A POSITA would only need to perform routine experimentation, consistent with what is ordinarily performed when designing devices that use pressurized fluids in the uterus, including monitoring the flow rate of fluids flowing into the uterus and monitoring uterine pressure.

284. The level of skill in the art is relatively high. A POSITA would have knowledge of engineering principles and experience designing or working with devices for use in the uterus. A POSITA would be familiar with the well-known relationship between flow rate and pressure in a closed system. A POSITA also would be familiar with prior art pressure sensors, including pressure sensors that directly detect force per unit area and pressure sensors that indirectly detect force per unit area.

285. In my opinion, in view of the specification and the state of the art (including the well-known relationship between flow rate and pressure), a POSITA would have found that monitoring for the presence of a perforation in the uterus using a pressure sensor in the form of a flow meter and a fixed orifice to be predictable. As discussed above (*see supra* Paragraphs 278-281), in a closed system, the flow rate of CO_2 into the uterus predictably will decrease as the

intrauterine pressure increases and approaches the source pressure.

286. In my view, the specification provides a sufficiently detailed explanation of how to make and use the claimed invention that is commensurate in scope with the type of technology here, which relates to systems and methods for detecting perforations in a body cavity. The amount of disclosure here is also consistent with that in the prior art reviewed by the examiner and which would be available to the POSITA. The prior art included examples of pressure sensors, including pressure sensors that indirectly detect force per unit area. In my opinion, given the broad disclosure in the specification, the state of the art, and a POSITA's background knowledge, it would have taken routine experimentation for a POSITA to decide whether to use a device whose input directly detects a force per unit area or one that indirectly detects a force per unit area and how to monitor for the presence of a perforation in the uterus using that device.

287. [redacted] The claims of the '183 patent generally recite methods of ablating a uterus and methods of detecting a perforation in a uterus that include the step of monitoring for the presence of a perforation in the uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding signal. In my opinion, the claims of the '183 patent are fairly narrow and would not require a POSITA to perform undue experimentation.

5. The "Thermal Ablation Device" Of Claim 15 Of The '183 Patent Is Enabled And Has Sufficient Written Description

288. [redacted] In my opinion, a POSITA reading the specification would conclude that the inventors had possession of the subject matter claimed in dependent

claim 15. Claim 15 is not limited to a particular ablation device. Claim 15 is directed to a method of detecting a perforation in a uterus performed in conjunction with a thermal ablation device.

289. The specification explains that the invention may be used in combination with a thermal ablation system:

> Naturally the perforation detection system may be provided in combination with the other medical devices as well. Such alternative devices include thermal ablation devices in which heated liquid is circulated through a balloon positioned within the body cavity of interest, or other device used for procedures besides ablation.

Ex. 1 at 2:66-3:5; *see also id.* at 2:13-20, 8:1-8. The specification does not disparage thermal ablation devices, but states that, with respect to RF ablation devices, "Greater control over ablation depth is thus achieved by allowing ablation to occur only (or primarily) by RF energy rather than by thermal conduction." *Id.* at 3:16-18.

290. [redacted] As I discussed with respect to written description, a thermal ablation device is not the claimed invention. The invention claimed in dependent claim 15 essentially is the method of detecting a perforation in a uterus performed in conjunction with a thermal ablation device. Thus, the specification need not enable a thermal ablation device, just the method of detecting a perforation in a uterus as in claim 9, wherein the ablation device is a thermal ablation device. The specification explains that, although the invention is described as part of an RF ablation system, the invention may be used in combination with a thermal ablation system:

> Naturally the perforation detection system may be provided in combination with the other medical devices as well. Such alternative devices include thermal ablation devices in which heated liquid is circulated through a balloon positioned

> within the body cavity of interest, or other device used for procedures besides ablation.

Ex. 1 at 2:66-3:5; *see also id.* at 2:13-20, 8:1-8. In an exemplary embodiment, the specification explains that the components for the body cavity assessment function are provided in the RF controller of an ablation device. In addition, the specification describes that:

> [S]ource line 22 is coupled, using a flexible Tygon® tubing for example, to the introducer sheath 38 (FIG. 2B) of the ablation device 12. The introducer sheath is located at the internal surface of the body cavity BC (the internal os, for example, in the case of a uterine cavity) so as to deliver gas into the body cavity BC that is to be treated.

Id. at 5:13-17. A POSITA would understand that the components of the perforation detection system can be included in the controller of a thermal ablation device and the source line and signal line can be coupled to the thermal ablation device's sheath.

291. In my opinion, as discussed above, the '183 patent's specification would have enabled a POSITA to make and use a system that includes the step of monitoring for the presence of a perforation in the uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal without undue experimentation. Further, in my opinion, the '183 patent's specification would have enabled a POSITA to make and use without undue experimentation a perforation detection system wherein the ablation device is a thermal ablation device.

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

Executed on January 4, 2018, at Dover, New Hampshire.

Karl R. Leinsing, MSME, PE.

CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on January 5, 2018, I caused to be electronically filed a true and correct copy of the foregoing sealed document with the Clerk of the Court using CM/ECF, and in addition caused true and correct copies of the foregoing sealed document to be served upon the following counsel of record by electronic mail:

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