

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MAGNOLIA MEDICAL TECHNOLOGIES, INC.,
Petitioner,

v.

KURIN, INC.,
Patent Owner.

Patent No. 12,138,052
Filing Date: July 24, 2024
Issue Date: November 12, 2024

Title: BLOOD SAMPLE OPTIMIZATION DEVICE

Inter Partes Review No.: IPR2026-00097

**DECLARATION OF KARL R. LEINSING, MSME, PE IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF U.S. PAT. NO. 12,138,052**

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I, Karl R. Leinsing, declare that I have personal knowledge of the facts set forth in this declaration and, if called to testify as a witness, could and would do so competently.

I. INTRODUCTION

1. I have been retained as an expert witness on behalf of the Petitioner, Magnolia Medical Technologies, Inc., for the above-referenced *inter partes* review proceeding.

2. I have been asked to provide a declaration with my opinions regarding certain matters pertaining to the patentability of U.S. Patent No. 12,138,052 (“the ’052 Patent”). I understand that the ’052 Patent is owned by Kurin, Inc. (“Patent Owner”).

3. I am being compensated at my usual consulting rate for my work on this matter. My compensation is in no way dependent upon my opinions or testimony or the outcome of this proceeding. I have no financial interest in the parties or in the outcome of this proceeding.

II. PROFESSIONAL BACKGROUND AND QUALIFICATIONS

4. My complete qualifications and professional experience are described in my *Curriculum Vitae*, a copy of which can be found in Exhibit 1003. The following is a brief summary of my relevant qualifications and professional experience.

5. I received a Bachelor of Science degree in mechanical engineering from the University of New Hampshire in 1988 and a Master of Science degree in mechanical engineering from North Carolina A&T State University in 1995. I am also a Professional Engineer in the State of New Hampshire (License No. 11437). I have worked as an engineer for more than 35 years and as a medical device engineer since 1992. Since 2006, I have served as the President of ATech Designs, Inc., where I design and develop various medical devices.

6. I have experience with various types of intravenous (IV) disposables in the medical field. I have consulted on and have experience with catheters, syringes, heparin locks, vacutainer tubes, blood sets, dialysis sets, needle-free valves, Luer fittings, and other related medical devices. I have invented, developed, and tested IV disposables, work that included material selection and qualification, molding and manufacturing, sterilization, verification, validation, FDA submissions, market training, and sales training.

7. My experience with materials used in medical devices is quite extensive, starting with my Master's Thesis on Strength of Medical Thermoplastic Female Luers Exposed to Chemicals.

8. I have gained significant experience with the development and life cycle of medical devices. I have worked as a Senior Product Design Engineer, Manager of Design Engineering, Director of Biomedical Engineering, and my

current role as President of ATech Designs, LLC where I have managed the development of various medical devices from conception to market. Many of my speaking engagements address the medical device product development process and include topics such as “The Science of Successful Product Design.”

9. Over my professional career, I have received several awards and honors. I have received a variety of awards for my medical product designs, with one design published on the cover of LIFE Magazine. One award, from Governor James B. Hunt of North Carolina, was presented for the design and development of a needle-free IV valve (United States Patent Number 5,676,346 and others) produced using completely automated manufacturing technology. This needle-free IV valve, called the SmartSite Needle-Free Valve, has been used since 1996 and is still in use today to infuse medicaments and withdraw blood to and from patients. In 1998, I won a Medical Design Excellence Award from the Medical Device & Manufacturing Conference and Exposition. In 2000, I received a New Product award from the National Society of Professional Engineers for innovative use of engineering principals and materials. In 2001, I won a Prototype Design Award and in 2003, I was a Gold Winner for yet another Medical Design Excellence Award. I have been recognized as one of the top medical device professionals in the country by MD&DI Magazine, and I was nominated for the 2010 PD&D (Product Design & Development) Design Engineer Hall of Fame.

10. I am listed as an inventor on forty-two (42) U.S. patents, and I am currently working on two new medical device inventions.

11. My company, ATech Designs, Inc., is being compensated for my time in connection with this matter at my standard consulting rate, which is \$600 per hour, plus reimbursement for actual expenses. My compensation is not dependent in any way upon the outcome of this matter.

12. I believe that my extensive industry experience and educational background qualify me as an expert in the relevant field of blood sample optimization systems for collecting blood samples. I also have expertise in mechanical engineering and design of medical devices, including those in the relevant field of devices for collecting blood samples. I am knowledgeable of the relevant skill set that would have been possessed by a hypothetical person of ordinary skill in the art (“POSITA”) at the time of the claimed invention of the ’052 Patent, which I have treated as July 24, 2015 for purposes of this proceeding. In particular, I have the necessary expertise to provide my informed opinions in this IPR, and I am an expert in the art of the ’052 Patent, due my qualifications discussed above.

III. MATERIALS REVIEWED

13. In connection with my study of this matter and reaching the opinions stated herein, I have reviewed a number of documents including the exhibits listed in Appendix A.

IV. UNDERSTANDING OF APPLICABLE LEGAL STANDARDS

14. Although I am not an attorney, I have a general understanding of the applicable legal standards pertaining to the patentability issues presented in this proceeding.

15. I understand that, in this *inter partes* review (IPR), Petitioner is challenging the patentability of claims 1-24 of the '052 Patent. I understand that Petitioner has the burden of proving that each challenged claim is unpatentable by a preponderance of the evidence.

16. I understand that to be valid, a patent claim must be “novel,” and is invalid if “anticipated” by a single prior art reference. I further understand that a reference anticipates if it discloses each and every element as arranged in the claim, so as to enable a person of ordinary skill in the art (“POSITA”) to make and use the claimed invention without undue experimentation.

17. I understand that a patent claim is unpatentable if, at the time of the invention, it would have been obvious to a POSITA to combine the teachings of the prior art to yield the patent claim. I also understand that it is not required (although

it is acceptable) that each element/limitation of a patent claim be found in a single reference in order to find a patent claim obvious. For a patent claim to be found obvious, all the elements/limitations of the patent claim may be found in a combination of references at which a person of ordinary skill in the art would have been reasonably expected to arrive. I understand that a proper analysis of whether an invention is unpatentable for obviousness includes a review of the scope and content of the prior art, the differences between the patent claims at issue and the prior art, the level of ordinary skill in the field of the invention at the time of the invention, and other objective considerations identified below.

18. It is my understanding that the prior art and claimed invention should be viewed through the knowledge and understanding of a POSITA – one should not use his or her own insight or hindsight in deciding whether a claim is obvious. I further understand that a claim may be rendered obvious if a POSITA can implement the claimed invention as a predictable variation of a known product. I also understand that a POSITA is presumed to have knowledge of the relevant prior art at the time of the claimed invention, which comprises any prior art that was reasonably pertinent to the particular problems the inventor faced.

19. I understand that a showing of obviousness requires some articulated reasoning with a rational underpinning to support the combination of the references. I understand that in consideration of the issue of obviousness it is important to

identify whether a reason existed at the time of the invention that would have led a POSITA to combine elements of the references in a way that yields the claimed invention.

20. I understand that a claim may be considered unpatentable for obviousness for various reasons. I have been informed that the following exemplary rationales may support a finding of obviousness:

- (A) combining prior art elements according to known methods to yield predictable results;
- (B) simply substituting one known element for another to obtain predictable results;
- (C) use of a known technique to improve similar devices in the same way;
- (D) applying a known technique to a known device ready for improvement to yield predictable results;
- (E) choosing from a finite number of identified, predictable solutions with a reasonable expectation of success;
- (F) known work in a field that prompts variations in the work in the same or a different field that leads to predictable results; and
- (G) some teaching, suggestion, or motivation in the prior art that would have led a person of ordinary skill in the art to modify a prior art reference or

combine multiple prior art references or teachings to arrive at the claimed invention.

21. I understand that various objective or “real world” factors, also referred to as secondary considerations, may be indicative of non-obviousness. I understand that such factors/considerations include:

- (A) the commercial success of the claimed invention;
- (B) the existence of a long-felt, unresolved need for a solution to the problem solved by the claimed invention;
- (C) failed attempts to solve the problem solved by the claimed invention;
- (D) copying of the claimed invention;
- (E) unexpected results of the claimed invention;
- (F) praise for the claimed invention by others in the relevant field; and
- (G) willingness of others to accept a license under the patent because of the merits of the claimed invention.

22. It is my understanding that the prior art references themselves may provide a suggestion, motivation, or reason to combine, but other times the link may be common sense. I further understand that the obviousness analysis recognizes that market demand, rather than scientific literature, often drives innovation, and that is sufficient motivation to combine references.

23. It is my understanding that a particular combination may be proven obvious merely by showing that it was obvious to try the combination. For example, common sense is a good reason for a person of ordinary skill to pursue known options when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions.

24. I further understand that a proper obviousness analysis focuses on what was known or obvious to a person of ordinary skill in the art, not just the patentee. Accordingly, it is my understanding that any need or problem known in the field at the time of invention and addressed by the patent can provide a reason for combining the limitations in the manner claimed.

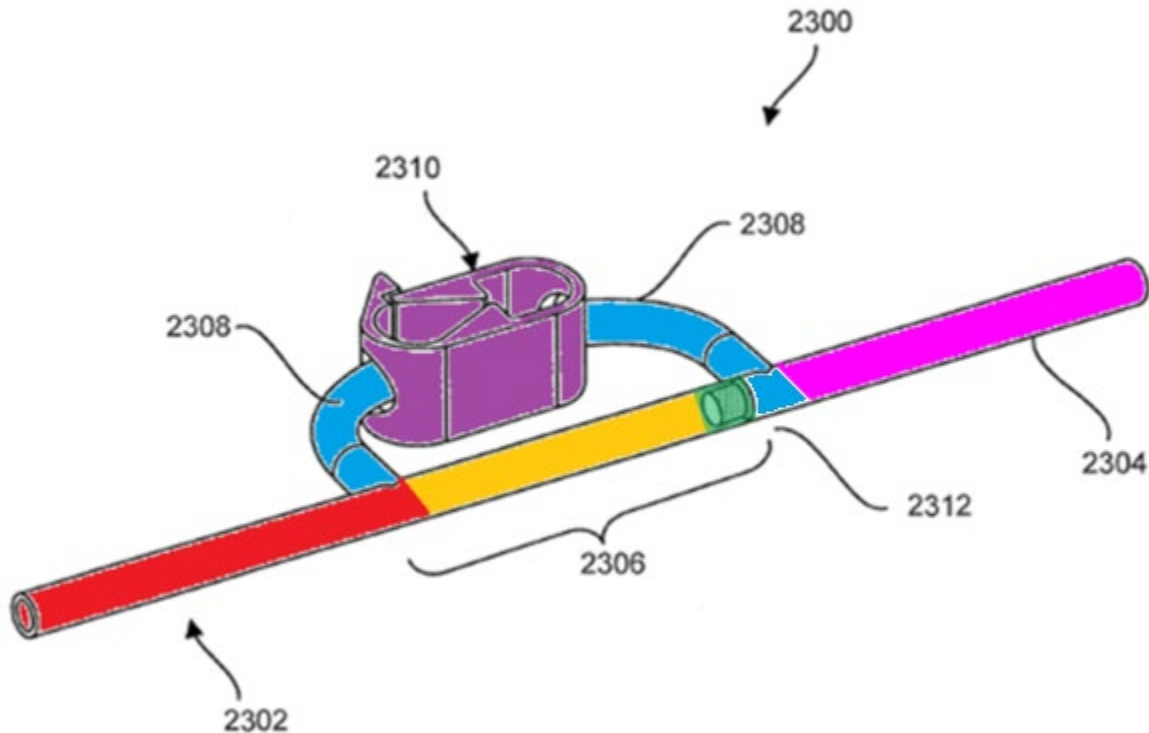
V. OVERVIEW OF THE '052 PATENT

25. The '052 Patent specification generally describes “systems and methods for reducing blood culture contamination” (Ex. 1001, 2:66-67) through the use of “a blood sequestration device located between a patient needle and a sample needle.” Ex. 1001, Abstract, 5:37-48; *see also id.*, 21:19-26. In particular, the device includes “a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood” Ex. 1001, Abstract, 5:47-51; *see also id.*, 21:19-26. A sampling channel then “bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the

initial aliquot of blood is sequestered” Ex. 1001, Abstract, 5:50-55; *see also id.*, 21:19-26.

26. The ’052 Patent includes illustrations of a number of blood sequestration devices with various configurations. *See* Ex. 1001, Figs. 1-23B. While many of the configurations share some similarities, I note that only Figures 23A and 23B depict a configuration that allows a “drawing force applied from the outlet port” to collect blood from the inlet port in a sequestration chamber as recited in the claims. *See* Ex. 1001, Figs. 23A-23B, claims 1, 13. I further note that the only place the claimed “drawing force applied from the outlet port” appears in the ’052 Patent specification is in the description of Figures 23A and 23B. Ex. 1001, 21:29-35. It is therefore my opinion that Figures 23A and 23B are illustrative of the claims of the ’052 Patent, involving a vacuum or other drawing force applied from the outlet port to draw blood into the inlet port and sequestration chamber. Ex. 1001, 5:29-31, 21:19-51, Figs. 23A-23B, claims 1, 13.

27. The device of Figure 23A, annotated below, includes an inlet port 2302 (**red**) “to connect with a patient needle,” an outlet port 2304 (**pink**) “to connect with a blood sample collection device,” a sequestration chamber 2306 (**yellow**), and a sampling channel 2308 (**blue**) “that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered.” Ex. 1001, 21:19-26, Figs. 23A-23B.



Ex. 1001, Fig. 23A (annotated)

28. The sequestration chamber (**yellow**) includes a hydrophobic plug 2312 (**green**) “at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302.” Ex. 1001, 21:26-28, Figs. 23A-23B. The device uses a “vacuum or other drawing force applied from the outlet port 2304” to “draw[] in blood into the inlet port 2302 and directly into the sequestration chamber 2306” Ex. 1001, 21:29-36. There, “the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there.” *Id.*

29. The drawing of the blood by the vacuum or other drawing force applied from the outlet port is facilitated by a valve¹ (purple) which initially is pinched shut to close off the sampling channel (blue). Ex. 1001, 21:35-37, Figs. 23A-23B. Upon release of the valve “and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.” Ex. 1001, 21:37-42, Figs. 23A-23B.

30. I note that the specification of the '052 Patent does not expressly describe a blood-impermeable membrane that is a “flexible material” that appears in the claims.

VI. RELATED PROSECUTION HISTORY

31. I understand that the '052 Patent is part of a larger patent family as shown in the family tree attached to this Petition as Appendix C. As shown in the family tree, the family begins with three provisional applications: Serial Nos. 62/318,194, 62/238,636, and 62/196,797. Ex. 1001, cover. The provisional

¹ I note that the '052 Patent references a “valve 2308,” but this appears to conflict with the '052 Patent’s previous description of “the sampling channel 2308” and the labeling in Figure 23A of the sampling channel as element 2308. Ex. 1001, 21:19-47, Fig. 23A.

applications were followed by U.S. Patent No. 10,010,282, followed by U.S. Patent No. 10,143,412, followed by U.S. Patent No. 11,185,266, followed by U.S. Patent No. 11,963,769, followed by U.S. Patent No. 11,832,944, followed by U.S. Patent No. 12,357,209 (“the ’209 patent”), followed by the ’052 Patent, followed by U.S. Patent No. 12,390,137, and followed by U.S. Patent Application No. 19/294,063. *Id.* The three provisional applications Nos. 62/318,194, 62/238,636, and 62/196,797 are also followed by U.S. Patent No. 9,820,682. See Appendix C. I understand that the family tree also includes IL286030B2, IL309380A, IL257137B, EP3324845B1 (followed by EP3622890B1, EP4215114A3), IL300848B2, AU2016297849A1 (followed by AU2021202622B2), CA2993646A1, and JP6643474B2 (followed by JP6734490B2, JP7277420B2, JP2023113621A5). See Appendix C.

32. I understand that the application that ultimately issued as U.S. Patent No. 10,010,282 did not receive an Office Action during prosecution, and received a Notice of Allowance on March 7, 2018 after an Examiner’s Amendment added, among other features, “a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.” Ex. 1005, pp. 333-44. I understand that the Examiner referenced the addition of the “housing” in a statement of reasons for allowance. *Id.*, pp. 342-43.

33. I understand that the application that ultimately issued as U.S. Patent No. 10,143,412 did not receive an Office Action during prosecution, and received a

Notice of Allowance on August 8, 2018. Ex. 1006, pp. 230-41. I understand that the Examiner noted the “prior art fairly suggest a blood/fluid sampling devices with vacuum chamber that collects/withdraws first portion of blood/fluid sample therein, where the vacuum chamber includes an outlet port that directs a second portion of blood/fluid to a sampling chamber.” *Id.*, pp. 239-40. I understand that the Examiner, in stating the reasons for allowance, referenced “a sequestration chamber and a sampling channel defined in a housing....” *Id.*

34. I understand that the application that ultimately issued as U.S. Patent No. 11,185,266 received a first Office Action during prosecution that did not include any rejections based on prior art. Ex. 1007, pp. 1146-49. I understand that the Applicant amended the independent claims to recite “an inlet port configured to receive the blood conveyed from the patient” rather than “an inlet port for receiving the blood conveyed from the patient” to address a subject matter eligibility rejection and filed a terminal disclaimer to overcome a double patenting rejection. *Id.*, pp. 1192-98. I understand that the application that ultimately issued as U.S. Patent No. 11,185,266 subsequently received a Notice of Allowance in which the Examiner indicated the prior art failed to teach “the sequestration chamber having a vent that includes an air permeable blood barrier, and wherein the junction is configured to allow a second portion of blood to bypass the sequestration chamber and the first

portion of blood sequestered therein to be directed into the sampling channel toward the outlet port” in the reasons for allowance. *Id.*, pp. 1200-07.

35. I understand that the application that ultimately issued as U.S. Patent No. 11,963,769 received a first Office Action on October 4, 2023, that did not contain any rejections based on prior art. Ex. 1008, pp. 3912-20. I understand that the application that ultimately issued as U.S. Patent No. 11,963,769 received a Notice of Allowance on January 17, 2024 in which the Examiner indicated that the claims were allowed because the prior art failed to teach “the chamber having a vent that includes an air permeable blood barrier, and wherein the junction is configured to allow a second portion of blood to bypass the chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port.” *Id.*, pp. 4040-48.

36. I understand that the application that ultimately issued as U.S. Patent No. 11,832,944 received a first Office Action on May 12, 2023 that included, amongst other non-prior art rejections of the only independent claim (claim 1), a rejection of claim 1 as anticipated by U.S. Patent App. Pub. No. 2010/057004 to Christensen et al. (“Christensen”). Ex. 1009, pp. 129-46. I understand that the Applicant filed a response on August 9, 2023 that did not amend the independent claims and argued that Christensen failed to teach “an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.” *Id.*,

pp. 3833-44. I understand that on August 25, 2023, the Examiner issued a Final Rejection that reiterated the rejection of claim 1 in view of Christensen and that indicated new independent claim 17 was allowable because the prior art allegedly did not teach “a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.” *Id.*, pp. 3846-59. I understand that the Applicant filed a response on August 29, 2023, canceling claim 1 and its dependent claims. *Id.*, pp. 3937-42. I understand that the Examiner issued a Notice of Allowance on September 8, 2023, indicating that the claims were allowable because the prior art allegedly did not teach “a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.” *Id.*, pp. 3946-52.

37. I understand that the application that ultimately issued as U.S. Patent No. 12,357,209 received a first Office Action on December 2, 2024, rejecting all but one dependent claim as obvious over U.S. Patent App. Pub. No. 2008/0145933 to Patton et al. (“Patton”) in view of U.S. Patent App. Pub. No. 2006/0009713 to Flaherty et al. (“Flaherty”), along with other non-prior art rejections. Ex. 1010, pp. 5684-97. I understand that dependent claim 9, which recited “wherein the housing defines the inlet port, the sampling channel, and the outlet port,” was not rejected over any prior art. *Id.*, pp. 5375, 5690. I understand that the Applicant filed a

response on May 30, 2025, in which the Applicant argued that Patton and Flaherty failed to teach “the chamber having a blood impermeable membrane.” *Id.*, p. 5823. I understand that the Examiner issued a Notice of Allowance on June 18, 2025, indicating that the claims were allowed because the prior art allegedly did not teach “the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample; and a housing, separate from the blood impermeable membrane.” *Id.*, pp. 5833-40.

38. I understand that the application that ultimately issued as the '052 Patent was filed on July 24, 2024, as a continuation of the U.S. Patent Application No. 18/494,622 (“the '622 application”, now the '209 patent). Ex. 1004, p. 119. The application was assigned U.S. Patent Application serial number 18/783,088 (“the '088 application”). *Id.*

39. I understand that '088 application was filed using the same specification as the '622 application. *Compare id.*, pp. 4-35 with Ex. 1010, pp. 13-44. I understand that the '052 Patent's parent (the '209 Patent) has similar claims to the '052 Patent, but independent claim 1 specifically recited “the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample” and did not recite the feature “a chamber connected with the inlet port and configured to collect a first portion of the blood sample **when under a drawing force applied from the outlet port from a blood sample**”

collection device” (emphasis added). Ex. 1025, claim 1. I understand that the “blood impermeable membrane” feature is included in the dependent claims of the ’052 Patent, and that the claims of the ’209 Patent recite “when a drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.” *Compare* Ex. 1025, claims 1-30 *with* Ex. 1001, claims 1-24. I understand that the ’209 Patent faced a single prior art rejection before it was allowed after the Applicant argued that one of skill in the art would not combine the references cited by the Examiner to teach “**the chamber having a blood impermeable membrane**” (emphasis added). Ex. 1010, 5823-26; *see also id.*, 5684-97, 5833-40.

40. I understand that on September 17, 2024, the Office issued a non-final action in prosecution of the ’052 Patent rejecting claims 1, 6-9, 11-12, 14, 19-22, 24-25 as anticipated by Patton. Ex. 1004, pp. 5571-76. I understand that, among other things, the Office found that the Patton reference disclosed “to collect a first portion of the blood sample...when under a drawing force applied from the outlet port from a blood sample collection device....” *Id.*, pp. 5573-76. In addition, I understand that the Office rejected dependent claims 2-5 and 15-18 as being obvious over Patton in view of U.S. Patent App. Pub. No. 2006/0009713 to Flaherty et al. (“Flaherty”), and dependent claims 13 and 26 as being obvious over Patton. *Id.*, pp. 5577-79. I understand that the Office allowed dependent claims 10 and 23. *Id.*, p. 5579. I

understand that in response to the non-final action, the Applicant amended independent claims 1 and 14 to incorporate the features “a housing that defines the inlet port, the sampling channel, and the outlet port” from claims 10 and 23. *Id.*, pp. 5825-32.

41. I understand that on October 10, 2024, the Office issued a Notice of Allowance. *Id.*, pp. 5899-5906. I understand that in the corresponding Notice of Allowability, the examiner stated that “[t]he prior art does not teach, disclose and/or fairly suggest a housing that defines the inlet port, the sampling channel, and the outlet port.” *Id.*, p. 5904. The ’052 patent was issued on November 12, 2024. *Id.*, p. 5969.

42. None of the art that I rely upon for my opinions at Section XII herein was applied or cited during prosecution of the ’052 Patent or its parent applications.

VII. RELATED LITIGATION

43. I understand that the ’052 Patent is the subject of pending litigation involving Petitioner: *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, 1-24-01124 (D. Del. filed Mar. 4, 2024) (“Corresponding District Court Litigation”), which is currently pending. Ex. 1031, pp. 46-47, 116.

VIII. TECHNICAL BACKGROUND

A. Hydrophobic Membranes

44. Hydrophobic devices have been around before at least 1992 when I started working at IVAC. Hydrophobic flexible membranes are often used to vent drip chambers and other ports used in IV (Intravenous) sets. They allow gas to enter while preventing potential contaminants in liquid from passing through. *See, e.g.*, Ex. 1033, 4:46-62, 5:25-30, 6:1-9, 6:17-26, Figs. 4, 11-13; *see also* Ex. 1032, Abstract, 6:14-49, 7:6-12, claims 1, 5; Ex. 1034, 7:43-66, 11:18-34, 15:65-16:12 (describing using a hydrophobic gas-permeable fiber membrane allow gas to pass through the membrane in devices that collect blood). Hydrophobic membranes have also long been used in fluid control devices, including medical devices, to allow certain gases (e.g., air or other gases) to pass from one portion of a device to another portion of the device while preventing the passage of liquids (e.g., blood) in the same manner. Ex. 1018, 1:39-49, 4:19-21, 4:62-67; Ex. 1013 ¶¶[0153]-[0154], Fig. 4; Ex. 1016, Abstract, 4:36-52, 5:52-57, 6:10-27, 14:1-10, 14:63-15:7. It was well known that there were a variety of materials that repel liquids, such as blood, that could be used to construct a hydrophobic membrane. Ex. 1015, 1:6-62, 2:13-38, claim 1; Ex. 1017, Abstract, ¶¶[0064]-[0065]; Ex. 1014 ¶¶[0021]-[0022], [0031], [0037]-[0038], [0052]. Different hydrophobic materials provide different characteristics and/or benefits. For example, it was known that certain materials provide both a high

hydrophobicity and flexibility (e.g., the ability to be flexed, bent, stretched, expanded, or compressed under normal conditions and to be easily hand-folded, flexed, twisted, and bent), which provides benefits to certain devices (e.g., devices requiring a hydrophobic barrier that can withstand liquid pressure under normal conditions). Ex. 1014, ¶[0052]; *see also id.* ¶¶[0021]-[0022], [0031], [0037]-[0038]; Ex. 1015, 1:6-62, 2:13-38, claim 1. It was further known to use the materials to construct the membrane between two regions of a device, thereby maintaining a separation between gaseous and liquid environments within the device. Ex. 1018, 1:39-49, 4:19-21, 4:62-67; Ex. 1013 ¶¶[0153]-[0154], Fig. 4; Ex. 1016, Abstract, 4:36-52, 5:52-57, 6:10-27, 14:1-10, 14:63-15:7; Ex. 1014 ¶¶[0021]-[0022], [0031], [0037]-[0038], [0052]. For example, the Brancazio reference that I discuss further below, where I apply the art to the claims, describes a blood extraction system having separate vacuum and storage chambers divided by a “material permeable to gas but not to...blood,” such as a hydrophobic membrane, to prevent blood from entering the vacuum chamber while maintaining pressure communication between the chambers. Ex. 1013 ¶¶[0153]-[0154], Fig. 4. Similarly, Liu discloses and/or renders obvious that hydrophobic membranes may be used in devices utilizing pressure differentials to control fluid movement, acting as barriers that allow gas displacement while blocking liquid flow. Ex. 1014, ¶¶[0007], [0010], [0021]-[0022], [0031], [0037]-[0038], [0041]-[0042], [0052], [0054]. A POSITA would

have recognized that using hydrophobic membranes in these contexts was a predictable design choice to prevent contamination, maintain chamber isolation, and regulate pressure in blood-handling devices.

45. It was also known that such membranes could readily be integrated into devices, such as fluid devices used in a medical and/or laboratory setting, to accommodate pressure changes and fluid movement. Ex. 1018, 1:39-49, 4:19-21, 4:62-67; Ex. 1014 ¶¶[0031], [0037]; Ex. 1013 ¶¶[0153]-[0157]. For example, it was known to use hydrophobic membranes constructed of flexible materials to improve the seal between the membrane and surrounding (especially rigid) materials such as a housing (e.g., by forming to the surrounding material), and/or to prevent liquids such as blood from transmitting through the membrane. Ex. 1018, 1:39-49, 4:19-21, 4:62-67; Ex. 1014 ¶¶[0031], [0037]; Ex. 1013 ¶¶[0153]-[0157].

B. Specimen Collection Using Vacuum Force

46. Vacuum force has long been used in medical devices to collect a sample specimen (e.g., blood) for at least as long as the syringe has been invented. For example, it was known to apply a vacuum force (that may, e.g., be created by a sample syringe, evacuated container, or similar devices) to a sample collection device (e.g., a blood collection device) to cause fluid (e.g., blood) to flow into a receptacle. The VACUTAINER® system is a well-established example of the use of a vacuum force to collect a sample specimen, where a sealed collection tube is

pre-evacuated to a sub-atmospheric pressure and used in conjunction with a double-ended hypodermic needle assembly. Ex. 1022, 4:42-56, 16:24-37. When one end of the needle is inserted into a patient's vein and the other end is inserted through the rubber stopper of the evacuated tube, the pressure differential between the vacuum within the tube and the venous pressure causes blood to flow automatically into the tube. Ex. 1022, 4:42-56, 16:24-37. U.S. Patent No. 7,087,047 ("Kraus") describes a vacuum tube (e.g., VACUTAINER) coupled to a sampling device, the sampling device used to "sample blood without any sampling bag 10, the blood been diverted into the vacuum tube." Ex. 1022, 16:23-37.

47. Using vacuum force to collect a specimen, particularly in the context of medical sample collection devices, was a predictable design choice before the '052 Patent. Further, it was known for certain specimen collection systems/devices to use the vacuum force to draw blood into a desired receptacle (e.g., for collection and/or sequestration). Ex. 1026, ¶¶[0079]-[0080], [0106], [0118]; Ex. 1027, ¶¶[0046], [0061]; Ex. 1028, ¶¶[0032], [0074]-[0075].

C. Sequestration of Samples

48. In fluid collection systems, particularly medical sample collection devices, sequestration refers to isolating a collected specimen (e.g., blood) within a sealed receptacle to prevent contamination, leakage, or backflow. Sequestration was well known in the art before the '052 Patent. It was well-known that sequestering a

collected specimen may be achieved using flow control mechanisms to block fluid communication after collection. *Id.*; Ex. 1026, ¶¶[0046], [0104], [0140], Fig. 36; Ex. 1028, ¶¶[0020]-[0024]. Sequestration, whether achieved through vacuum retention, rubber stoppers, valve-based isolation, or other means, was a well-known and predictable design feature for safely retaining collected specimens and preventing contamination or loss of the collected specimens. Ex. 1026, ¶¶[0046], [0104], [0140], Fig. 36; Ex. 1028, ¶¶[0020]-[0024].

IX. OVERVIEW OF THE RELIED UPON PRIOR ART

A. Bullington800

49. I understand that PCT Patent App. Pub. No. 2014/085800 to Bullington et al. (“Bullington800”), which is being submitted as Ex. 1012, was filed December 2, 2013, and published June 5, 2014. Ex. 1012, cover. Accordingly, I understand that Bullington800 is prior art under AIA 35 U.S.C. §102(a)(1) regardless of whether the ’052 Patent is entitled to an earliest priority date of April 4, 2016, October 7, 2015, or July 24, 2015. Ex. 1012, cover. Bullington800 relates to “devices and methods for parenterally-procuring bodily-fluid samples with reduced contamination from microbes or other contaminants exterior to the bodily-fluid source...” and, in my opinion, is analogous art to the ’052 Patent. Ex. 1012, ¶[1002].

50. I note that, like the ’052 Patent, Bullington800 describes a device that sequesters an initial (potentially contaminated) aliquot of blood in a sequestration

chamber and then uses a sampling channel to bypass the sequestration chamber to convey likely uncontaminated blood between a patient needle and a sample needle. Ex. 1012, ¶¶[1006], [1107]-[1114], Figs. 1, 11-17. Figures 16 and 17 of Bullington800, annotated below, “illustrate at least a portion of a syringe-based transfer device 500” configured to operate in such a manner. Ex. 1012, ¶¶[1107]-[1114], Figs. 16-17. Specifically, Figures 16 and 17 are cross-sectional schematic illustrations of two different configurations of the syringe-based transfer device 500. Ex. 1012, ¶¶[1022], [1107]-[1114]. Figure 16 shows a first configuration where blood can initially flow from an inlet port into a sequestration chamber (as shown by the path of arrow OO). Arrow NN illustrates the movement of a portion of Bullington800’s device that converts the device from the Figure 16 configuration to the configuration at Figure 17, where a pre-sample portion of bodily-fluid (e.g., blood) is sequestered from a subsequent sample of blood that follows the path of arrow RR towards the outlet port. Ex. 1012, ¶¶[1107]-[1114], Figs. 16-17.

member 537 (green) can be a “relatively flexible and/or compressible material” that “can fluidically isolate the fluid reservoir 580 from, for example, a portion of the inner volume 511 in fluid communication with the proximal port 515” (i.e., the second channel 507 (blue), either alone or in combination with the remaining portion of the inner volume 511 (blue) in fluid communication with the proximal port 515 (pink)). Ex. 1012, ¶¶[1109], [1111], Figs. 16-17.

53. Figure 16 illustrates a first position of the flow control mechanism 530 where the first channel 506 (yellow) is in fluid communication with the distal port 505 (red), while the second channel 507 (blue) is fluidically isolated from the distal port 505 (red) and the proximal port 515 (pink). Ex. 1012, ¶[1111], Fig. 16. That is, as shown in Figure 16, the second channel 507 (blue) is closed off on either end by the second member 538 (purple) and the third member 539 (purple) such that no fluid may flow into the second channel 507 from the distal port 505 (red) or out of the second channel 507 (blue) toward the proximal port 515 (pink). *Id.* In operation, a negative pressure (e.g., at the proximal port 515 (pink)) exerts a suction force that rotates the first member 537 (green) from its first position in Figure 16 to its second position in Figure 17 while simultaneously causing the suction force through the first channel 506 (yellow) and the distal port 505 (red) to urge a flow of blood from a patient through the first channel 506 (yellow) and into the fluid reservoir 580 (yellow) to be sequestered. Ex. 1012, ¶¶[1111]-[1114], Figs. 16-17.

Figure 17 illustrates a second position of the flow control mechanism 530 where the second member 538 (purple) and the third member 539 (purple) operate as valves (purple) that are opened to place the second channel 507 (blue) in fluid communication with the distal port 505 (red) and the proximal port 515 (pink) in order to urge a flow of bodily-fluid that is substantially free from contaminants into, e.g., a syringe. Ex. 1012, ¶[1114], Fig. 17. This flow bypasses the fluid reservoir 580 (yellow) and first channel 506 (yellow), which are fluidically isolated from the distal port 505 (red) and the proximal port 515 (pink) by the first member 537 (green) and the second member 538 (purple) in order to sequester the initial volume of bodily-fluid. Ex. 1012, ¶[1114], Fig. 17.

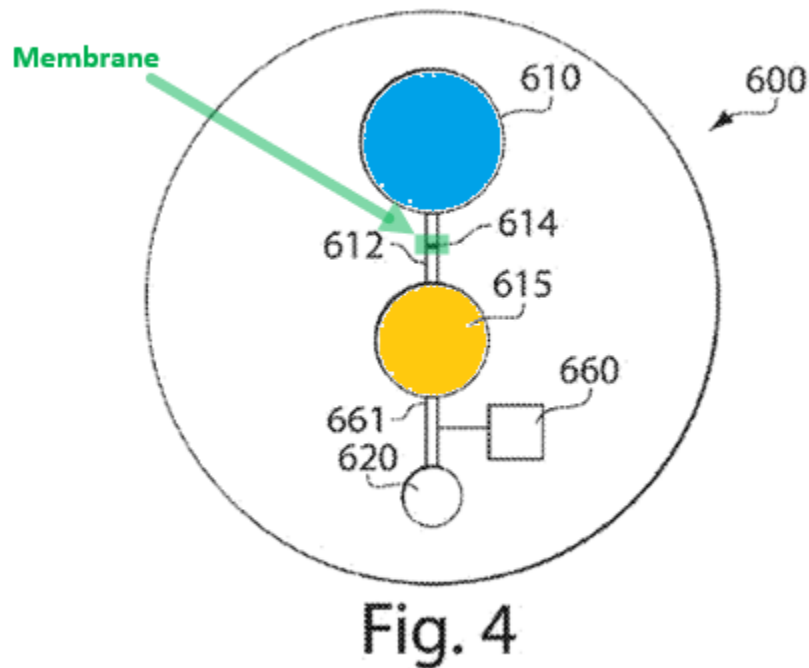
B. Brancazio

54. I understand that U.S. Patent App. Pub. No. 2014/0336536 to Brancazio (“Brancazio”), which is being submitted as Ex. 1013, was filed July 10, 2014 and published November 13, 2014. Ex. 1013, cover. Accordingly, I understand that Brancazio is prior art under AIA 35 U.S.C. §102(a)(1) regardless of whether the ’052 Patent is entitled to an earliest priority date of April 4, 2016, October 7, 2015, or July 24, 2015. Ex. 1013, cover. Brancazio relates to extracting blood from a subject using a reduced pressure or vacuum chamber. Ex. 1013, Abstract; *see also id.*, ¶¶[0003], [0013], [0041]-[0042], [0048]-[0049], [0052], [0059], [0087]-[0120], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. Brancazio and the ’052 Patent

both describe extracting blood from a subject using negative pressure from a vacuum (e.g., a Vacutainer™) to draw the blood into a collection chamber. Ex. 1013, ¶¶[0003], [0013], [0041]-[0042], [0052], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1001, Abstract, 3:17-4:34, 5:37-6:3, 21:19-52, Figs. 1, 23A-23B. Further, both Brancazio and the '052 Patent describe the use of an air-permeable but blood-impermeable barrier to sequester blood in a particular chamber of a blood collection device (e.g., to prevent contamination of another chamber of the device). Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1001, 6:24-47, 14:39-63, 19:41-57, claim 3. For the foregoing reasons, it is my opinion that Brancazio is analogous to the '052 Patent.

55. More specifically, Brancazio describes a device that includes a “separate vacuum chambers and storage chambers” where the vacuum from the vacuum chamber is used to receive fluid which is then directed into the storage chamber. Ex. 1013, ¶[0153], Fig. 4. To prevent blood from entering the vacuum chamber, Brancazio’s device includes a “material permeable to gas but not to...blood” such as a hydrophobic membrane, a porous structure, or other gas-permeable blood-impermeable materials. *Id.*, ¶¶[0153]-[0154], Fig. 4. As illustrated below, Brancazio’s membrane (**green**) is positioned between the vacuum chamber (**blue**) and the storage chamber (**yellow**), allowing the chambers to remain in fluid

communication while preventing blood from entering the vacuum chamber as the vacuum force (i.e., negative pressure) draws blood into the storage chamber (yellow):



Ex. 1013, Fig. 4 (annotated)

Ex. 1013, ¶¶[0153]-[0154], Fig. 4.

56. Brancazio's Figure 13 (annotated below) also discloses and/or renders obvious utilizing a vacuum chamber in conjunction with a collection chamber separated by a gas-permeable, blood-permeable membrane. Ex. 1013, ¶¶[0111], [0153]-[0154], Figs. 13A-13E. As shown in Figure 13B, the device includes a vacuum or reduced-pressure region positioned above a collection chamber into

which blood is drawn from a subject. *Id.* In Figure 13B, “the blood from the subject is then urged or moved into second module 910, and in particular, into collection chamber 908 within second module 910,” which is “in fluidic communication with piercing member 912.” *Id.*, ¶¶[0103], [0111], [0153]-[0154], Figs. 13A-13E. For example, Brancazio describes “an opposing end of collection chamber 908 [(yellow)] is in fluidic communication with the reduced pressure environment of vacuum chamber 907 [(blue)] via piercing member 912, thereby providing the driving force for blood to flow into collection chamber 908 [(yellow)].” *Id.*

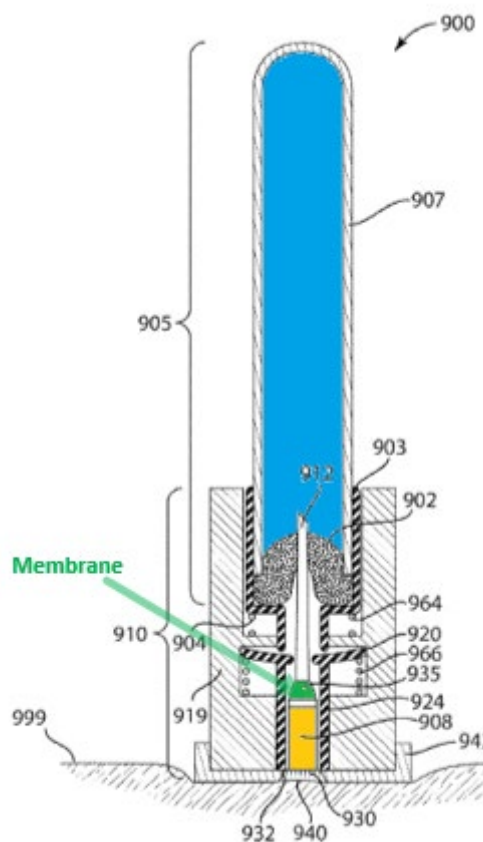


Fig. 13B

Ex. 1013, Fig. 13B (annotated)

Brancazio discloses that the blood entering the collection chamber 908 (yellow) cannot move into the vacuum chamber 907 (blue) due to the “gas-permeable membrane 935 [(green)] that is present at the opposing end of piercing member 912.” *Id.*, ¶¶[0103], [0111], [0153]-[0154], Figs. 13A-13E. The gas-permeable membrane acts as a hydrophobic or blood-impermeable barrier, allowing blood to be collected into the collection chamber 908 (yellow) without entering the vacuum chamber 907 (blue). *Id.*

57. Figure 13B teaches the same principle as Figure 4, showing use of a vacuum chamber to generate negative pressure for blood collection with a selectively permeable membrane positioned between a vacuum chamber and a collection chamber. Figures 4 and 13 teach systems analogous to those of the '052 Patent, both employing a vacuum-driven blood collection mechanism and a hydrophobic membrane to sequester blood and maintain separation between collection and vacuum containers.

C. Liu

58. I understand that U.S. Patent App. Pub. No. 2012/0245042 to Liu et al. (“Liu”), which is being submitted as Ex. 1014, was filed February 16, 2012 and published September 27, 2012. Ex. 1014, cover. Accordingly, I understand that Liu is prior art under AIA 35 U.S.C. §102(a)(1) regardless of whether the '052 Patent is entitled to an earliest priority date of April 4, 2016, October 7, 2015, or July 24,

2015. Ex. 1014, cover. Liu relates to the use of hydrophobic membranes (e.g., for degassing) in the field of fluid mechanics and devices that utilize pressure within a fluid channel to move fluids. Ex. 1014, Abstract, ¶¶[0002], [0007]-[0008], [0021]-[0022], [0031], [0037]-[0038], [0052]. Liu and the '052 Patent both describe the use of a hydrophobic membrane that acts as a barrier to liquid (e.g., bodily-fluid) in a fluid flow path while allowing gas (e.g., air) to be displaced. Ex. 1001, 6:24-47, 13:58-63, claims 2-4, 14-16; Ex. 1014, ¶¶[0002], [0007]-[0008], [0021]-[0022], [0031], [0037]-[0038], [0052]. Further, both Liu and the '052 Patent describe the use of the hydrophobic membrane in a system that utilizes pressure within a fluid channel to move the fluids towards the membrane. Ex. 1014, ¶¶[0031], [0037]; Ex. 1001, 21:20-48, Figs. 23A-23B. For the foregoing reasons, it is my opinion that Liu is analogous to the '052 Patent.

59. Additionally, it is my opinion that Liu would also be considered analogous to Bullington800 by a POSITA. A POSITA would have understood that both Liu and Bullington800 address controlling the movement of liquid under pressure while preventing gas or liquid contamination across a membrane barrier. Liu teaches that the system includes “a flexible gas-permeable hydrophobic membrane sealing an outlet of the first fluid channel” that is “essentially impermeable to liquids when the liquid pressure is below a certain threshold” and which “deflects when sufficient pressure is exerted on the membrane by a pressure

source (e.g., fluid).” Ex. 1014, ¶¶[0007], [0022], [0031]. Similarly, Bullington800 describes maintaining separation between blood and gas regions of a device, where a flexible member or barrier “fluidically isolate[s] the fluid reservoir...from, for example, a portion of the inner volume” connected to the vacuum or sampling channel. Ex. 1012, ¶¶[1109]-[1111]. A POSITA would have recognized that both Liu and Bullington800 rely on the same principle of using a gas-permeable, liquid-impermeable structure to regulate movement of gas and liquid in pressure-driven systems. Although Liu is directed to microfluidic or analytical devices, the mechanisms it describes, such as controlling pressure and preventing fluid breakthrough across a hydrophobic membrane, are applicable to Bullington800’s blood collection device, which likewise employs pressure differentials to direct fluid and maintain isolation between liquid and gas regions. Ex. 1014, ¶¶[0022], [0037]; Ex. 1012, ¶¶[1109]-[1114]. Accordingly, a POSITA would have found Liu to be reasonably pertinent to the problem addressed by Bullington800, and thus analogous art.

X. THE RELEVANT ART AND LEVEL OF ORDINARY SKILL IN THE RELEVANT ART

60. In my opinion, the relevant field of art for the ’052 Patent is blood sample optimization systems for collecting blood samples. Ex. 1001, Abstract.

61. I understand that obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art (POSITA) at the time of the

alleged invention, which, for purposes of this declaration, I have assumed is the earliest claimed invention date of July 24, 2015.

62. I understand that the following four factors may be considered when identifying the appropriate level of a POSITA: (i) the types of problems encountered by those working in the field and prior art solutions thereto; (ii) the sophistication of the technology in question, and the rapidity with which innovations occur in the field; (iii) the educational level of active workers in the field; and (iv) the educational level of the inventor(s). I understand that a POSITA is one who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity.

63. It is my opinion that, for the '052 Patent, a POSITA would have had a bachelor's degree in mechanical engineering, biomechanical engineering, physics, or a similar technical discipline, along with four years of experience with the design of medical devices. Such work experience may include designing, manufacturing, and/or testing medical devices, including those related to syringe-based devices. Experience could take the place of some formal training, as design skills and materials knowledge may be learned on the job. This description is approximate, and a higher level of education or skill might make up for less experience, and vice-versa. For example, it is my opinion that a Master's degree or Doctorate in mechanical engineering, biomechanical engineering, physics, or a similar technical

discipline would decrease the years of experience required to three years and two years, respectively. In addition, the prior art references discussed herein, which assume knowledge on how to design medical devices for sample collection and on how to select materials for the construction of such devices, also reflect the appropriate level of skill at the time of the claimed invention.

64. I worked in the relevant field with persons meeting this definition of a POSITA at, and leading up to, the time of the alleged invention of the '052 Patent (i.e., July 24, 2015). Therefore, I am familiar with the knowledge and skills that such persons had at the time. In my opinion, a POSITA's skill set would have included mechanical design skills for medical devices. A POSITA's skill set would have also included knowledge of hydrophobic materials and their uses in design of medical devices. Based on my qualifications as described at Section II, above, I am a POSITA for the relevant field of the '052 Patent.

XI. CLAIM CONSTRUCTION

65. I understand that my analysis requires an understanding of the scope of the claims of the '052 Patent. I understand that claim terms subject to *inter partes* review, absent some other definition provided in the patent, are given their plain and ordinary meaning to a POSITA in light of the patent specification. It is my understanding that the parties in the Corresponding District Court Litigation agreed that the term "flexible material" is to be given its plain and ordinary meaning: a

“material that can be flexed, bent, stretched, expanded, or compressed without breaking under normal conditions.” Ex. 1035, p. 7. It is also my understanding that the parties agreed that the term “a housing that defines” means “a casing that fixes or marks the limits of.” Ex. 1036, p. 1. I further understand that Petitioner first proposed the following construction for “flexible material”: “[m]aterial that is easily hand-folded, flexed, twisted, and bent. *See* Ex. 1035, p. 7. My positions below apply the agreed upon constructions and are consistent with Petitioner’s first proposed construction for “flexible material” in the Corresponding District Court Litigation. I understand that the Petition applies the agreed upon constructions listed above and that Petitioner’s position is that plain and ordinary meaning should apply to all other terms for purposes of this proceeding. Therefore, in my analysis below, I have assumed that all claim terms are given their plain and ordinary meaning as would have been understood by a POSITA reading the patent specification at the time of the earliest claimed priority date (i.e., July 24, 2015) and have also considered the definitions agreed upon by the parties and first proposed by Petitioner in the Corresponding District Court Litigation. For the reasons I explain below at Section XII, where I apply the art to the claims, it is my opinion that the claims of the ’052 Patent are invalid in view of the prior art under any reasonable construction, including those agreed upon in the Corresponding District Court Litigation.

XII. ANALYSIS

66. For the reasons that I discuss in detail below, it is my opinion that, at least by July 24, 2015 (the earliest claimed priority date), claims 1-24 of the '052 Patent would have been obvious to a POSITA. To summarize, it is my opinion that:

- Claims 1-24 would have been anticipated based on Bullington800;
- Claims 1-24 would have been obvious based on Bullington800;
- Claims 1-24 would have been obvious based on Bullington800 in view of Brancazio; and
- Claims 13-24 would have been obvious based on Bullington800 in view of Brancazio and Liu.

67. Further, I understand that Petitioner has assigned labels (e.g., [1PRE], [1A], [1B], etc.) to different limitations of the claims to facilitate analysis of the claims. Accordingly, in my analysis below, I have referred to the claim limitations using those same labels, which are shown in the Claim Listing Appendix attached to this declaration as Appendix B.

A. Bullington800

68. As I explained above, Bullington800 is similar to the '052 Patent because Bullington800 describes a similar device that sequesters an initial (potentially contaminated) aliquot of blood in a sequestration chamber and then uses a sampling channel to bypass the sequestration chamber to convey likely

uncontaminated blood between a patient needle and a sample needle. Section IX.A, above; Ex. 1012, ¶¶[1006], [1107]-[1114], Figs. 1, 11-17. More specifically, Figures 16 and 17 of Bullington800 show configurations of a syringe-based transfer device that in a first configuration sequesters an initial, potentially contaminated portion of bodily fluid (e.g., blood, as described by Bullington800) in a chamber and, in a second configuration, collects a sample of blood through a sampling channel isolated from the chamber. Ex. 1012, ¶¶[1107]-[1114], Figs. 16-17. The below annotated Figures illustrate these configurations of Bullington800's device. For example, Figure 16 shows a first configuration where blood can initially flow from an inlet port into a sequestration chamber (as shown by the path of arrow OO) and arrow NN illustrates the movement of a portion of Bullington800's device that converts the device from the Figure 16 configuration to the configuration at Figure 17, where a pre-sample portion of bodily-fluid (e.g., blood) is sequestered from a subsequent sample of blood that follows the path of arrow RR towards the outlet port. Ex. 1012, ¶¶[1107]-[1114], Figs. 16-17.

(purple) such that no blood may flow into the second channel 507 (blue) from the distal port 505 (red) or out of the second channel 507 (blue) toward the proximal port 515 (pink), while a negative pressure exerts a suction force that rotates the first member 537 (green) from its first position in Figure 16 to its second position in Figure 17 causing the suction force to urge a flow of blood from a patient through the first channel 506 (yellow) and into the fluid reservoir 580 (yellow) to be sequestered. Ex. 1012, ¶¶[1111]-[1114], Figs. 16-17. Once in the Figure 17 configuration, the second member 538 (purple) and the third member 539 (purple) operate as valves (purple) that are opened to place the second channel 507 (blue) in fluid communication with the distal port 505 (red) and the proximal port 515 (pink) in order to urge a flow of bodily-fluid that is substantially free from contaminants into, e.g., a syringe. Ex. 1012, ¶[1114], Fig. 17.

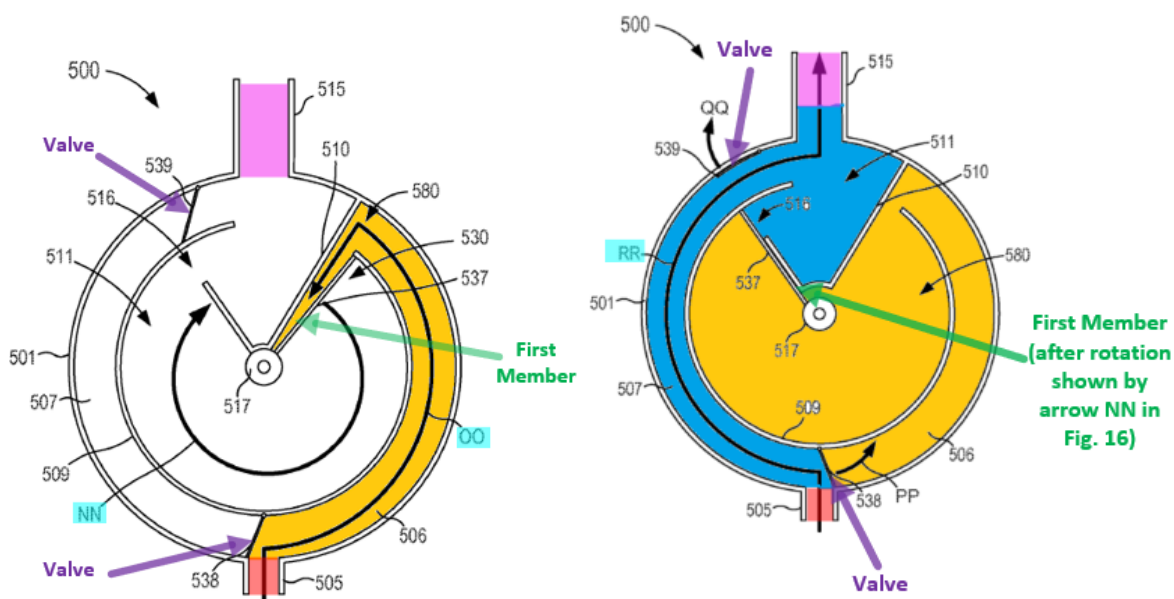
70. For the reasons I explain below, where I apply Bullington800 to the claims of the '052 Patent, it is my opinion that Bullington800 anticipates claims 1-24, and/or renders obvious claims 5, 7-8, 17, and 19-20.

1. Independent Claim 1

a. [1PRE]: “A device comprising:”

71. A POSITA would have understood that Bullington800 discloses this preamble. Bullington800 describes “[a] device” as recited in claim 1 because Bullington800 discloses devices for procuring bodily-fluid (e.g., blood) samples “with reduced contamination from microbes exterior to the bodily-fluid source, such

as dermally-residing microbes.” Ex. 1012, ¶¶[1006], [1037], [1107]-[1114], Figs. 1, 16-17, claim 33. Specifically, Bullington800 discloses a device that sequesters an initial (potentially contaminated) aliquot of blood in a sequestration chamber and then uses a sampling channel to bypass the sequestration chamber to convey likely uncontaminated blood between a patient needle and a sample needle. Ex. 1012, ¶¶[1006], [1107]-[1114], Figs. 1, 11-17.



Ex. 1012, Figs. 16 & 17 (annotated)

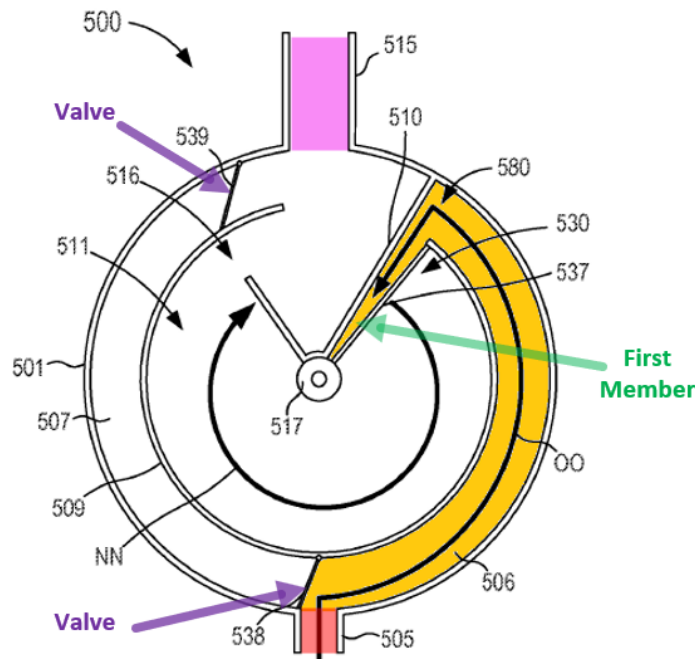
72. As I previously explained and as shown above, Bullington800’s device includes, among other features, a distal port 505 (**red**) that is in fluid communication with a proximal port 515 (**pink**), a first channel 506 (**yellow**) leading from the distal port 505 (**red**) into a fluid reservoir 580 (**yellow**), a second channel 507 (**blue**) either alone or in combination with the remaining portion of the inner volume 511 (**blue**), that is selectively coupled to the a distal port 505 (**red**) and the proximal port 515

(pink), a first member 537 (green), a second member 538 (purple), and a third member 539 (purple). Together with their respective disclosures, these and other features of Bullington800 teach the claimed “device.” Bullington800’s device further discloses and/or renders obvious limitations [1A]-[1E] for the reasons I set forth below. See Sections XII.A.1.b-f, below. Thus, Bullington800 discloses and/or renders obvious limitation [1PRE].

b. [1A]: “an inlet port for receiving a blood sample;”

73. It is my opinion that Bullington800 discloses “an inlet port for receiving a blood sample.” Bullington800’s device is configured for the “procurement of bodily-fluid samples” such as blood samples. Ex. 1012, ¶¶[1002], [1037] (“herein, ‘bodily-fluid’ can include any fluid obtained from a body of a patient, including,...blood”); *see also id.*, ¶¶[1030], [1107]-[1108], [1111]-[1112]. Bullington800’s device has a housing 501 “includ[ing] a distal port 505” that “can be coupled to a proximal end portion of lumen-defining device such as, for example, a butterfly **needle**, a cannula assembly, a trocar (which in some cases is used to insert a catheter into a patient), or the like.” Ex. 1012, ¶[1111] (emphasis added); *see also id.*, ¶[1108], Figs. 16-17. In addition to the fact that Bullington800 expressly recites a butterfly needle, a POSITA would have understood that lumen-defining devices include needles that are inserted into a patient to withdraw blood. Ex. 1012,

¶¶[1043], [1050], [1055]. Thus, the needle can be disposed within a portion of the body of a patient. Ex. 1012, ¶¶[1108], Figs. 16-17.

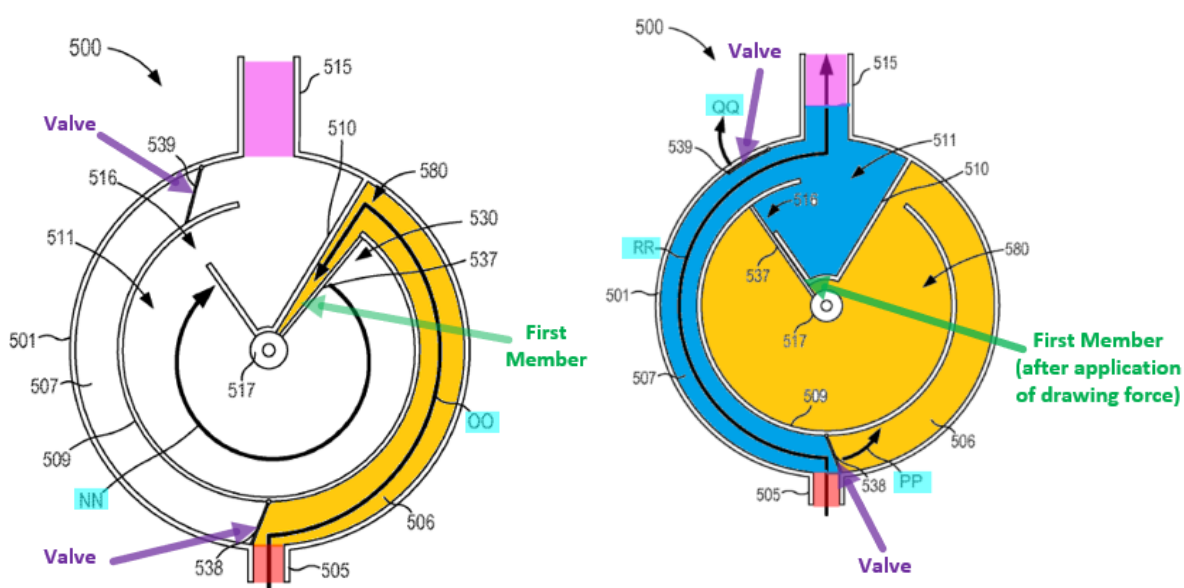


Ex. 1012, Fig. 16 (annotated)

74. Bullington800 describes that in order to procure a blood sample, a “negative pressure in the fluid reservoir 580 can exert a suction force through...the distal port 505 that can urge a flow of bodily-fluid from the patient.” Ex. 1012, ¶¶[1112], Figs. 16-17. The negative pressure urges the flow of the blood to a sample reservoir defined by Bullington800’s device, and collects the blood sample. Ex. 1012, ¶¶[1114], Figs. 16-17. Therefore, the distal port 505 (**red**) as shown is “an inlet port for receiving a blood sample” as claimed. Ex. 1012, ¶¶[1108], [1111]-[1112], [1114], Figs. 16-17. Thus, it is my opinion that Bullington800 discloses and/or renders obvious [1A]. *Id.*

c. [1B]: “an outlet port;”

75. It is my opinion that Bullington800 discloses “an outlet port” as claimed. As shown in the below annotated Figures, Bullington800’s device includes the distal port 505 (“inlet port” (red)) and a proximal portion 515 (pink) (claimed “outlet port”) that is, in the Figure 17 configuration, in fluid communication with the inlet port (red). Ex. 1012, ¶¶[1108], [1114], Figs. 16-17.



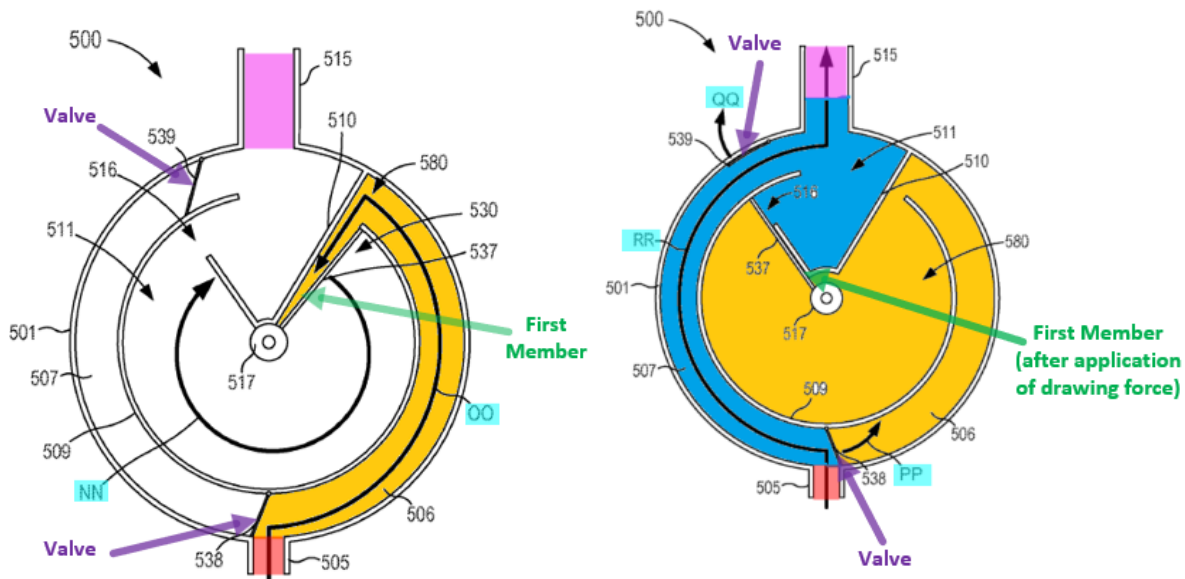
Ex. 1012, Figs. 16 & 17 (annotated)

76. Bullington800 describes that a user of the device may physically and fluidically couple the proximal portion 515 (pink) “to a syringe or the like” that “can form a sample reservoir ...or the like configured to receive a flow of bodily-fluid....” Ex. 1012, ¶[1111]. The bodily-fluid (i.e., blood) initially flows through the inlet port (red) and into Bullington800’s device before proceeding through the proximal portion 515 (pink) and into the sample reservoir of the syringe. Ex. 1012, ¶¶[1108],

[1111], [1114], Figs. 16-17. Because the sample reservoir is the “outlet” through which the blood flows, the proximal portion 515 (**pink**) is an “outlet port” as claimed. Thus, Bullington800 discloses and/or renders obvious limitation [1B].

d. [1C]: “a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device;”

77. Limitation [1C] requires “a chamber connected with the inlet port” and that the chamber is “configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device.” Ex. 1001, claim 1. As I have previously explained and as shown below, Bullington800 discloses the inlet port (**red**), the outlet port (**pink**), and a first channel 506 that is “in fluid communication with” a fluid reservoir 580 (both **yellow**). Ex. 1012, ¶[1112], Figs. 16-17; *see also id.*, ¶¶[1107]-[1108], [1113]-[1114]; Sections XII.A.1.b-c, above. As I will explain below, the fluid reservoir 580 (**yellow**), either alone or when considered in combination with the first channel 506 (**yellow**), is the “chamber” as claimed in [1C]). Ex. 1012, ¶[1112], Figs. 16-17; *see also id.*, ¶¶[1107]-[1108], [1113]-[1114].



Ex. 1012, Figs. 16 & 17 (annotated)

78. As depicted in the above figures, both the first channel 506 and the fluid reservoir 580 (both **yellow**) of Bullington800's device are fluidically isolated (i.e., by the first member 537 (**green**) and the diverter 509 with wedge-shaped portion 510) from a portion of the inner volume 511 that is in fluid communication with the outlet port (**pink**). Ex. 1012, ¶¶[1108]-[1109], Figs. 16-17. In an initial configuration, shown in Figure 16, the first channel 506 (**yellow**) is in fluid communication with the inlet port (**red**). Ex. 1012, ¶[1111], Fig. 16; *see also id.*, ¶¶[1108], [1112]. Bullington800's first channel 506 connects the fluid reservoir 580 (both **yellow**) to the inlet port (**red**), and the fluid reservoir 580, alone or in combination with the first channel 506 (both **yellow**), is "a chamber connected with the inlet port" as claimed. Ex. 1012, ¶¶[1107]-[1109], [1111]-[1112], Figs. 16-17.

79. Bullington800 describes its fluid reservoir 580 (yellow), which Bullington800 also refers to as the “first reservoir” or “pre-sample reservoir,” is (alone or with the first channel 506 (yellow)) configured to “collect a first portion of the blood sample” as claimed. Bullington800 describes that its devices collect a first predetermined amount (a “pre-sample”) of blood prior to collection of a second amount (i.e., “a sample”) of blood. Ex. 1012, ¶¶[1051], [1112]-[1114], Figs. 16-17. That is, as a POSITA would have understood, Bullington800’s fluid reservoir 580, alone or with the first channel 506 (both yellow), collects a first portion of blood and sequesters the first portion of blood (e.g., to prevent a health care practitioner from including the potentially contaminated first portion of blood in the second amount that is used for blood sample analysis) and thus teaches a chamber “configured to collect a first portion of the blood sample” as claimed. *Id.*

80. Bullington800 also discloses that the fluid reservoir 580, alone or with the first channel 506 (both yellow, referred to further in my analysis as the “chamber”), collects the first portion of the blood sample “when under a drawing force applied from the outlet port from a blood sample collection device.” Bullington800 describes the process for collecting the first portion of the blood sample in the chamber (yellow) as beginning when the outlet port (pink) is “coupled to a syringe or the like.” Ex. 1012, ¶[1107]; *see also id.*, ¶¶[1111]-[1114], Figs. 16-17. Bullington800 explains that the syringe “or the like” defines another “fluid

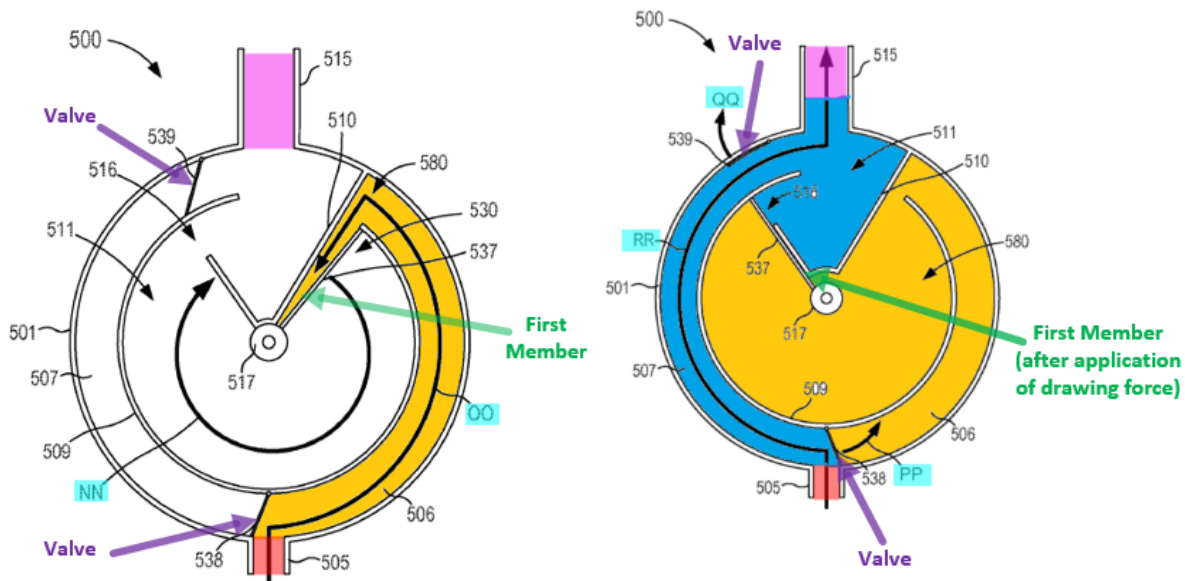
reservoir (e.g., a sample reservoir not shown in FIGS. 16 and 17) that can receive a flow of bodily-fluid” (claimed “blood sample collection device”). *Id.* Bullington800 further describes that when coupled to the outlet port (pink) the blood sample collection device “introduce[s] a negative pressure in a portion of the inner volume 511 that exerts a suction force...operable in rotating the first member 537.” Ex. 1012, ¶¶[1112], [1107], Fig. 16. As shown by arrow NN in Figure 16 above, the rotation of the first member 537 (green) “increases a volume of the fluid reservoir 580” and thus causes the negative pressure (and resulting suction force) to be exerted within the chamber (yellow). *Id.* More specifically, this negative pressure “exert[s] a suction force through the first channel 506 and the distal port 505 that can urge a flow of bodily-fluid from the patient, through...the first channel 506, and into the fluid reservoir 580.” *Id.* It is my opinion that, because the chamber (yellow) draws the initial flow of blood from the patient when the suction force introduced by the syringe coupled to the outlet port (pink) acts upon the first member 537 (green) (increasing the volume of the chamber) and thus also pulls the blood from the patient into the chamber (yellow) as the volume of the chamber (yellow) is increased, a POSITA would have understood that Bullington800’s chamber (yellow) is a “chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a

blood sample collection device” as claimed. Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17.

81. For all the above reasons, it is my opinion that Bullington800 discloses and/or renders obvious [1C].

- e. **[1D]: “a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port; and”**

82. As I have previously explained and as shown below, Bullington800 discloses the inlet port (**red**), the outlet port (**pink**), and a second channel 507 (**blue**) that “can be selectively placed in fluid communication with the proximal port 515 and the distal port 505.” Ex. 1012, ¶¶[1108], [1114], Figs. 16-17; Section IX.A, above. In an initial configuration (as shown below in annotated Figure 16), the second channel 507 (**blue**) is fluidically isolated from the inlet port (**red**) and the outlet port (**pink**) when the chamber (**yellow**) is in fluid communication with the inlet port (**red**). Ex. 1012, ¶[1111], Fig. 16. Specifically, the second member 538 and third member 539 (both labeled as “valves,” **purple**), along with the diverter 509, form a barrier around the second channel 507 (**blue**) that prevents blood flowing into the inlet port (**red**) to the chamber (**yellow**) from reaching the second channel 507 (**blue**), while simultaneously closing the second channel 507 (**blue**) off from the outlet port (**pink**). *Id.*; see also Section XII.A.1.d, above.



Ex. 1012, Figs. 16 & 17 (annotated)

83. As I have explained above, once a predetermined amount of blood (i.e., the “first portion of the blood sample”) is transferred to the chamber (yellow) Bullington800’s device moves to a configuration (as shown by Figure 17 above) where the valves (purple) are rotated (as shown by arrows PP and QQ) such that “the fluid reservoir 580 and the first channel 506 are fluidically isolated from the distal port 505 and the proximal port 515 to sequester the predetermined volume of bodily-fluid in the fluid reservoir 580.” Ex. 1012, ¶[1114], Fig. 17; *see also id.*, ¶¶[1112]-[1113]; Section IX.A, above. That is, the valves (purple) are rotated so that, as explained for [1C] above, the first portion of the blood sample is sequestered in the chamber (yellow) to prevent a subsequent portion of the blood sample from mixing with the potentially contaminated first portion. Ex. 1012, ¶[1114], Fig. 17; *see also id.*, ¶¶[1112]-[1113]; Section XII.A.1.d, above.

84. In the Figure 17 configuration, the only portions of Bullington800's device that are in fluid communication with the inlet port (**red**) and with the outlet port (**pink**) are the second channel 507 and what I will refer to as a wedge-shaped portion of the inner volume 511 (both shown in **blue**), as illustrated by the arrow **RR**. Ex. 1012, ¶[1114], Fig. 17. It is my opinion that a POSITA would have understood that the second channel 507, either alone or in combination with the wedge-shaped portion of the inner volume 511 (both **blue**) constitute the claimed "sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port" because the inlet port (**red**) is placed in fluid communication with the sample syringe, coupled to the outlet port (**pink**), via the sampling channel (**blue**) to convey the subsequent portion of the blood sample to the outlet port (**pink**). Ex. 1012, ¶¶[1107]-[1108]; *see also id.*, ¶¶[1111]-[1114], Figs. 16-17. More specifically, the sample syringe "exert[s] a suction force through proximal port 515, the second channel 507, [and] the distal port 505...that can urge a flow of bodily-fluid from the patient to, for example, a sample reservoir defined by the [device]...." Ex. 1012, ¶[1114], Fig. 17. A POSITA would thus have understood that when the sample syringe exerts the suction force through the sampling channel (**blue**) to urge blood to the sample syringe, the blood flow also goes to the outlet port (**pink**) to reach the sample syringe. Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17. Accordingly, for the reasons I describe above,

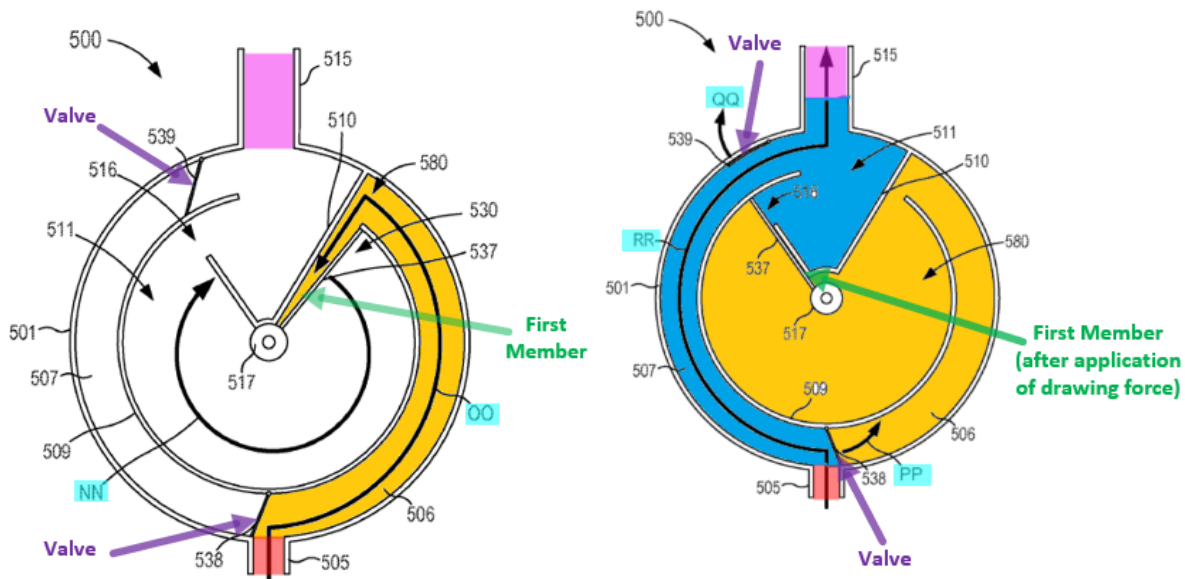
Bullington800 discloses and/or renders obvious [1D]. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17.

f. [1E]: “a housing that defines the inlet port, the sampling channel, and the outlet port.”

85. It is my opinion that Bullington800 discloses and/or renders obvious “a housing that defines the inlet port, the sampling channel, and the outlet port” within the meaning of the ’052 Patent. As I have previously explained and as illustrated in the annotated drawings below, Bullington800 discloses the inlet port (**red**), the outlet port (**pink**), and the sampling channel (**blue**). Sections XII.A.1.b-c, XII.a.1.e, above. Bullington800 is replete with explicit descriptions of a housing for its device. *See, e.g.*, Ex. 1012, ¶¶[1006], [1030], [1044], [1053]-[1054], [1107]-[1112], [1114], Figs. 1-2, 16-17. Specifically with reference to Figures 16 and 17, Bullington800 describes a device that “includes a housing 501.” Ex. 1012, ¶[1107], Figs. 16-17. A POSITA would have understood that the housing 501 fixes and marks the limits of the inlet port (**red**) and the outlet port (**pink**) at least because Bullington800 explicitly describes the housing 501 as including both the inlet port (**red**) and the outlet port (**pink**), and as shown below the walls of the housing 501 constitute physical borders of the inlet port (**red**) and the outlet port (**pink**). Ex. 1012, ¶¶[1107]-[1108]; *see also id.*, Figs. 16-17; Sections XII.A.1.b-c, above. Bullington800’s housing is also a casing that, by nature of the housing including the inlet port (**red**) and the outlet port (**pink**) and forming the physical borders of those

elements, fixes or marks the limits of the inlet port (**red**) and the outlet port (**pink**) for the above reasons.

86. To the extent Patent Owner argues that Bullington800's housing 501 does not define the sampling channel (**blue**), Bullington800 does describe that "the diverter 509 and a set of wall[s] of the housing 501 defining the inner volume 511 define, at least partially...second channel 507...." Ex. 1012, ¶[1108]. Bullington800 also describes that the housing includes the diverter 509. *Id.* The diverter 509 includes a set of walls that can form a "substantially wedge-shaped portion 510 of the diverter 509" that, as shown below, defines the wedge-shaped portion of the inner volume 511 (**blue**), that is in fluid communication with the outlet port (**pink**) in the Figure 17 configuration of Bullington800's device. Ex. 1012, ¶[1109], Figs. 16-17. Accordingly, as shown below, regardless of whether the second channel alone, or in combination with the wedge-shaped portion of the inner volume 511 (both **blue**), is treated as the claimed "sampling channel," the housing 501 fixes or marks the limits of each of the inlet port (**red**), outlet port (**pink**), and the sampling channel (**blue**). Ex. 1012, ¶¶[1107]-[1108], [0114], Figs. 16-17 (see arrow **RR** passing through each of the inlet port (**red**), second channel 507 (**blue**), part of the wedge-shaped portion of the inner volume 511 (**blue**) and proximal port 515 (**pink**)).



Ex. 1012, Figs. 16 & 17 (annotated)

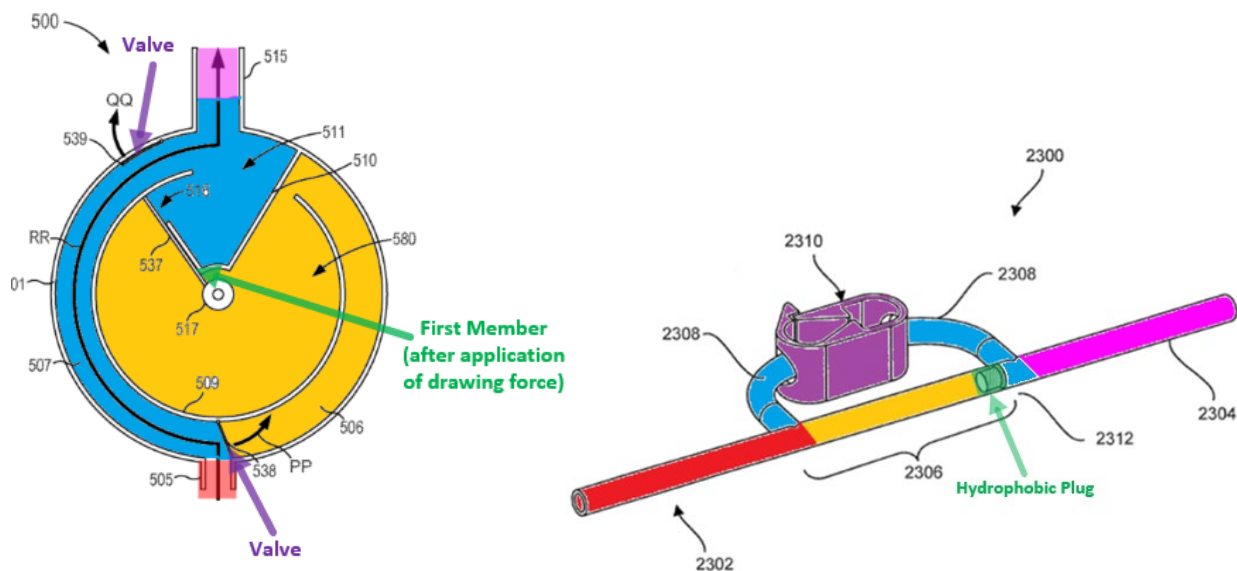
87. I have been asked to consider a scenario where it is argued that Bullington800 does not expressly disclose “a housing that defines the inlet port, the sampling channel, and the outlet port” and therefore does not teach [1E] as claimed. It is my opinion that, to any extent Bullington800 does not disclose [1E], those features would have been obvious to a POSITA in view of Bullington800’s disclosures. To the extent Patent Owner argues that Bullington800’s housing 501 does not “define” the inlet port (**red**) and the outlet port (**pink**) (e.g., at least not in the same way that it states the housing 501 defines the sampling channel sampling channel (**blue**); Ex. 1012, ¶[1108]); Bullington800 renders a housing that defines the inlet port (**red**) and the outlet port (**pink**) obvious because the housing 501 substantially forms the bordering structure that walls off (i.e., fixes or defines the limits of) the **inlet port** to the **outlet port**. Ex. 1012, ¶¶[1006], [1030], [1044],

[1053]-[1054], [1107]-[1112], [1114], Figs. 1-2, 16-17. It is my opinion that the depictions in Bullington800, along with the description that the housing 501 “includes” the inlet port (**red**) and the outlet port (**pink**), would have rendered [1E] obvious to a POSITA. I also note that the ’052 Patent does not provide a precise definition of what it means for the housing to “define” the inlet port, the outlet port, and/or the sampling channel. For example, the ’052 Patent simply describes that a housing may “include[] a sampling channel...defining a pathway,” or that walls can “define” a housing, and also uses the term in relation to other features, such as to describe that an inlet port “defines an opening into the blood sequestration device.” Ex. 1001, 10:1-10, 12:27-36, 13:12-28. Nowhere does the ’052 Patent specifically describe “a housing that defines the inlet port, the outlet port, and the sampling channel.”² It is my opinion that Bullington800’s housing is at least consistent with what is described in the ’052 Patent. To illustrate this point, I include the below

² I take no position, and offer no opinion, on whether the ’052 Patent provides adequate written description support for [1E]. Regardless of whether the ’052 Patent supports [1E], the features of [1E] are taught by Bullington800. And as I explain in detail in this section, it is my opinion that to any extent the ’052 Patent has such a “housing,” the housing disclosed by Bullington800 discloses and/or renders obvious [1E].

comparison of Figure 17 of the Bullington800 and Figure 23A of the '052 Patent, which as I previously described is the figure from which the '052 Patent appears to draw support for claim 1. *See* Section V, above. As shown in Figure 17 of Bullington800, the housing 501 (including the diverter 509 with and the wedge-shaped portion 510 of the diverter 509) composes nearly the entire boundary of each of the inlet port (**red**), outlet port (**pink**), and the sampling channel (**blue**). Ex. 1012, ¶¶[1107]-[1108], [0114], Figs. 16-17. As shown, there is only a small portion of the wedge-shaped portion of the inner volume 511 (**blue**), near the outlet port (**pink**) and located between the corresponding wedge-shaped portion 510 of the diverter 509 and another wall of the diverter 509, that touches a portion of the first member 537 (**green**) that keeps the sampling channel (**blue**) fluidically isolated from the chamber (**yellow**). *See* Ex. 1012, ¶¶[1109]-[1111], [1114], Figs. 16-17. The comparison below illustrates that Bullington800's Figure 17 is consistent with the '052 Patent, where there is a set of walls that substantially forms the boundaries/borders of each of the inlet port (**red**), outlet port (**pink**), and the sampling channel (**blue**) but the back side of the hydrophobic plug (**green**) delineates a small portion of the sampling channel (**blue**) near the outlet port (**pink**) and keeps the sampling channel (**blue**) fluidically isolated from the chamber (**yellow**). Ex. 1001, 21:19-48, Figs. 1, 23A-23B. To any extent that these walls can

be considered a “housing that defines the inlet port, the outlet port, and the sampling channel” as claimed, it is my opinion that Bullington800 discloses these features.



Ex. 1012, Fig. 17 (left, annotated); Ex. 1001, Fig. 23A (right, annotated)

88. As shown and explained above, in both the '052 Patent and Bullington800 there are walls that substantially, but not completely, enclose the sampling channel (**blue**) taking blood from the inlet port (**red**) to the outlet port (**pink**). Ex. 1012, ¶¶[1107]-[1108], [0114], Figs. 16-17; Ex. 1001, 21:19-48, Figs. 1, 23A-23B. For all the above reasons, Bullington800's housing (which is a casing, providing the outer structural boundary of the entire device) fixes or marks the limits of the sampling channel (**blue**) taking blood from the inlet port (**red**) to the outlet port (**pink**). Ex. 1012, ¶¶[1107]-[1108], [0114], Figs. 16-17; Ex. 1001, 21:19-48, Figs. 1, 23A-23B. Therefore, it is my opinion that Bullington800 discloses and/or renders obvious “a housing that defines” under any reasonable construction,

including the meaning agreed upon by the parties in the Corresponding District Court Litigation. Ex. 1036, p. 1.

89. Accordingly, it is my opinion that Bullington800 discloses and/or renders obvious “a housing that defines the inlet port, the sampling channel, and the outlet port” as claimed. Therefore, for the reasons I explained above, Bullington800 discloses and/or renders obvious all of the features of claim 1. Sections XII.A.1.a-f, above.

2. Dependent Claim 2

The device in accordance with claim 1, wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

90. Claim 2 of the '052 Patent depends from claim 1 and further requires “wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.” Ex. 1001, claim 2. As discussed above, claim 1 is disclosed and/or rendered obvious by Bullington800. See Sections XII.A.1.a-f, above. As I discuss in more detail below, Bullington800 also discloses that its device includes a “blood impermeable membrane” that “is configured to facilitate the chamber collecting the first portion of the blood sample.”

91. I previously explained how Bullington800 discloses a chamber (yellow) that collects a first portion of a blood sample (e.g., to sequester potentially contaminated blood from a second portion of the sample). Section XII.A.1.d, above;

Ex. 1012, ¶¶[1107]-[1114], Figs. 16-17. As I have also previously explained, Bullington800's device further includes a flow control mechanism 530 having a first member 537 (**green**). Section IX.A, above; Ex. 1012, ¶[1109], Figs. 16-17. Bullington800 describes that the first member 537 (**green**) is a structure formed of a relatively flexible and/or compressible material that "can fluidically isolate the fluid reservoir 580 from, for example, a portion of the inner volume 511 in fluid communication with the proximal port 515." Ex. 1012, ¶¶[1109], [1111], Figs. 16-17. Bullington800 does not give an explicit example of a material from which the first member 537 (**green**) might be constructed, but describes the first member 537 (**green**) along with the second member 538 (also **green**, below) and third member 539 (**purple**) as being arranged in a gate configuration. *Id.* As I will explain below, it is my opinion that a POSITA would have understood that either or both of first member 537 or second member 538 (both **green**, below) are "a blood impermeable membrane [that] is configured to facilitate the chamber collecting the first portion of the blood sample" as claimed.

92. First, as shown in Figures 16 and 17 of Bullington800, the first member 537 (**green**) defines at least a portion of the chamber (**yellow**). Ex. 1012, ¶[1109], Figs. 16-17.

the patient, through...the first channel 506, and into the fluid reservoir 580.” Ex. 1012, ¶[1112], Fig. 16 (see arrow OO); Section XII.A.1.d, above.

93. Second, Bullington800 additionally describes that second member 538 (green) is movable to selectively place the chamber (yellow) in fluid communication with the inlet port (red) via which the blood sample is collected. Ex. 1012, ¶[1111], Figs. 16-17. More specifically, in the initial configuration shown in Figure 16, the second member 538 (green) places the chamber (yellow) in fluid communication with the inlet port (red) to facilitate collection of the first portion of the blood sample in the chamber (yellow), and in the configuration shown in Figure 17 the second member 538 (green) is positioned (see arrow PP) to fluidically isolate the chamber (yellow) from the inlet port (red), thus sequestering the first portion of the blood sample. Ex. 1012, ¶¶[1109]-[1111], [1114], Figs. 16-17.

94. Based on the disclosures of Bullington800 that I explained above, each of the first member 537 and the second member 538 (both green) facilitate, in the initial Figure 16 configuration, the flow of the first portion of the blood sample into the chamber (yellow) and, in the later Figure 17 configuration, fluidically isolate the chamber (yellow) to sequester the first portion of the blood sample, the first member 537 and the second member 538 (both green). Ex. 1012, ¶¶[1107], [1109], [1111]-[1114], Figs. 16-17. A POSITA would have understood that to isolate the first portion of the blood in the chamber (yellow) and prevent it from contaminating the

subsequent portion of the sample of blood (e.g., as I described for Section XII.A.1.e, above), the first member 537 and the second member 538 (both **green**) are each a “blood impermeable membrane” as recited in claim 2. Ex. 1012, ¶¶[1107], [1109], [1111]-[1114], Figs. 16-17. Further, the first member 537 and the second member 538 (both **green**), either alone or in combination, aid in the collection of the first portion of the sample in the chamber as explained above, and thus they are (either alone or in combination) “configured to facilitate the chamber collecting the first portion of the blood sample” as recited. I note that a POSITA would have understood that the first member 537 and the second member 538 (both **green**) are both membranes, even though Bullington800 does not explicitly label the first member 537 and the second member 538 (both **green**) as such. Bullington800 expressly describes that the first member 537 (**green**) is “thin,” that it “fluidically isolate[s]” the chamber (**yellow**), and as I noted above, is “flexible.” Ex. 1012, ¶¶[1109], Figs. 16-17. A POSITA would have understood that the first member 537 (**green**) is therefore a “membrane” at least because it has the requisite properties of a membrane. Ex. 1039, p. 1 (“a very thin piece of material that covers an opening”); Ex. 1037, p. 1 (“[a] thin, enveloping or lining substance, which divides a space or an organ”); Ex. 1038, p. 1 (“any thin, pliable material used as a filter, separator, resonator, etc.”); Ex. 1030, p. 4 (“a thin pliable sheet or skin of various kinds”). Put differently, Bullington800’s first member 537 (**green**) is a membrane because it is

“thin,” pliable (by nature of it being “flexible”), and because it covers an opening/divides a space/is used as a separator by separating the chamber (yellow) from the sampling channel (blue). Ex. 1012, ¶¶[1108]-[1110], [1114], Figs. 16-17; Sections XII.A.1.d-e, above. I further note that Bullington800 describes that the second member 538, like the first member 537 (both green) “can be any suitable shape, size, or configuration” and that the second member 538 “can be arranged in a similar manner” to the first member 537. Ex. 1012, ¶¶[1109]-[1110]. Thus, a POSITA would have understood that the second member 538 is a “membrane” for the same reasons as the first member 537 (both green).

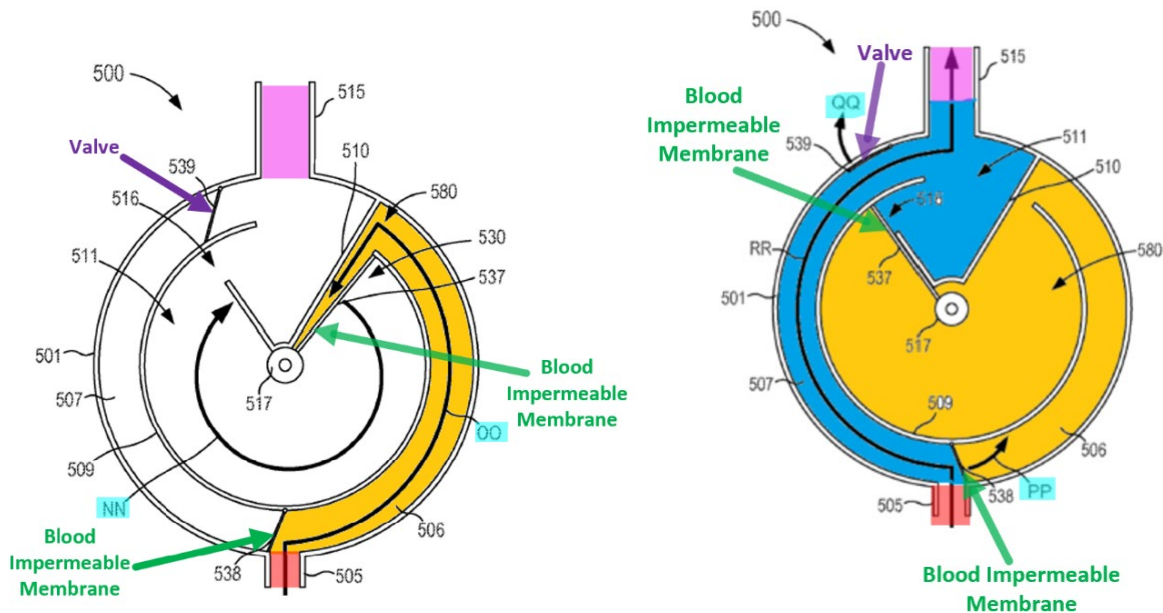
95. Accordingly, Bullington800 discloses and/or renders obvious claim 2.

3. Dependent Claim 3

The device in accordance with claim 1, wherein a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.

96. Claim 3 of the '052 Patent depends from claim 1 and further requires “wherein a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.” Ex. 1001, claim 3. As discussed above, claim 1 is disclosed and/or rendered obvious by Bullington800. See Sections XII.A.1.a-f, above. As I further explained above, Bullington800’s device further includes at least one blood-impermeable membrane (green) that isolates the chamber (yellow) from

the outlet port (**pink**). Section XII.A.2, above. As I discuss in more detail below, Bullington800 also discloses that its membrane (**green**) “causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.”



Ex. 1012, Figs. 16 & 17 (annotated)

97. As I have previously explained, Bullington800 discloses a sample syringe coupled to the outlet port (pink) that “introduce[s] a negative pressure in a portion of the inner volume 511 that exerts a suction force...operable in rotating the first member 537.” Ex. 1012, ¶[1112], Fig. 16; Section XII.A.1.d, above. The suction force at the outlet port (pink) causes rotation (see arrow NN) of the first member 537 (one of the membranes (green), above) and increases a volume of the chamber (yellow), thus causing a suction force that draws the first portion of the

blood into the chamber (yellow). Ex. 1012, ¶[1112], Fig. 16; Section XII.A.1.d, above. As I explained for claim 2, the first member 537 (green) fluidically isolates the chamber (yellow) from the outlet port (pink) (i.e., the first member 537 (green) prevents the blood from passing through it and leaving the chamber (yellow) and flowing through the outlet port (pink), as shown in Figures 16 and 17). Section XII.A.2, above; Ex. 1012, ¶[1109], Figs. 16-17. The second member 538 (green) (the other membrane, above) similarly directs blood into and isolates the chamber (yellow), because in its Figure 16 configuration it directs blood into the chamber (yellow) and when Bullington800's device transitions from its Figure 16 configuration to its Figure 17 configuration, the second member 538 (green) is positioned (see arrow PP) to fluidically isolate the chamber (yellow) from the inlet port (red) (and therefore, from the sampling channel (blue) and outlet port (pink)). Section XII.A.2, above; Ex. 1012, ¶¶[1109]-[1111], [1114], Figs. 16-17.

98. It is my opinion that because both membranes (green) facilitate the flow of blood into the chamber (yellow) and/or prevent the first portion of the blood sample from flowing into the syringe and the outlet port (pink), the first member 537 (green) and the second member 538 (green) each, alone or together, causes the first portion of the blood sample to back up into (i.e., fill) the chamber (yellow). Ex. 1012, ¶¶[1109], [1112], Fig. 16. I note that this function of the membranes (green) is consistent with the '052 Patent. The only portion of the Specification of the '052

Patent that describes backing up states that “the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there.” Ex. 1001, 21:32-35, Figs. 23A-23B. The membranes (**green**) in Bullington800 both cause the first portion of the blood sample to back up into the chamber (**yellow**) because the first portion of blood, when drawn into Bullington800’s chamber (**yellow**), will contact the membranes (**green**) as it flows into the chamber (**yellow**) (see arrow **OO** in Figure 16) and will be prevented from flowing through the membranes (**green**), causing the first portion of blood to back up like the initial aliquot of blood described in the ’052 Patent. Ex. 1012, ¶¶[1109], [1112], Fig. 16; Ex. 1001, 21:32-35, Figs. 23A-23B. The backing up caused by Bullington800’s membranes (**green**) is also consistent with definitions of the term “back up” with which a POSITA would have been familiar. See Ex. 1029, p. 3 (“[t]o accumulate in a clogged state”); Ex. 1030, p. 3 (“an overflow caused by stoppage, as in water or automobile traffic”).

99. Accordingly, Bullington800 discloses and/or renders obvious claim 3.

4. Dependent Claim 4

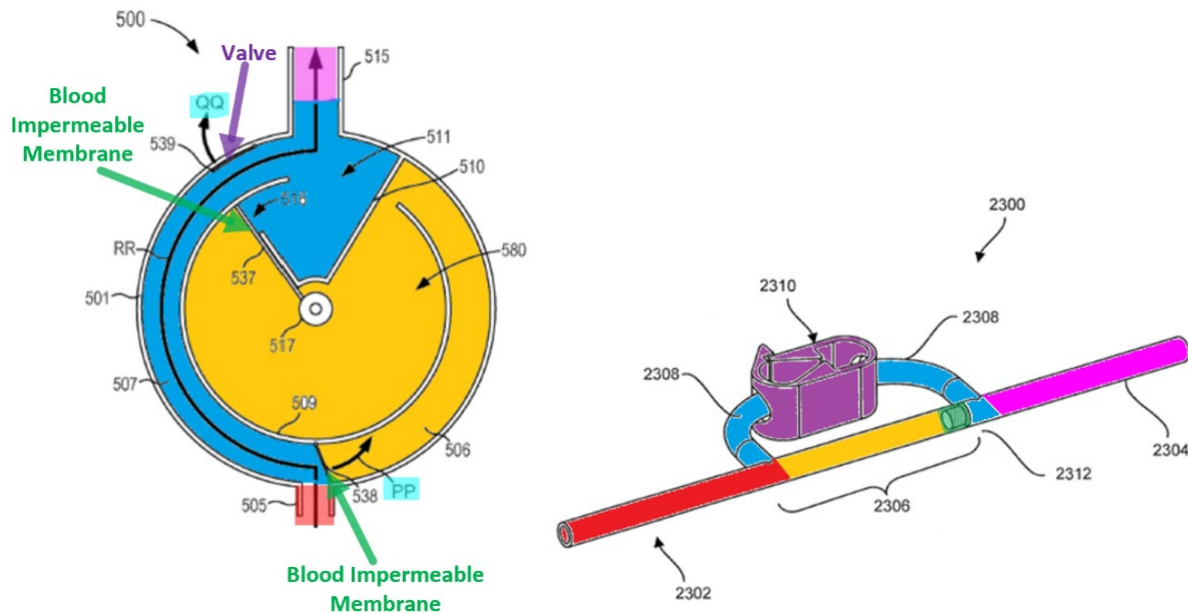
The device in accordance with claim 2, wherein the housing is separate from the blood impermeable membrane.

100. Claim 4 of the ’052 Patent depends from claim 2 and further requires “wherein the housing is separate from the blood impermeable membrane.” Ex. 1001, claim 4. As discussed above, claim 2 is disclosed and/or rendered obvious by

Bullington800 explains that the first member 537/membrane (**green**) “can extend in a radial direction from the hub 517 to be placed in contact with an inner surface of the annular wall forming at least a portion of the diverter 509.” Ex. 1012, ¶[1109]. Similarly, the second member 538/membrane (**green**) “can be rotatably coupled to an outer surface of the annular wall defining a portion of the diverter 509.” *Id.* The first member 537/membrane (**green**) also “can be selectively placed in contact with an inner surface of the housing 501” *Id.* It is my opinion that a POSITA would thus have understood that the membrane (**green**) is separate from the housing (housing 501 and/or diverter 509) because the membrane (**green**) is placed in contact with and/or coupled to portions of the housing but is not itself part of the housing. Put differently, the membrane (**green**) is a component separate from the housing 501 placed in contact with the housing 501 (claimed “wherein the housing is separate from the blood impermeable membrane”). *Id.*

102. To any extent that it is argued that the membrane (**green**) (whether referring to the first member 537, the second member 538, and/or both) is not separate from the housing, I note that Bullington800’s disclosure of the membrane (**green**) is consistent with the description of the membrane in the ’052 Patent. For example, as I have explained above at Section V, the ’052 Patent describes that its sequestration chamber 2306 includes a hydrophobic plug 2312 (i.e., a hydrophobic/blood-impermeable membrane). Ex. 1001, 21:26-35, 5:28-47, Figs.

23A-23B. I have produced a comparison of Figure 23A of the '052 Patent and Figure 17 of Bullington800 below to illustrate how the hydrophobic plug 2312 (green) contacts the housing like the membrane (green) contacts the housing of Bullington800.



Ex. 1012, Fig. 17 (annotated); Ex. 1001, Fig. 23A (annotated)

103. Specifically, the hydrophobic plug 2312 (green) contacts the walls of the device depicted in Figure 23A consistent with the way the first member 537/membrane (green) and second member 3358/membrane (green) contacts the housing 501/diverter 509 of Bullington800. Ex. 1001, 21:26-35, Figs. 23A-23B; Ex. 1012, ¶¶[1107], [1109], Figs. 16-17. Therefore, it is my opinion that Bullington800 discloses and/or renders obvious the claimed “wherein the housing is separate from the blood impermeable membrane” to any extent that the '052 Patent discloses such

a “housing.” Ex. 1001, 5:28-47, 21:26-35, Figs. 23A-23B; Ex. 1012, ¶¶[1107], [1109], Figs. 16-17.

104. Accordingly, Bullington800 discloses and/or renders obvious claim 4.

5. Dependent Claim 5

The device in accordance with claim 1, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

105. Claim 5 of the '052 Patent depends from claim 1 and further requires “wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.” Ex. 1001, claim 5. As discussed above, claim 1 is disclosed by Bullington800. See Sections XII.A.1.a-f, above. As I further explained above, Bullington800 discloses a chamber (yellow) that collects a first portion of blood when a drawing force is applied at the outlet port (pink). Section XII.A.1.c-d, above. As I discuss in more detail below, Bullington800 also discloses that “when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.”

106. I have already explained above that Bullington800 discloses the chamber (yellow) receives the first portion of the blood sample as the first portion is drawn into the chamber (yellow) by a drawing force generated by, e.g., a syringe

recognized that Bullington800 discloses that the membrane (**green**) is a “material that is blood impermeable” as claimed. Additionally, to any extent that Bullington800 does not expressly disclose that the membrane (**green**) is a material that is blood-impermeable, it would have been obvious to a POSITA that *any* material (e.g., the first member 537, the diverter 509, the second member 538, wedge-shaped portion 510, the exterior wall of the housing) that the blood in the chamber (**yellow**) contacts would beneficially be blood-impermeable in order to prevent the blood from leaving the chamber (**yellow**). Ex. 1012, ¶¶[1108]-[1114]. It would have been obvious to a POSITA that there is at least strong teaching or suggestion (See Section IV, above (referring to obviousness rationale (G))) in Bullington800 that the materials (e.g., the first member 537, the diverter 509, the second member 538, wedge-shaped portion 510, the exterior wall of the housing) must be blood-impermeable because Bullington800 frequently describes that a goal of its device is to reduce contamination of a blood sample, which would require that the materials making up the chamber (**yellow**) be blood-impermeable to keep the potentially contaminated blood in that chamber (**yellow**) from contaminating the follow-on blood sample. Ex. 1012, ¶¶[1002]-[1006], [1030], [1050]-[1051], [1112], [1114]. Additionally, it would have been obvious to a POSITA to try constructing the materials that the blood in the chamber (**yellow**) contacts out of a blood-impermeable material because it is one of a finite number of solutions (i.e., blood-

permeable or blood-impermeable) for materials to use in constructing those components of Bullington800's device. Section IV, above (referring to obviousness rationale (E)).

108. Accordingly, for the reasons explained above, Bullington800 discloses claim 5, or renders claim 5 obvious to a POSITA.

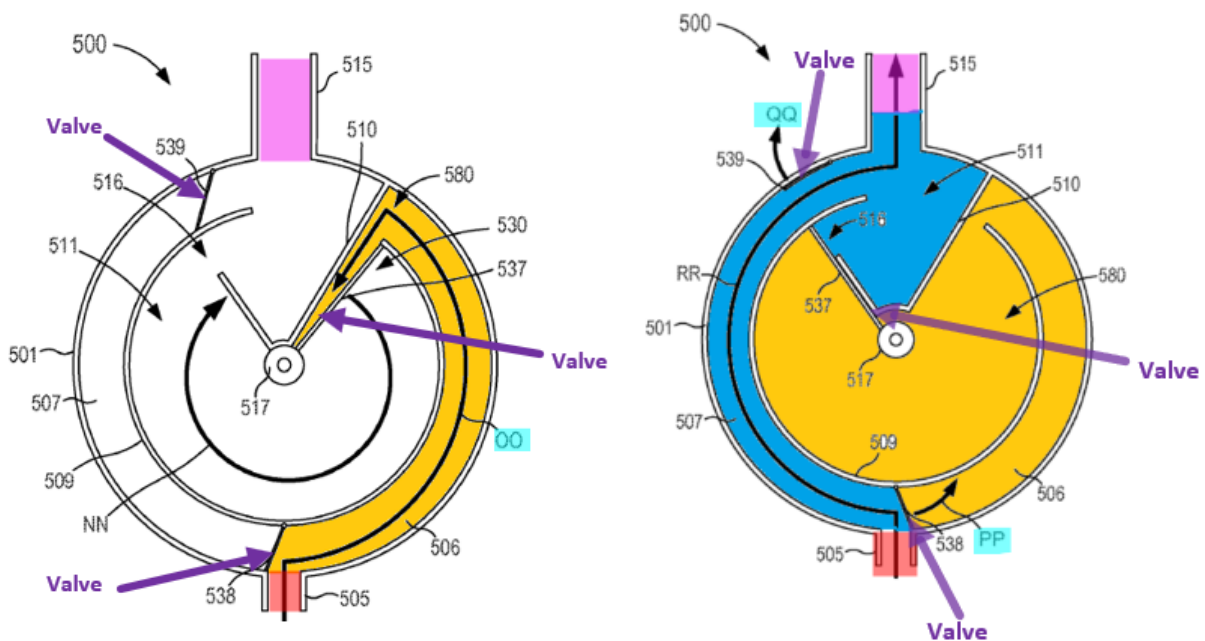
6. Dependent Claim 6

The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel.

109. Claim 6 of the '052 Patent depends from claim 1 and further requires "a valve configured to initially close off the sampling channel." Ex. 1001, claim 6. As discussed above, claim 1 is disclosed and/or rendered obvious by Bullington800. See Sections XII.A.1.a-f, above. As I further explained above, Bullington800 discloses a sampling channel (blue) that is selectively placed in fluid communication with the outlet port (pink) to convey a subsequent portion of the blood sample to the outlet port (pink). Section XII.A.1.e, above; Ex. 1012, ¶[1108]-[1111], [1114], Figs. 16-17. As I discuss in more detail below, Bullington800 also discloses "a valve configured to initially close off the sampling channel."

110. I previously described how the first member 537 and second member 538 are both blood impermeable membranes. Section XII.A.2, above. As is clearly shown below in Figure 16 of Bullington800, "in their first position relative to the housing 501," each of the first member 537 and second member 538, along with the

third member 539 (all labeled as “valves” in **purple** below) also close off a portion of the sampling channel (**blue**) shown in Figure 17. Ex. 1012, ¶¶[1109], [1111], [1114], Figs. 16-17. Specifically, the first member 537 (**purple**) initially is configured to close off the inner volume 511 (the wedge-shaped portion of which forms part of the sampling channel (**blue**) in Figure 17); the second member 538 (**purple**) is configured to close off the portion of the second channel 507 (**blue**), that is closest to the inlet port (**red**), from the inlet port (**red**); and the third member 539 (**purple**) is configured to close off the portion of the second channel 507 (**blue**), that is closest to the outlet port (**pink**), from the outlet port (**pink**). *Id.*



Ex. 1012, Figs. 16 & 17 (annotated)

111. I note that Bullington800 explicitly states that “the first member 537, the second member 538, and the third member 539 can be valves or the like that can

be arranged in a gate configuration or the like.” Ex. 1012, ¶[1109]. Therefore, a POSITA would have understood that each of the first member 537, second member 538, and third member 539 (all labeled as “valves” in **purple** above) is “a valve configured to initially close off the sampling channel” as claimed, as are any combination of 537, 538, and 539. Ex. 1012, ¶¶[1108]-[1111], [1114], Figs. 16-17. I also note that a POSITA would have understood that the valves as shown in Figures 16 and 17 are merely exemplary in form and that the disclosures of Bullington800 do not expressly require that the valves be attached to the exact positions shown or opened in the exact manner shown. Ex. 1012, ¶¶[1108]-[1111], [1114], Figs. 16-17. For example, third member 539 (**purple**) may be fixed to the diverter 509 and initially in contact with the outer portion of housing 501, as opposed to being fixed to the outer portion of housing 501 and initially in contact with the diverter 509 as shown in Figures 16 and 17. In this example, the third member 539 (**purple**) might have opened in the direction of the flow through the sampling channel (**blue**), as opposed to opening against the flow, but this would not have changed how third member 539 (**purple**) teaches the features of claim 6 as I have described above. Ex. 1012, ¶¶[1108]-[1111], [1114], Figs. 16-17.

112. Accordingly, it is my opinion that Bullington800 discloses and/or renders obvious claim 6.

7. Dependent Claim 7

The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.

113. Claim 7 of the '052 Patent depends from claim 1 and further requires “a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.” Ex. 1001, claim 7. As discussed above, claim 1 is disclosed and/or rendered obvious by Bullington800. See Sections XII.A.1.a-f, above. As I further explained above, Bullington800 discloses a sampling channel (blue), a chamber (yellow) that collects a first portion of the blood sample, and at least one valve or valves (purple) “configured to initially close off the sampling channel.” Sections XII.A.1.d-e, XII.A.6, above; Ex. 1012, ¶¶[1108]-[1114], Figs. 16-17, above. As I discuss in more detail below, Bullington800 also discloses one or more valves (purple) “configured to initially close off the sampling channel **until the first portion of the blood sample is in the chamber**” (emphasis added).

sample syringe coupled to the outlet port (**pink**). Ex. 1012, ¶¶[1108]-[1111], Fig. 16. Arrow **RR** in Figure 17 depicts how, after initially closing off the sampling channel (**blue**) in Figure 16, the valves (**purple**) are opened (as shown by arrows **PP** and **QQ**) to allow the subsequent portion of the blood sample to flow along the path of arrow **RR** through the sampling channel (**blue**) toward and through the outlet port (**pink**). *Id.* Figure 16 depicts how those same valves (**purple**) initially close off the sampling channel until the first portion of the blood sample is in the chamber (**yellow**) (as shown by the path of arrow **OO**). Section XII.A.1.e, above; Ex. 1012, ¶¶[1111]-[1114], Figs. 16-17.

115. For the foregoing reasons, each of the valves (**purple**) as shown above initially closes off the sampling channel (**blue**) until the first portion of the blood sample is sequestered in the chamber (**yellow**). Section XII.A.1.e, above; Ex. 1012, ¶¶[1111]-[1114], Figs. 16-17. Accordingly, the valves (**purple**) (each alone or collectively) discloses the claimed “valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.” Therefore, Bullington800 discloses and/or renders obvious claim 7.

8. Dependent Claim 8

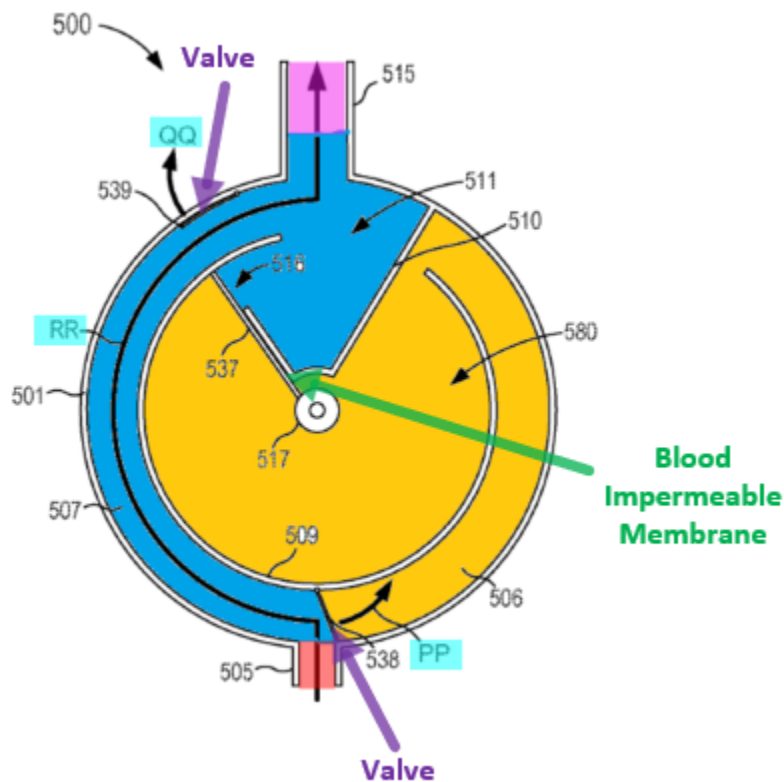
The device in accordance with claim 1, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts

of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.

116. Claim 8 of the '052 Patent depends from claim 1 and further requires “a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.” Ex. 1001, claim 8. As discussed above, claim 1 is disclosed and/or rendered obvious by Bullington800. See Sections XII.A.1.a-f, above. As I further explained above, Bullington800 discloses a sampling channel (blue), a chamber (yellow) that collects a first portion of the blood sample, and discloses at least one valve (purple) “configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.” Sections XII.A.1.d-e, XII.A.6-7, above; Ex. 1012, ¶¶[1101], [1108]-[1114], Figs. 14, 16-17. As I discuss in more detail below, for the same reasons, Bullington800 also discloses that the valves 538 and 539 (purple) are “configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port” as required by claim 8.

117. As I have explained above, Bullington800 discloses that the valves (purple) transition from a first configuration to a second configuration, as shown by arrows PP and QQ in Figure 17 (below). Sections XII.A.6-7, above; Ex. 1012,

¶¶[1109], [1111], [1114], Figs. 16-17. Specifically, the valves (purple) transition as shown by arrows PP and QQ once the first portion of the blood sample is in the chamber (yellow) to isolate the chamber (yellow) and sequester the potentially-contaminated first portion of the blood sample within. Sections XII.A.1.e, XII.A.6-7, above; Ex. 1012, ¶¶[1109], [1111], [1114], Figs. 16-17.



Ex. 1012, Fig. 17 (annotated)

The movement of the valves (purple) is the claimed “release” of claim 8, because the valves (purple) no longer impede the flow of subsequent portions of blood through the sampling channel (blue) after moving and, as a result, the suction force from the sample syringe urges the claimed “follow-on amounts of the blood sample”

toward the outlet port (**pink**) along arrow RR. Sections XII.A.1.d, XII.A.6-7, above; Ex. 1012, ¶[1114], Fig. 17. As I explained for [1C] and [1D], the suction force draws the “follow-on amounts of the blood sample” along arrow **RR**, bypassing the chamber (**yellow**). Section XII.A.1.d-e, IX.A, above; Ex. 1012, ¶¶[1006], [1107]-[1114], Figs. 1, 11-17.

118. Accordingly, it is my opinion that Bullington800 discloses and/or renders obvious claim 8.

9. Dependent Claim 9

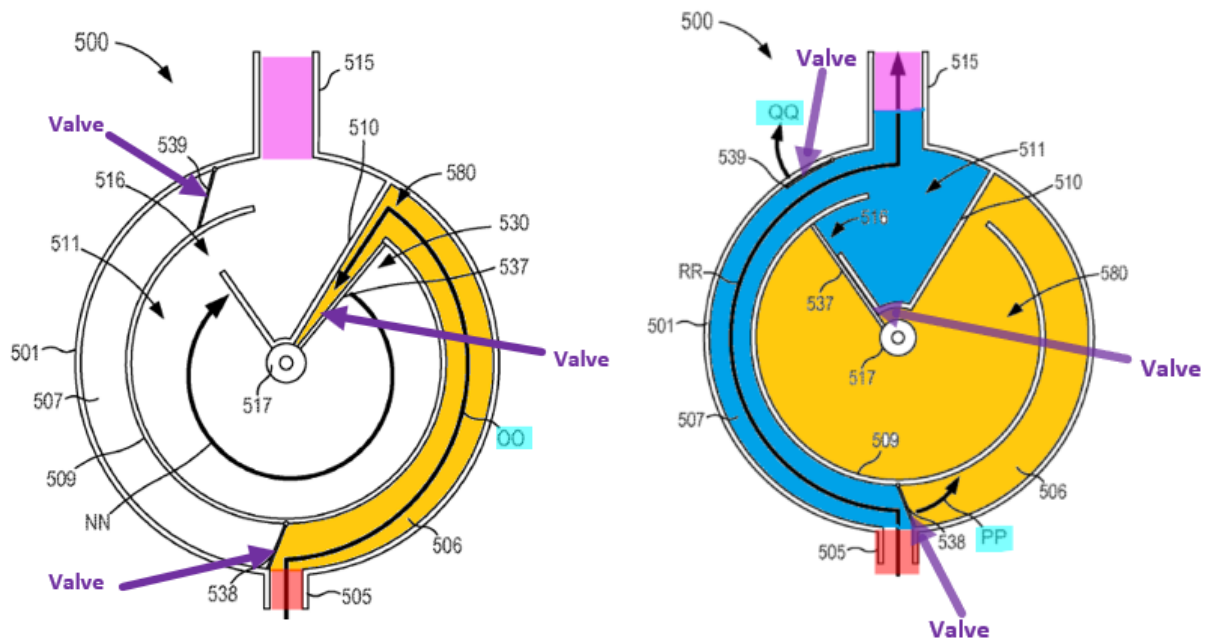
The device in accordance with claim 6, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.

119. Claim 9 of the '052 Patent depends from claim 6 and further requires that the valve “is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.” Ex. 1001, claims 6, 9. As discussed above, claim 6 is disclosed and/or rendered obvious by Bullington800. See Section XII.A.6, above. As I further explained above, the first member 537, second member 538, and third member 539 (all **purple**) are each (and also in any combination are) a “valve” as recited in claim 6. *Id.*; Ex. 1012, ¶¶[1109], [1111], [1114], Figs. 16-17. As I discuss in more detail below, Bullington800 discloses that the valves (**purple**) are “configured to pinch, shunt,

bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.”

120. Bullington800 explains that in Figure 16, the first member 537, second member 538, and third member 539 (all **purple**) are each in their “first position.” Ex. 1012, ¶[1111], Fig. 16. As shown below, in Figure 16, the first position of the valves (**purple**) close off the region that is the sampling channel (**blue**) in Figure 17. Ex. 1012, ¶¶[1109], [1111], [1114], Figs. 16-17. That is, the valves (**purple**) close off the sampling channel (**blue**) “such that the first channel 506 is in fluid communication with the distal port 505, while the second channel 507 is fluidically isolated from the distal port 505 and the proximal port 515.” Ex. 1012, ¶¶[1109], [1111]-[1113], Fig. 16. As I have further explained above, in the initial configuration of Bullington800’s device, before the sample syringe is coupled to the outlet port (**pink**) (and thus, before the suction force causes the first portion of the blood sample to be drawn into the chamber (**yellow**) as shown by arrow **OO**) the valves (**purple**) close off the sampling channel (**blue**) and only after the first portion of the blood sample is drawn into the chamber (**yellow**) do the valves (**purple**) transition to their second configuration, opening the sampling channel (**blue**). Section XII.A.1.d-e, XII.A.6-7, above. Therefore, Bullington800 discloses that each of the valves (and any combination of the valves) (**purple**) “is configured to pinch,

shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.”



Ex. 1012, Figs. 16 & 17 (annotated)

121. Accordingly, Bullington800 discloses and/or renders obvious claim 9.

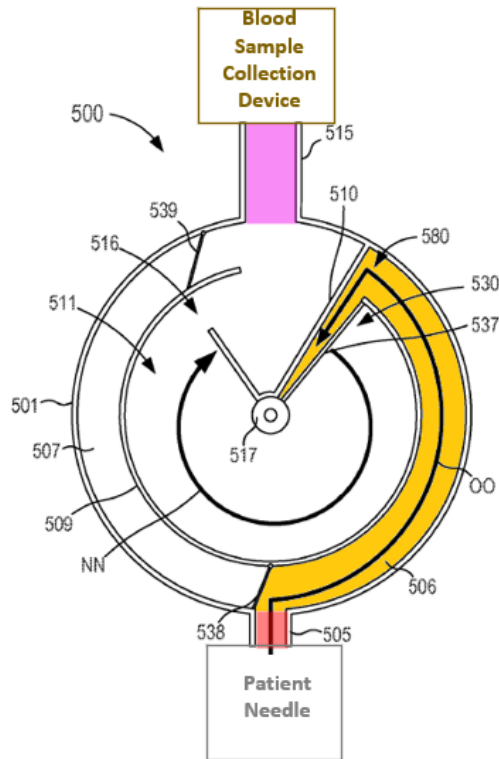
10. Dependent Claim 10

The device in accordance with claim 1, further comprising a patient needle and the blood sample collection device.

122. Claim 10 of the '052 Patent depends from claim 1 and further requires that the device comprise “a patient needle and the blood sample collection device.”

Ex. 1001, claim 10. As discussed above, claim 1 is disclosed and/or rendered obvious by Bullington800. See Sections XII.A.1.a-f, above. As I further explained above, Bullington800 discloses that its device, which is configured for collecting blood from a patient, includes an inlet port (red) that is “coupled to a proximal end

portion of a lumen-defining device such as, for example, a butterfly needle...or the like.” Ex. 1012, ¶[1111]; *see also id.*, ¶¶[1043], [1108], Figs. 1, 16-17; Section XII.A.1.a, above. Bullington800 also includes the outlet port (**pink**) that is coupled to a blood sample collection device, such as a syringe. Ex. 1012, ¶[1107]; *see also id.*, ¶¶[1043], [1108], [1111], Figs. 1, 16-17; Section XII.A.1.d, above. Thus, while not expressly shown in Figures 16 and 17, Bullington800 discloses that its device includes the claimed “patient needle” (i.e., the needle coupled to the inlet port (**red**)) and the claimed “blood sample collection device” coupled to the outlet port (**pink**). Ex. 1012, ¶[1111]; *see also id.*, ¶¶[1043], [1108], Figs. 1, 16-17. I produce a modified Figure 16 below to illustrate the claimed patient needle (**gray**) and blood sample collection device (**brown**) as disclosed by Bullington800. *Id.*



Ex. 1012, Fig. 16 (modified to show the location of the disclosed patient needle and blood sample collection device, and annotated)

123. Accordingly, it is my opinion that Bullington800 discloses and/or renders obvious claim 10.

11. Dependent Claim 11

The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.

124. Claim 11 of the '052 Patent depends from claim 1 and further requires “the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood

to be sequestered.” Ex. 1001, claim 11. As discussed above, claim 1 is disclosed and/or rendered obvious by Bullington800. See Sections XII.A.1.a-f, above. As I further explained above, Bullington800 discloses a chamber (yellow) that collects a first portion of the blood sample. Sections XII.A.1.d-e, above; Ex. 1012, ¶[1112], Figs. 16-17; *see also id.*, ¶¶[1107]-[1108], [1113]-[1114]. As I discuss in more detail below, Bullington800 also discloses that the chamber (yellow) has “a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.”

125. The chamber (yellow) collects and sequesters the first portion of the blood sample as I explained above. Sections XII.A.1.d-e, above; Ex. 1012, ¶[1112], Figs. 16-17; *see also id.*, ¶¶[1107]-[1108], [1113]-[1114]. Bullington800 discloses that the sequestered blood “can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants.” Ex. 1012, ¶[1112]. Bullington800 also describes that sequestering the potentially contaminated first portion of the blood sample keeps the later flow of blood from the patient to the sample syringe substantially free from contaminants. Ex. 1012, ¶[1114]. Bullington800 explains that because the contaminants are “dermally-residing” and “external,” they will be contained within the very first portion of blood travelling through the collection needle because the contaminants will be introduced into the needle as it punctures the skin or port. Ex. 1012, ¶¶[1004]-[1006], [1030], [1112],

[1114]. Accordingly, any later amount of blood collected through the sampling channel after the first portion of the blood sample is sequestered in the chamber (yellow) is less prone to contamination, because the patient needle has already punctured the skin or port and the first portion of blood from that puncturing is isolated from the subsequent portions. *Id.*; *see also* Sections XII.A.1.d-e, above. It is thus my opinion that Bullington800 discloses that the sequestered volume of blood in the chamber (yellow) is “the first portion of the blood sample that is more prone to contamination,” and the chamber (yellow) has “a volume sufficient to collect the first portion of the blood sample that is more prone to contamination” as claimed. Ex. 1012, ¶¶[1004]-[1006], [1030], [1112], [1114]. Indeed, avoiding potential contamination of blood samples by sequestering the first, potentially more contaminated portion of the blood sample is the stated aim of Bullington800. Ex. 1012, ¶¶[1002]-[1006], [1030]-[1033], [1051], claim 1. Bullington800 repeatedly describes that its device is used to achieve this goal by reducing contamination from microbes or other contaminants by sequestering the first portion of the blood sample, which is more prone to contamination. Ex. 1012, ¶¶[1002], [1005]-[1006], [1030]-[1033], [1050]-[1051], [1112], [1114].

126. As for the chamber (yellow) “having a volume sufficient...to minimize an amount of blood to be sequestered,” I note that Bullington800 discloses various volumes that may be used for the chamber (yellow). For example, the chamber

(yellow) may have a volume “sufficient to contain the first centiliter or few centiliters of bodily-fluid,” “from about 0.1 ml to about 3.0 ml,” or “from about 3.0 ml, 4.0 ml, 5.0 ml....50 ml, or any volume or fraction of volume therebetween.” Ex. 1012, ¶[1113]. It is my opinion that a POSITA would have understood that at least the smaller disclosed volumes “minimize an amount of blood to be sequestered” as claimed. The ’052 Patent does not describe what volume would be small enough “to minimize an amount of blood to be sequestered,” stating only that “[t]he predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.” Ex. 1001, 6:20-23. And I note that the ’052 Patent merely describes that in some embodiments the “volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc’s), or more.” Ex. 1001, 9:8-10. The smaller ranges of volumes that are expressly recited in Bullington800 (e.g., “from about 0.1 ml to about 3.0 ml”), by the simple fact of being smaller than the other disclosed ranges in Bullington800, minimize the amount of blood being sequestered. Further, at least some of the volumes disclosed by Bullington800 are consistent with what a POSITA would have expected for a volume “to minimize an amount of blood to be sequestered.” It was well-known that volumes of approximately 0.1 ml to approximately 0.5 ml were “sufficiently large to adequately collect undesirable microbes....” Ex. 1019, 7:43-49. I note that these volumes fall within the exact

range of volumes described in the '052 Patent. Ex. 1001, 9:8-10; *see also id.*, 6:20-23. Further, because volumes of approximately 0.1 ml to approximately 0.5 ml were sufficiently large to adequately collect undesirable microbes (e.g., dermal microbes), and because the very first portion of the blood sample is more likely to be contaminated than later portions, a POSITA would have understood that even these smaller chamber (yellow) volumes disclosed by Bullington8000 would remain sufficient to collect the first portion of blood that is more prone to contamination. Ex. 1019, 7:43-49; Ex. 1012, ¶[1113]. I note further that the claim does not require that the follow-on amounts of blood be completely free from contamination, or even that the chamber contain blood that is more contaminated than the follow-on blood, only that the portion in the chamber be more prone to contamination. Ex. 1001, claim 11. Accordingly, a POSITA would have understood that Bullington800 discloses a chamber (yellow) having a volume (e.g., from about 0.1 ml up to 3.0 ml) that receives the first portion of the blood sample that is more prone to contamination, while still minimizing the amount of blood being sequestered. Ex. 1012, ¶¶[1002], [1005]-[1006], [1030]-[1033], [1050], [1112]-[1114].

127. Thus, it is my opinion that Bullington800 discloses “the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered” and therefore discloses and/or renders obvious claim 11.

12. Dependent Claim 12

The device in accordance with claim 1, wherein the chamber has a volume of less than 1.5 cubic centimeters.

128. Claim 12 of the '052 Patent depends from claim 1 and further requires “wherein the chamber has a volume of less than 1.5 cubic centimeters.” Ex. 1001, claim 12. As discussed above, claim 1 is disclosed and/or rendered obvious by Bullington800. See Sections XII.A.1.a-f, above. As I further explained above, Bullington800 discloses a chamber (yellow) that may have a volume “sufficient to contain the first centiliter to few centiliters of bodily-fluid,” or “from about 0.1 ml to about 3.0 ml.” Section XII.A.11, above; Ex. 1012, ¶[1113]. 1.5 cubic centimeters is equal to 1.5 milliliters.

129. Accordingly, it is my opinion that Bullington800 discloses and/or renders obvious claim 12.

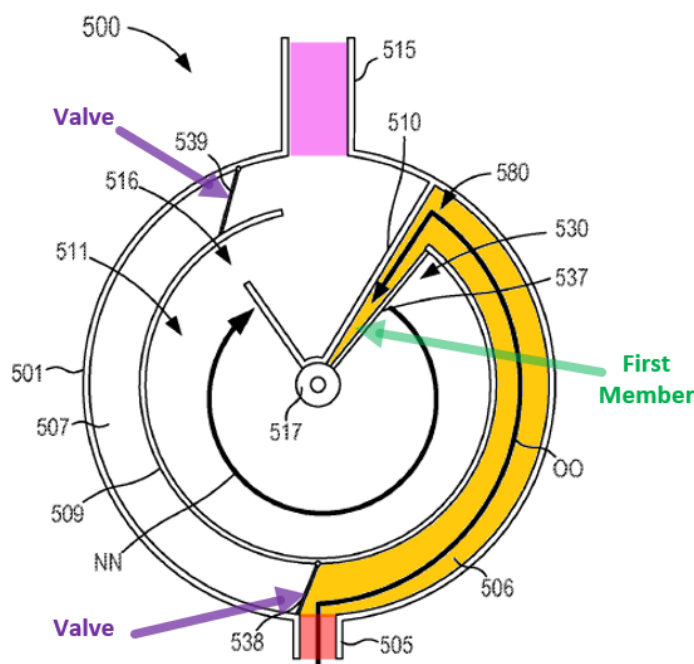
13. Independent Claim 13

a. [13PRE]: “A device comprising:”

130. This preamble is identical to claim 1, and as I explained, Bullington800 discloses preamble [1PRE]. Section XII.A.1.a, above. For the reasons I explain in more detail below, Bullington800’s device discloses and/or renders obvious the remaining elements [13A]-[13E] of claim 13. Sections XII.A.13.b-f, below. Therefore, Bullington800 discloses and/or renders obvious [13PRE].

b. [13A]: “an inlet port for receiving blood;”

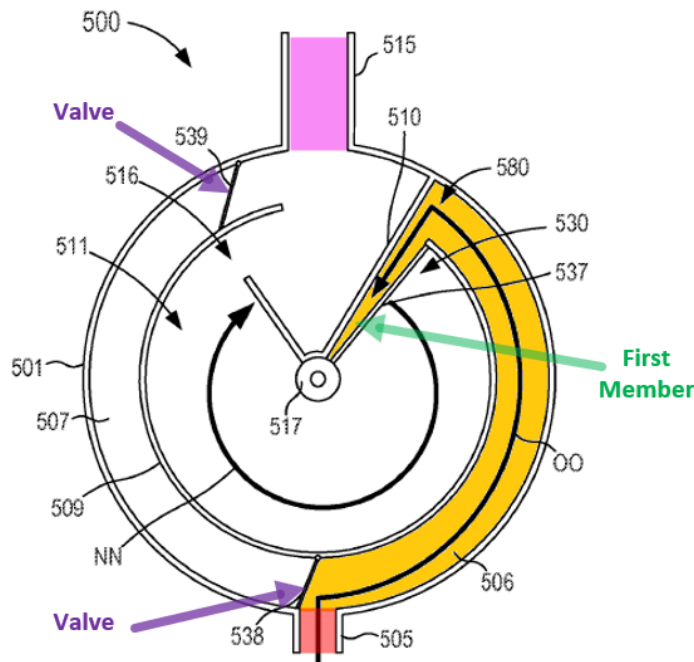
131. Limitation [13A] is nearly identical to [1A] and, as I explained above, Bullington800 discloses “an inlet port for receiving a blood sample” as recited in [1A]. Section XII.A.1.b, above. Specifically, Bullington800’s distal port 505 (**red**) is the claimed “inlet port” and, because this inlet port (**red**) receives blood samples, it is “an inlet port for receiving blood” as claimed. Section XII.A.1.b, above; Ex. 1012, ¶¶[1043], [1050], [1055], [1108], [1111]-[1112], [1114], Figs. 16-17. Therefore, Bullington800 discloses and/or renders obvious [13A].



Ex. 1012, Fig. 16 (annotated)

c. [13B]: “an outlet port;”

132. Limitation [13B] is identical to [1B] and, as I explained above, Bullington800 discloses a proximal port 515 (pink) that is an “outlet port” as claimed. Section XII.A.1.c, above; Ex. 1012, ¶¶[1108], [1111], [1114], Figs. 16-17.



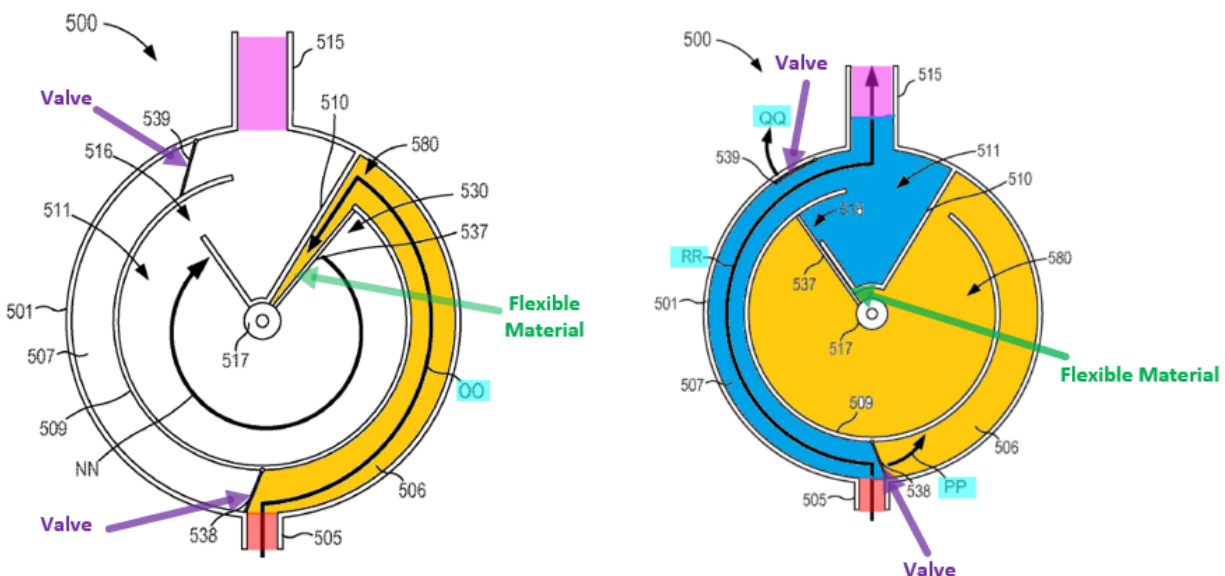
Ex. 1012, Fig. 16 (annotated)

133. Accordingly, Bullington800 discloses and/or renders obvious [13B].

d. [13C]: “a chamber comprising a flexible material, the chamber connected with the inlet port and configured to collect a first portion of the blood when under a drawing force applied from the outlet port;”

134. Limitation [13C] is nearly identical to [1C], except that [13C] recites that the chamber comprises “a flexible material.” Ex. 1001, claims 1, 13. As I have previously explained for [1C], Bullington800’s device includes a chamber (yellow)

connected with the inlet port (**red**) and “configured to collect a first portion of the blood when under a drawing force applied from the outlet port.” Section XII.A.1.d, above; Ex. 1012, ¶[1107]; *see also id.*, ¶¶[1111]-[1114], Figs. 16-17.



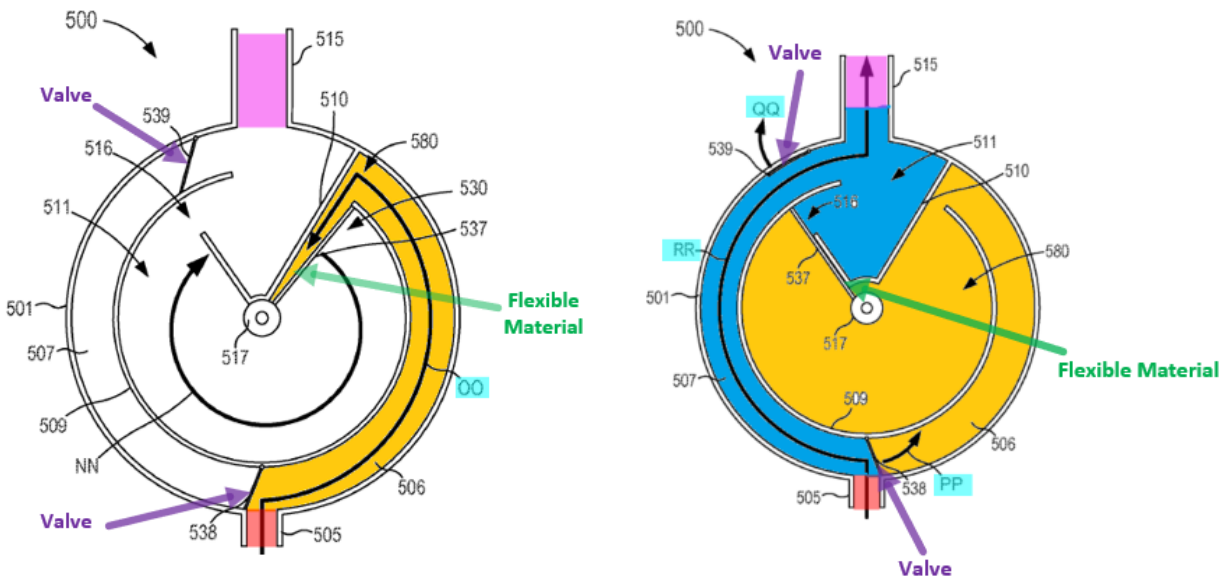
Ex. 1012, Figs. 16 & 17 (annotated)

135. As I have also previously explained, Bullington800 discloses that the chamber (**yellow**) includes a first member 537 that is a structure formed of a relatively flexible and/or compressible material (**green**) that “can fluidically isolate the fluid reservoir 580 from, for example, a portion of the inner volume 511 in fluid communication with the proximal port 515.” Ex. 1012, ¶¶[1109], [1111], Figs. 16-17; Section XII.A.2, above. A flexible and/or compressible material is one that “can be **flexed**, stretched, expanded, or **compressed** without breaking under normal conditions.” Therefore, if the plain and ordinary meaning described at Section XI

(above) is applied, Bullington800 discloses a “flexible material” as claimed. Moreover, a POSITA would understand that Bullington800’s first member that is “thin,” “fluidically isolate[s]” the fluid reservoir 508 from the inner volume 511, and “flexible” in order form a substantially fluid tight seal with the inner surface of the diverter 509 would also be easily hand-folded, flexed, twisted, and bent. For all the above reasons, Bullington800 discloses “a chamber comprising a flexible material” as claimed, and Bullington800 discloses and/or renders obvious [13C]. Ex. 1012, ¶¶[1109], [1111], Figs. 16-17; Sections XII.A.1.d, XII.A.2, above.

e. [13D]: “a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port; and”

136. Limitation [13D] is nearly identical to [1D] except that [13D] recites “a subsequent portion of the blood” rather than “a subsequent portion of the blood sample.” Ex. 1001, claims 1, 13. As I have previously explained, Bullington800 discloses [1D]. Section XII.A.1.e, above. A POSITA would have understood that the sampling channel (blue) that conveys the subsequent portion of the blood sample to the outlet port (pink) (i.e., as shown by arrow RR) similarly discloses conveying “a subsequent portion of the blood” as claimed in [13D]. See Section XII.A.1.e, above.



Ex. 1012, Figs. 16 & 17 (annotated)

137. Accordingly, Bullington800 discloses and/or renders obvious [13D].

f. [13E]: “a housing that defines the inlet port, the sampling channel, and the outlet port.”

138. Limitation [13E] is identical to [1E], which is disclosed and/or rendered obvious by Bullington800 for the reasons I described above. Section XII.A.1.f, above. Accordingly, Bullington800 discloses and/or renders obvious [13E] and thus discloses and/or renders obvious all of claim 13. Sections XII.A.13.a-f, above.

14. Dependent Claims 14-24

139. Each of dependent claims 14-24 corresponds to one of claims 2-12. As such, I have not repeated all of my analysis from above for claims 14-24. Instead, I have prepared the following table to show the claim language side-by-side and to address any minor differences. Specifically, the following tables show how

dependent claims 14-24 are disclosed or rendered obvious by Bullington800 for the same reasons that claims 2-12 are disclosed or rendered obvious by Bullington800.

Claims 2-12	Claims 14-24	Comparison
[2] The device in accordance with claim 1, wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.	[14] The device in accordance with claim 13, wherein the flexible material is a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood.	Aside from their dependencies, the claims are nearly identical. Claim 14 recites “wherein the flexible material is a blood impermeable membrane...” which is taught by the first member 537 made of a flexible/compressible material and/or the second member 538, as discussed for claim 2. See Sections XII.A.2, XII.A.1.c, above. Claim 14 also recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800 discloses and/or renders obvious claim 14 for the same reasons Bullington800 discloses and/or

		renders obvious claim 2. See Section XII.A.2, above. Thus, claim 14 is disclosed and/or rendered obvious for the same reasons as claim 2. See Section XII.A.2, above.
[3] The device in accordance with claim 1, wherein a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.	[15] The device in accordance with claim 13, wherein the flexible material is a blood impermeable membrane causes the first portion of the blood to back up into the chamber following application of the drawing force applied from the outlet port.	Aside from their dependencies, the claims are nearly identical. Claim 15 recites “wherein the flexible material is a blood impermeable membrane...” which is taught by the first member 537 made of a flexible/compressible material and/or by the second member 538, as discussed for claim 3. See Sections XII.A.3, XII.A.1.c, above. Claim 15 also recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800 discloses and/or

		renders obvious claim 15 for the same reasons Bullington800 discloses and/or renders obvious claim 3. See Section XII.A.3, above. Thus, claim 15 is disclosed and/or rendered obvious for the same reasons as claim 3. See Section XII.A.3, above.
[4] The device in accordance with claim 2, wherein the housing is separate from the blood impermeable membrane.	[16] The device in accordance with claim 14, wherein the housing is separate from the blood impermeable membrane.	Aside from their dependencies and statutory class, the claims are identical. Thus, claim 16 is disclosed and/or rendered obvious for the same reasons as claim 4. See Section XII.A.4, above.
[5] The device in accordance with claim 1, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to	[17] The device in accordance with claim 13, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a	Aside from their dependencies, the claims are nearly identical. Claim 17 recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800

contact a material that is blood impermeable.	material that is blood impermeable.	discloses and/or renders obvious claim 17 for the same reasons Bullington800 discloses and/or renders obvious claim 5. See Section XII.A.5, above. Thus, claim 17 is disclosed and/or rendered obvious for the same reasons as claim 5. See Section XII.A.5, above.
[6] The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel.	[18] The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel.	Aside from their dependencies, the claims are identical. Thus, claim 18 is disclosed and/or rendered obvious for the same reasons as claim 6. See Section XII.A.6, above.
[7] The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.	[19] The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.	Aside from their dependencies, the claims are nearly identical. Claim 19 recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800

		discloses and/or renders obvious claim 19 for the same reasons Bullington800 discloses and/or renders obvious claim 7. See Section XII.A.7, above. Thus, Bullington800 discloses and/or renders obvious claim 19. See Section XII.A.7, above.
[8] The device in accordance with claim 1, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.	[20] The device in accordance with claim 13, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, follow-on amounts of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.	Aside from their dependencies and minor wording differences (e.g., “the first portion of the blood sample” vs. “the first portion of the blood”) that does not change how Bullington800 discloses and/or renders obvious claims 8 and 20, the claims are identical. Thus, claim 20 is disclosed and/or rendered obvious for the same reasons as claim 8. See Section XII.A.8, above.

[9] The device in accordance with claim 6, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.	[21] The device in accordance with claim 18, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.	Aside from their dependencies, the claims are nearly identical. Claim 21 recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800 discloses and/or renders obvious claim 21 for the same reasons Bullington800 discloses and/or renders obvious claim 9. See Section XII.A.9, above. Thus, Bullington800 discloses and/or renders obvious claim 21. See Section XII.A.9, above.
[10] The device in accordance with claim 1, further comprising a patient needle and the blood sample collection device.	[22] The device in accordance with claim 13, further comprising a patient needle and a sample collection device.	Aside from their dependencies, the claims are identical. Thus, claim 22 is disclosed and/or rendered obvious for the same reasons as claim 10. See Section XII.A.10, above.

[11] The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.	[23] The device in accordance with claim 13, the chamber having a volume sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.	Aside from their dependencies, the claims are nearly identical. Claim 23 recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800 discloses and/or renders obvious claim 23 for the same reasons Bullington800 discloses and/or renders obvious claim 11. See Section XII.A.11, above. Thus, Bullington800 discloses and/or renders obvious claim 23. See Section XII.A.11, above.
[12] The device in accordance with claim 1, wherein the chamber has a volume of less than 1.5 cubic centimeters.	[24] The device in accordance with claim 13, wherein the chamber has a volume of less than 1.5 cubic centimeters.	Aside from their dependencies, the claims are identical. Thus, claim 24 is disclosed and/or rendered obvious for the same reasons as claim 12. See Section XII.A.12, above.

B. Bullington800 In View Of Brancazio

140. I have previously described how Bullington800 discloses and/or renders obvious the claimed “chamber connected with the inlet port and configured to collect a first portion of the [blood/blood sample] when under a drawing force applied from the outlet port” because the blood sample collection device (e.g., syringe coupled to the proximal port 515) exerts a drawing force on the chamber (fluid reservoir 580, alone or in combination with first channel 506) that causes the chamber to draw the initial flow of blood from the patient. See Section XII.A.1.d, above. I have also previously described that Bullington800 discloses a “blood impermeable” membrane/material as recited in some of the claims at least because Bullington800’s first member 537 is blood-impermeable. See, e.g., Section XII.A.2, above.

141. I have been asked to consider a scenario where Patent Owner might argue that Bullington800 does not disclose the “chamber connected with the inlet port and configured to collect a first portion of the [blood/blood sample] when under a drawing force applied from the outlet port” (claims 1, 13) and/or a “blood impermeable” membrane/material (claims 2-5, 14-17). Even if that were true, it is my opinion that a POSITA would have found it obvious to combine Bullington800 with Brancazio to incorporate a hydrophobic (i.e., “blood impermeable”) membrane into Bullington800’s device, which would render obvious all of claims 1-24.

142. As I described above at Section IX.B and as further shown below, Brancazio teaches collecting a blood sample using a device that houses a vacuum chamber (**blue**) that applies a suction force (i.e., due to the negative pressure in the vacuum), transmitted through a gas-permeable but blood-impermeable membrane (**green**), in order to draw blood into a collection/storage chamber (**yellow**). Section IX.B, above; Ex. 1013, ¶¶[0042], [0048]-[0049], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. Brancazio expressly describes that the membrane (**green**) is made of a “material permeable to gas but not to...blood,” in order to prevent blood from entering the vacuum chamber (**blue**) via the collection chamber (**yellow**) and potentially contaminating the vacuum chamber (**blue**). Ex. 1013, ¶¶[0153]-[0154], Fig. 4.

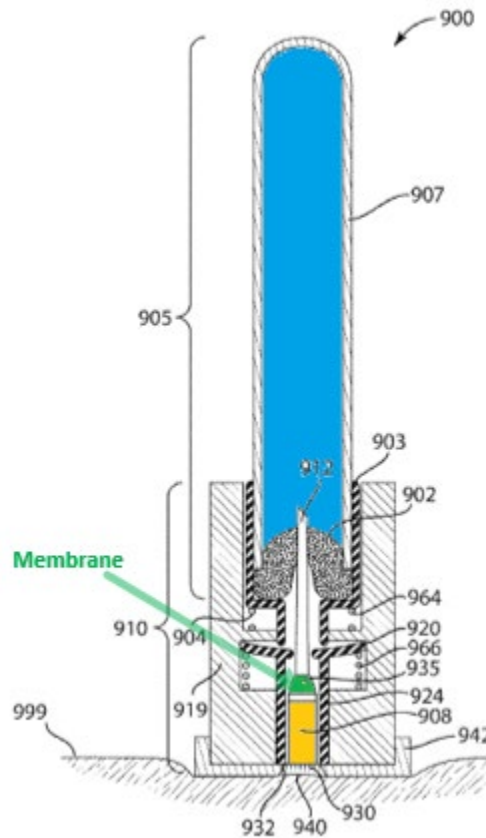
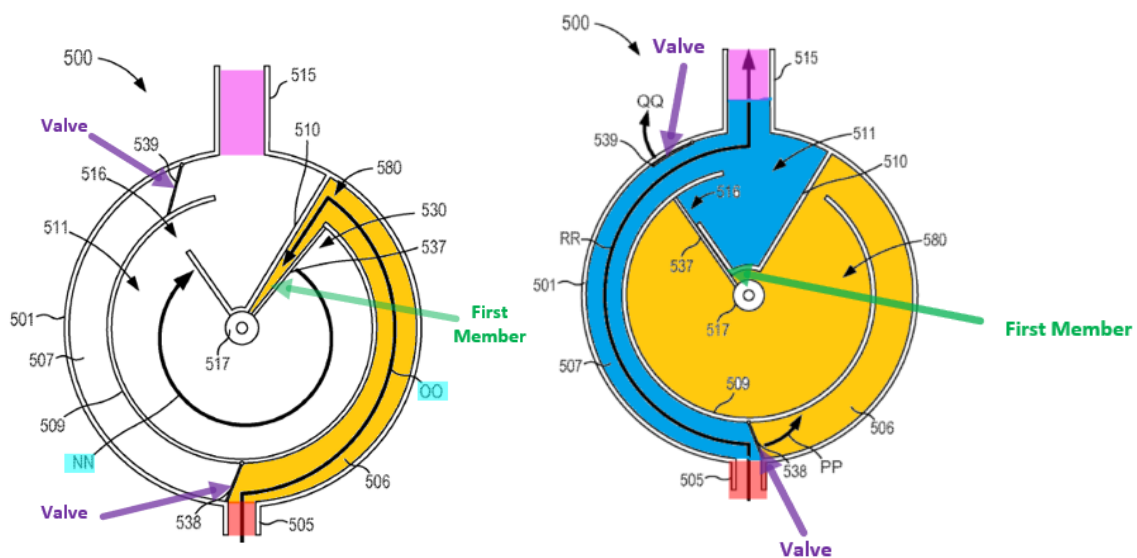


Fig. 13B

Ex. 1013, Fig. 13B (annotated)

143. There are a number of similarities between the devices described in Bullington800 and in Brancazio. At a high level, both Bullington800 and Brancazio relate to medical devices for collecting blood from a patient. Ex. 1012, Abstract, ¶¶[1006], [1107]-[1114], Figs. 1, 11-17; Ex. 1013, Abstract, ¶¶[0003], [0013], [0041]-[0042], [0048]-[0049], [0052], [0059], [0087]-[0120], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. Further, Brancazio's above-described use of negative pressure to draw blood into a collection chamber (yellow, above) while a blood-impermeable, gas-permeable (i.e., hydrophobic) membrane (green, above) is

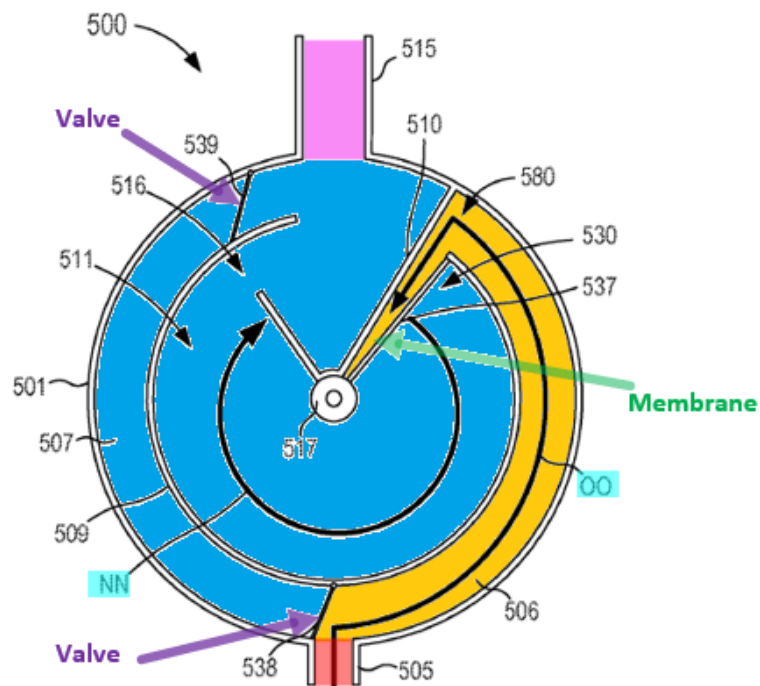
positioned to prevent the blood from exiting the collection chamber (yellow, above) into a second portion of the device (i.e., the vacuum chamber (blue, above)) is similar to how Bullington800 uses negative pressure to collect the initial portion of a blood sample into its chamber (yellow, below) while the first member 137 (green, below) prevents blood from entering the sampling channel (blue, below). Sections XII.A.1.d-e, above; Ex. 1012, ¶¶[1108]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0099], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. However, as I previously explained, in Bullington800 the negative pressure causes Bullington800's first member 537 (green, below) to rotate from a first configuration to a second configuration (as shown by arrow NN, below), which increases the volume of the chamber (yellow, below) and draws blood into the chamber (yellow, below). Ex. 1012, ¶¶[1108]-[1112], Figs. 16-17.



Ex. 1012, Figs. 16 & 17 (annotated)

144. There are a number of advantages provided by Brancazio's use of its membrane (**green**), which is air-permeable and blood-impermeable, that would have motivated a POSITA to combine Bullington800 and Brancazio. For example, it would have been obvious to modify Bullington800's device by constructing the first member 537 (**green**) out of a "material permeable to gas but not to...blood" as taught by Brancazio because doing so would prevent air from compressing inside the chamber (**yellow**). A POSITA would have recognized that a small pocket of air would have existed within the chamber (**yellow**) prior to the blood sample being collected by Bullington800's device. Ex. 1012, Figs. 16, 17. In Bullington800's normal operation, this pocket of air would be pushed, by the blood drawn into the chamber (**yellow**), up against the first member 537 (**green**) in a way that compresses the air, reducing the amount of space available for the blood and causing compressed air that pushes blood away from, or out of, the chamber (**yellow**). Ex. 1012, ¶¶[1114], [1112]-[1113], Figs. 16, 17. By constructing the first member 537 (labeled as a "membrane" below, **green**) out of an air-permeable but blood-impermeable material as described in Brancazio, the combination of Bullington800 and Brancazio would allow for any air that is in the chamber (**yellow**) and/or in the patient needle to be pulled through the now air-permeable membrane (**green**) (as shown in Bullington800-Brancazio Drawing 1A, below) as blood from the patient enters the chamber (**yellow**), preventing the air from compressing inside the chamber and

avoiding the risks described above. Ex. 1013, ¶¶[0042], [0048]-[0049], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. Specifically, the negative pressure being applied by the vacuum chamber would be transmitted through the membrane (green) to draw a flow of blood from the patient into the chamber (yellow) similar to how the vacuum force caused by moving the first member 537 in Bullington800 draws blood into the chamber (yellow). Section XII.A.1.c, above. The blood would fill the chamber (yellow) until the blood contacts the membrane (green) (e.g., as shown by arrow OO below), while the negative pressure also pulls any air in the chamber (yellow) through the membrane (green). *Id*; Ex. 1012, ¶¶[1114], [1112]-[1113], Figs. 16, 17.



Bullington800-Brancazio Drawing 1A (Ex. 1012, Fig. 16 (modified to show
Bullington-Brancazio's membrane))

As the blood contact the membrane (**green**), the negative pressure would continue pulling the blood towards the outlet port (**pink**), and the blood would therefore push the membrane (**green**) to move (e.g., as shown by arrow **NN**, above) in the same manner that the first member 537 in Bullington800 moves to transition from a first configuration to a second configuration. Ex. 1012, ¶¶[1114], [1112]-[1113], Fig. 17.

145. Another advantage of Brancazio's use of its membrane (**green**) over Bullington800's use of the first member 537 (**green**) is that Brancazio's membrane is simpler, in that it does not move. Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. Rather, Brancazio's membrane (**green**) simply transmits the negative pressure (and resulting suction force) being applied by the vacuum chamber because the membrane (**green**) is constructed of a gas-permeable material. *Id.* It is therefore also my opinion that it would have been obvious to a POSITA to modify Bullington800's device by, in an alternative implementation of the combination of Bullington800 and Brancazio, permanently positioning the first member 537 (**green**) in its second configuration (shown in Figure 17, further above) and constructing it from a "material permeable to gas but not to...blood" (e.g., a hydrophobic membrane) as taught by Brancazio in order to advantageously simplify Bullington800's device. Ex. 1013, ¶¶[0059],

[0090], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; See Section IV, above (referring to obviousness rationale (G)). This would have produced an alternative implementation of the combination to that which I described above, but both implementations would have been obvious to a POSITA at least because of the benefit of allowing the air to be removed from the chamber (yellow) as I previously described. The second, alternative, implementation, where the membrane (green) is fixed in

146. In the combination of Bullington800 and Brancazio (“Bullington800-Brancazio”), the simplification of Bullington800’s device would have beneficially eliminated the need to rotate the first member 537 from its first position to its second position (*i.e.*, as indicated by arrow NN in Figure 16 of Bullington800). Ex. 1012, ¶¶[1111]-[1112], Fig. 16. Therefore, in the alternative implementation of the combination of Bullington800 and Brancazio that I illustrate below, the membrane (green) would simply begin (and remain) in the “second configuration,” where the volume of Bullington800’s chamber (yellow) is at its maximum, and the suction force created by the negative pressure from the syringe at the outlet port (pink) would be exerted within the chamber (yellow) through the gas permeable, blood-impermeable membrane (green). Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1012, ¶¶[1111]-[1113], Figs. 16-17. My below drawing of Bullington800-Brancazio is a modified version of

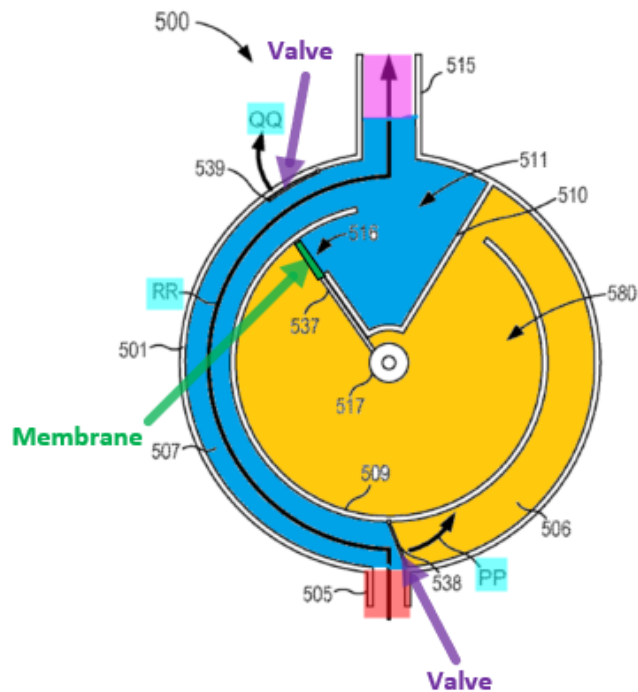
Bullington800-Brancazio Drawing 1B (Ex. 1012, Fig. 16 (modified to show the combination's use of a blood-impermeable air-permeable membrane that does not move))

147. Regardless of whether Bullington800's first member 537 remains movable (e.g., as I showed above in the first implementation of the combination, at Bullington800-Brancazio Drawing 1A) or is secured in place (e.g., as I showed above in the second, alternative implementation, with Bullington800-Brancazio Drawing 1B), the membrane (**green**) in Bullington800-Brancazio is a gas-permeable but blood-impermeable membrane. Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. Accordingly, the membrane (**green**) would prevent the blood drawn into the chamber (**yellow**) from entering the outlet port (**pink**) in the same way that Brancazio's membrane prevents blood from entering the vacuum chamber from the collection chamber. Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

148. The combination of Bullington800 and Brancazio is straightforward. In the first implementation, the first member 537 (**green**) functions in a similar manner as in Bullington800 but is constructed from an air-permeable, blood-impermeable material as taught by Brancazio. In the second, alternative, implementation, other than permanently positioning the first member 537 (**green**) in its second configuration (shown in Figure 17, above) and constructing it from a

“material permeable to gas but not to...blood” (e.g., a hydrophobic membrane), Bullington800’s device would remain essentially unchanged by the combination. In either implementation, the membrane (**green**) could still be a flexible/compressible material, as described in Bullington800, because such a membrane would be gas-permeable and blood-impermeable. Ex. 1012, ¶[1109]; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. And in both implementations, once the chamber (**yellow**) is filled with the initial (potentially contaminated) portion of the blood ample, the combination of Bullington and Brancazio would operate in essentially the same manner as I previously described with respect to Bullington800’s Figure 17. See Section XII.A.1.e, above. That is, the second member 538 and the third member 539 (both “valves,” **purple**) would be rotated into their second positions to place the sampling channel (**blue**) in fluid communication with both the inlet port (**red**) and the outlet port (**pink**) in order to collect the remaining blood sample in the blood sample collection device located at the outlet port (**pink**). *Id.*; Ex. 1012, ¶[1114], Fig. 17; *see also* Ex. 1012, ¶¶[1107]-[1108], [1111]-[1113]. As I show in the drawing of Bullington800-Brancazio in its second configuration (for collecting the remaining blood sample), regardless of which implementation is used the second member 538 (**purple**) and the blood-impermeable membrane (**green**) isolate the sequestered contaminated blood in the chamber (**yellow**) and keep the sampling channel (**blue**) free of contamination. Ex.

1012, ¶[1114], Fig. 17; *see also id.*, ¶¶[1107]-[1108], [1111]-[1113]; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.



Bullington800-Brancazio Drawing 2 (Ex. 1012, Fig. 17 (modified to show Bullington-Brancazio's use of Brancazio's membrane in Bullington's device))

149. It is my opinion that there are a number of reasons a POSITA would have been motivated to combine Bullington800 and Brancazio in the manner I described above. See Section IV, above (referring to obviousness rationale (G)). For example, producing Bullington800-Brancazio in either implementation I discussed above allows any air that is in the chamber (yellow) to exit the chamber (yellow) through the membrane (green), due to the negative pressure at the outlet

port (**pink**) drawing the air towards the outlet port (**pink**), so that the air does not compress in the chamber (**yellow**). As I previously explained, this provides the advantage of preventing the risk of the compressed air that pushes blood out of the chamber (**yellow**). The alternative implementation I described, where the membrane (**green**) is secured in place, advantageously simplifies the Bullington800 device, yielding a lower cost device with fewer moving parts for transmitting a drawing force produced at the outlet port to draw blood with unwanted contaminants into a chamber where it can be sequestered to avoid contamination of remaining portions of the blood sample. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0003], [0013], [0041]-[0042], [0052], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. The design of either implementation retains the benefits of avoiding contamination of blood samples—both Brancazio and Bullington800 are alike in that they seek to avoid contamination of portions of their respective devices, and Brancazio is clear that the blood-impermeable membrane sequesters blood to prevent contamination. Ex. 1012, ¶¶[1002]-[1006], [1030], [1050]-[1051], [1112], [1114]; Ex. 1013, ¶[0103]; *see also* Ex. 1013, ¶¶[0059], [0090], [0111], [0115], [0153]-[0154], [0157]. The same would be true for the blood-impermeable membrane in Bullington800-Brancazio.

150. Other rationales also support my opinion that it would have been obvious to a POSITA to produce Bullington800-Brancazio. For example, the combination merely combines known prior art elements according to known methods in order to yield predictable results. See Section IV, above (referring to obviousness rationale (A)). The known elements would be 1) Bullington800's device having a first chamber for storing the first portion of a blood sample, that chamber being isolated from an outlet yet allowing a drawing force from the outlet to draw fluid (i.e., blood) into the first chamber via a moveable blood-impermeable membrane, and 2) Brancazio's gas-permeable yet blood-impermeable membrane that similarly allows a drawing force at the outlet to draw fluid into a first chamber where it is isolated by the membrane. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0003], [0013], [0041]-[0042], [0052], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. The known method would be constructing the membrane using Brancazio's gas-permeable, blood-impermeable (i.e., hydrophobic) material (and, in the second, alternative, implementation, simply securing Bullington800's membrane into place in its second configuration (i.e., where the chamber is at its maximum volume)). Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1012, ¶¶[1111]-[1114], Figs. 16-17. The predictable result of the combination in either implementation would be that the device draws (i.e., using a

suction force exerted from the outlet port through the gas-permeable, blood-impermeable membrane) a potentially contaminated first portion of blood into the chamber, where the potentially contaminated first portion of blood can be sequestered away from the sampling channel that leads to the outlet. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

151. The predictable result described above is also achieved by the simple substitution of one known element with another. See Section IV, above (referring to obviousness rationale (C)). Specifically, it would have been obvious to substitute Brancazio's gas-permeable, blood-impermeable membrane with Bullington800's moveable first member, both of which are used to prevent potential contamination of a portion of a blood collection device, to achieve the result of drawing a potentially contaminated first portion of blood into the chamber, where the potentially contaminated first portion of blood can be sequestered away from the sampling channel that leads to the outlet. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

152. It is my opinion that a POSITA would have had a reasonable expectation of success in producing Bullington800-Brancazio. The combination described above merely involves routine and simple mechanical design techniques

with known, predictable results. Specifically, the combination merely requires constructing the first member 537 out of the same material as Brancazio's blood-impermeable membrane (and, in the second implementation, securing the first member 537 in its second configuration). Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1012, ¶¶[1111]-[1114], Figs. 16-17. A POSITA would have had the mechanical design skills necessary to implement Bullington800-Brancazio. See Section X, above.

1. Independent Claim 1

a. [1PRE]: “A device comprising:”

153. I previously explained how Bullington800 discloses a device as recited in [1PRE]. Section XII.A.1.a, above. For the reasons I explain below, where I apply the combination of Bullington and Brancazio to the claims, elements [1A]-[1E] of claim 1 are obvious in view of Bullington800-Brancazio. Sections XII.B.1.b-f, below. Therefore, Bullington800-Brancazio renders obvious [1PRE].

b. [1A]: “an inlet port for receiving a blood sample;”

154. I previously explained how Bullington800's distal port 505 (**red**) teaches “an inlet port for receiving a blood sample.” Section XII.A.1.b, above. As I explained above in this section, Bullington800-Brancazio involves constructing the first member 537 (**green**) from a blood-impermeable material (and, in the second alternative implementation, simply securing the first member 537 (**green**) in its

second configuration (i.e., where the chamber (**yellow**) is at its maximum volume). Section XII.B, above. Bullington800-Brancazio thus renders obvious the claimed inlet port (**red**) for the same reasons as Bullington800, and therefore renders obvious [1A] for the same reasons as I previously described. Section XII.A.1.b, above.

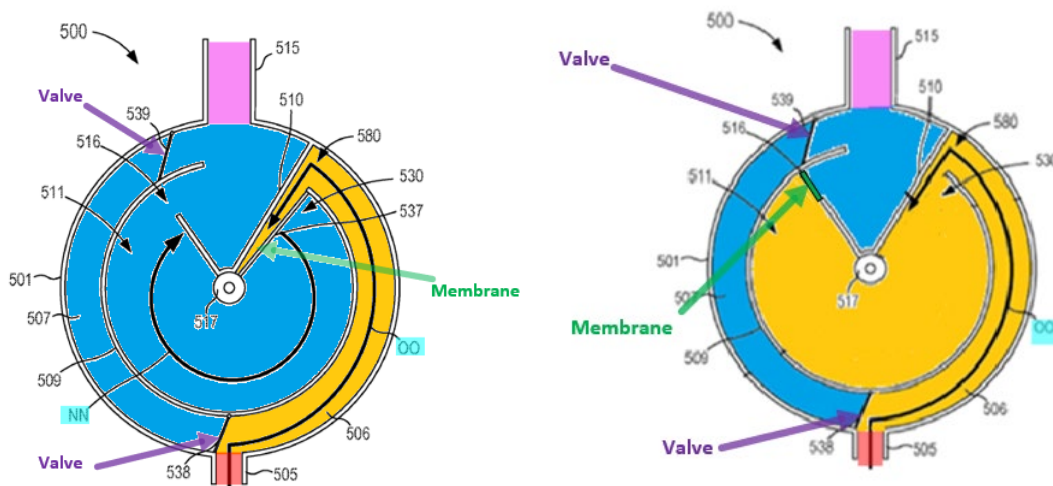
c. [1B]: “an outlet port;”

155. I previously explained how Bullington800’s proximal port 515 (**pink**) teaches “an outlet port.” Section XII.A.1.c, above. As I explained above in this section, Bullington800-Brancazio involves simply constructing first member 537 (**green**) from a blood-impermeable material (and, in the second, alternative implementation, securing it in place). Section XII.B, above. Bullington800-Brancazio thus teaches the claimed outlet port (**pink**) for the same reasons as Bullington800, and therefore renders obvious [1B] for the same reasons as I previously described. Section XII.A.1.c, above.

d. [1C]: “a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device;”

156. It is my opinion that Bullington800-Brancazio renders obvious [1C]. In Bullington800-Brancazio Drawing 1A and Bullington800-Brancazio Drawing 1B, both reproduced below and showing Bullington800-Brancazio in two different implementations of its first configuration, the device includes a first channel 506 that is “in fluid communication with” a fluid reservoir 580 (both in **yellow** below, and

the reservoir, either alone or in combination with the first channel, constitutes the claimed “chamber”). Ex. 1012, ¶¶[1108]-[1109], [1112], Figs. 16-17; *see also id.*, ¶¶[1107], [1113]-[1114]. The chamber (yellow) occupies a portion of the inner volume 511 of the device and that is isolated from other portions of the inner volume. Ex. 1012, ¶¶[1108]-[1109], [1112], Figs. 16-17; *see also id.*, ¶¶[1107], [1113]-[1114].



Bullington800-Brancazio Drawing 1A; Bullington800-Brancazio Drawing 1B

157. Bullington800-Brancazios Drawing 1A and 1B illustrate that the device is initially configured so that the chamber (yellow) is connected to, and in fluid communication with, the inlet port (red). Sections XII.A.1.c, XII.B, above. As I previously explained, the chamber (yellow) is configured to receive a first portion of a blood sample from a patient. Sections XII.A.1.c, XII.B, above; Ex. 1012, ¶¶[1112]-[1114], Figs. 16-17.

158. As I explained above in this section, Bullington800-Brancazio involves simply constructing first member 537 (**green**) from a blood-impermeable material to produce the membrane (**green**) shown above (and, in the second alternative configuration, securing the first member 537 (**green**) in place). Section XII.B, above. As I also described above, Bullington800-Brancazio also sequesters blood drawn into the chamber (**yellow**) by a drawing force. Section XII.B, above. Thus, like in Bullington800, in order for the chamber (**yellow**) of Bullington800-Brancazio to receive the first portion of the blood sample, the outlet port (**pink**) is coupled to a sample syringe (claimed “blood sample collection device”). Ex. 1012, ¶[1107]; *see also id.*, ¶¶[1111]-[1114], Figs. 16-17. Just as in Bullington800, the coupling of the sample syringe (e.g., a vacuum container) to the outlet port (**pink**) of Bullington800-Brancazio introduces a negative pressure in a portion of the inner volume 511 that exerts a suction force. Ex. 1012, ¶[1112], Fig. 16. The gas-permeable, but blood-impermeable, membrane (**green**) in the chamber (**yellow**), which separates the chamber (**yellow**) from the outlet port (**pink**), transmits the suction force from the negative pressure of the syringe (i.e., the claimed “drawing force applied from the outlet port from a blood sample collection device”) to draw blood from the patient into the chamber (**yellow**). Section XII.B, above; Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0042], [0048]-[0049], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

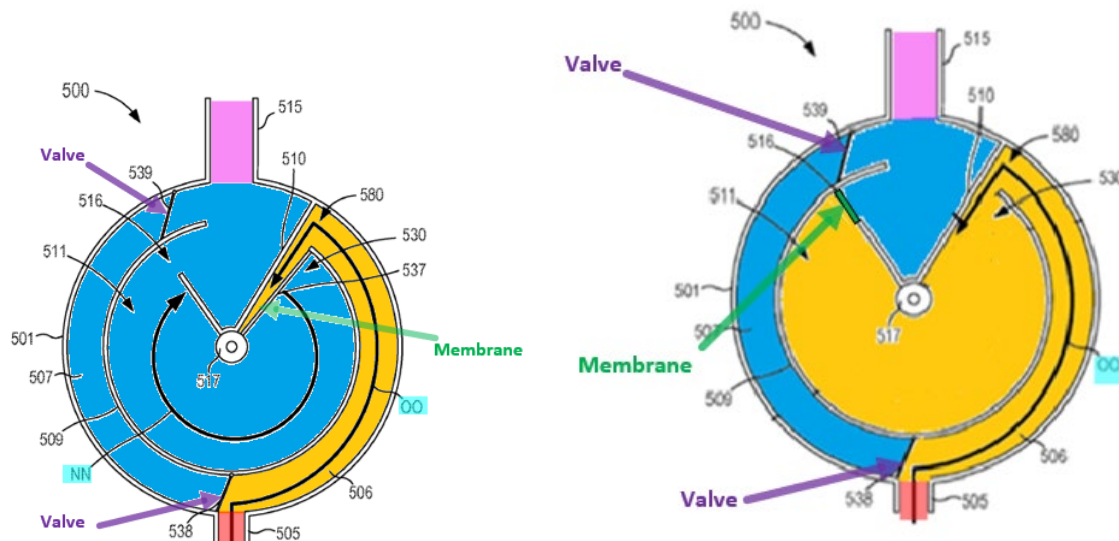
Throughout this process, the membrane (**green**), by nature of its blood-impermeable (i.e., hydrophobic) properties, would also prevent the blood in the chamber (**yellow**) from reaching the outlet port (**pink**), allowing the device to collect and sequester the blood in the chamber (**yellow**). Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

159. For the foregoing reasons, Bullington800-Brancazio renders obvious “a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device” and thus renders [1C] obvious.

- e. **[1D]: “a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port; and”**

160. As I explained above, it is my opinion that Bullington800 discloses [1D]. Section XII.A.1.e, above. And as I explained above in this section, Bullington800-Brancazio involves simply constructing the first member 537 (**green**) from a blood-impermeable material and, in the second, alternative implementation, securing the first member 537 (**green**) in its second configuration (i.e., where the chamber (**yellow**) is at its maximum volume). Section XII.B, above. Accordingly, Bullington800-Brancazio would have retained Bullington800’s second channel 507 that “can be selectively placed in fluid communication with the proximal port 515 and the distal port 505” and that, alone or in combination with the wedge-shaped

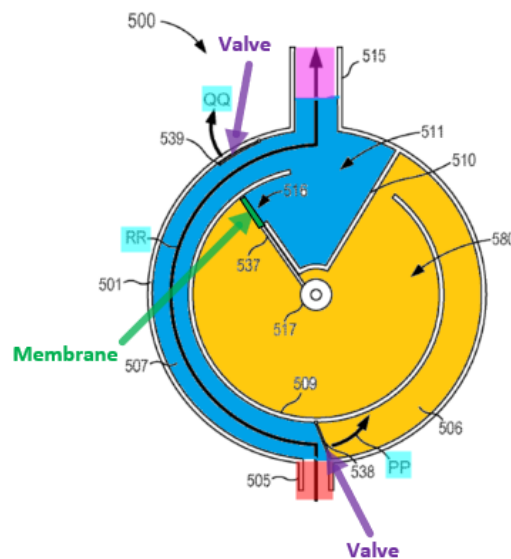
portion of the inner volume 511 (both **blue**), teaches the claimed “sampling channel.” Ex. 1012, ¶[1108]; Section XII.A.1.e, above. As I illustrate in the combined Bullington800-Brancazio Drawing 1A (below left) and Bullington800-Brancazio Drawing 1B (below right), the device is initially configured with the sampling channel isolated from the inlet port (**red**) and from the outlet port (**pink**) when the chamber (**yellow**) is in fluid communication with the inlet port (**red**). Ex. 1012, ¶[1111], Fig. 16; Sections XII.B.1.d-e, above.



Bullington800-Brancazio Drawing 1A; Bullington800-Brancazio Drawing 1B

161. Bullington800-Brancazio Drawings 1A and 1B (above) and Bullington800-Brancazio Drawing 2 (below) show how the sampling channel (**blue**) is “connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port” as claimed. Specifically, in Bullington800-Brancazio Drawing 2, once the initial portion of the blood sample has been

transferred to the chamber (yellow) (i.e., as shown by arrow OO in Bullington800-Brancazio Drawings 1A and 1B), second member 538 and third member 539 (both “valves,” purple) are rotated (i.e., as shown by arrows PP and QQ in Bullington800-Brancazio Drawing 2) to the second configuration. Ex. 1012, ¶[1114], Fig. 17; *see also id.*, ¶¶[1112]-[1113]; Section XII.A.1.e, above.



Bullington800-Brancazio Drawing 2

With the valves (purple) in their second configuration, the chamber (yellow) is isolated from the inlet port (red) and from the outlet port (pink) by a valve (purple) and by the blood-impermeable membrane (green) to sequester the predetermined volume of blood in the chamber (yellow). Ex. 1012, ¶[1114], Fig. 17; *see also id.*, ¶¶[1112]-[1113]; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. Like Bullington800’s Figure 17 configuration that I described above (Section XII.A.1.e), in the second configuration of Bullington800-

Brancazio (Bullington800-Brancazio Drawing 2) the sampling channel (**blue**) is placed in fluid communication with the inlet port (**red**) and the outlet port (**pink**) based on the valves (**purple**) opening. Ex. 1012, ¶[1114], Fig. 17. The inlet port (**red**) is thus placed in fluid communication with the sample syringe coupled to the outlet port (**pink**), via the sampling channel (**blue**), and the syringe “exert[s] a suction force through the proximal port 515, the second channel 507, the distal port 505...that can urge a flow of bodily-fluid from the patient to, for example, a sample reservoir defined by the syringe....” Ex. 1012, ¶[1114], Fig. 17. The suction force exerted by the syringe draws the subsequent blood through the sampling channel (**blue**) toward the syringe, and the blood travels through the outlet port (**pink**) to reach the syringe. Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17.

162. Accordingly, Bullington800-Brancazio renders obvious “a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port” and thus renders [1D] obvious to a POSITA. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17.

f. [1E]: “a housing that defines the inlet port, the sampling channel, and the outlet port.”

163. I previously explained how Bullington800 discloses and/or renders obvious that its device includes “a housing that defines the inlet port, the sampling channel, and the outlet port” as claimed. Section XII.A.1.f, above. As I explained above in this section, Bullington800-Brancazio involves simply constructing first

member 537 (**green**) from a blood-impermeable material (and, in the second, alternative implementation, securing the first member 537 (**green**) in its second configuration (i.e., where the chamber (**yellow**) is at its maximum volume)). Section XII.B, above. Bullington800-Brancazio thus leaves the housing unchanged in all aspects material to element [1E], and therefore renders obvious [1E] for the same reasons as I previously described. Section XII.A.1.f, above.

2. Dependent Claim 2

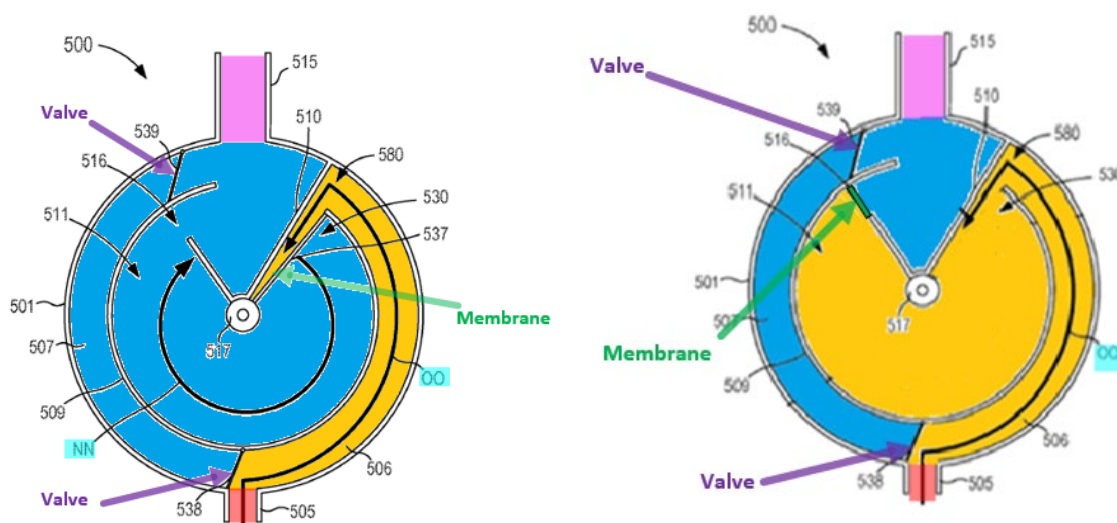
The device in accordance with claim 1, wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

164. Claim 2 of the '052 Patent depends from claim 1 and further requires “wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.” Ex. 1001, claim 2. As discussed above, claim 1 is taught by Bullington800-Brancazio. See Sections XII.B.1.a-f, above. As I discuss in more detail below, Bullington800-Brancazio also teaches a device that includes a “blood impermeable membrane” that “is configured to facilitate the chamber collecting the first portion of the blood sample.”

165. As I have explained above, Bullington800-Brancazio teaches the claimed chamber (**yellow**) that collects the first portion of the blood sample. Section XII.B.1.d, above. As I also explained above, a POSITA would have found it obvious, in producing Bullington800-Brancazio, to construct the first member 537

from a gas-permeable but blood-impermeable material as taught by Brancazio (claimed “blood impermeable membrane”). Section XII.B, above.

166. The membrane (**green**) is “configured to facilitate the chamber collecting the first portion of the blood sample” in at least two ways. First, as I previously explained, the blood-impermeable membrane (**green**) is, like Brancazio’s membrane, gas-permeable (Ex. 1013, ¶[0059]) and therefore transmits the negative pressure of the syringe that is exerted through the outlet port (**pink**) into the chamber (**yellow**), drawing the claimed “first portion of the blood sample” into the chamber (**yellow**) as shown by arrow **OO** below. Section XII.B.1.d, above; Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0042], [0048]-[0049], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. A POSITA would have understood that having a gas-permeable membrane (**green**) allows the vacuum force in Brancazio to be transmitted through the membrane, and the same would be true of Bullington800-Brancazio’s membrane (**green**) that is likewise made of a gas-permeable, blood-impermeable material. Ex. 1013, ¶¶[0042], [0048]-[0049], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

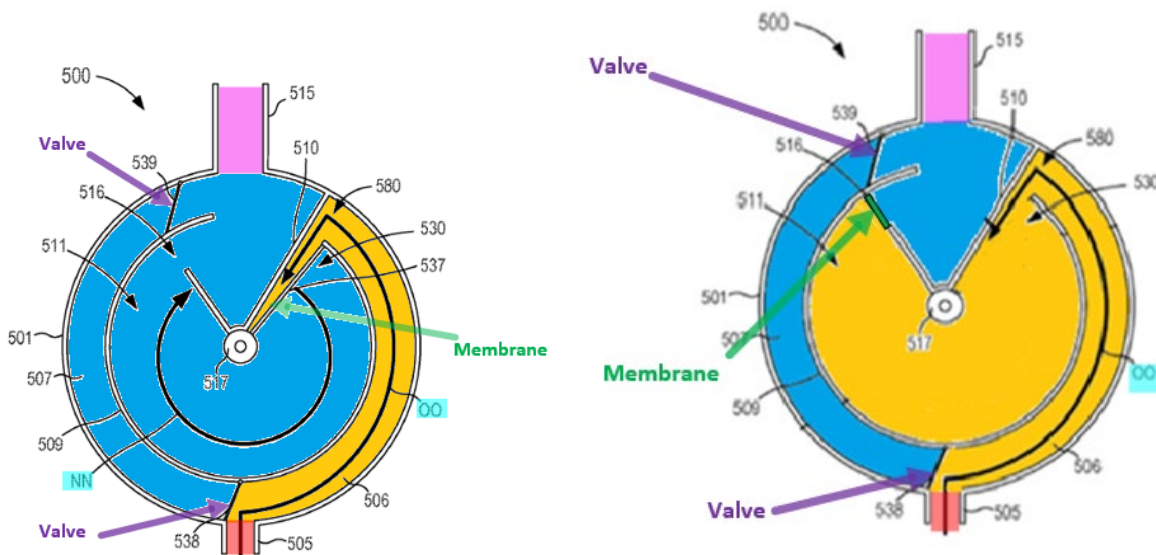


Bullington800-Brancazio Drawing 1A; Bullington800-Brancazio Drawing 1B

167. The second way in which the membrane (**green**) “is configured to facilitate the chamber collecting the first portion of the blood sample” is that the blood-impermeable membrane (**green**) prevents the blood that is in the chamber (**yellow**) from reaching the outlet port (**pink**) in both the first (Bullington800-Brancazio Drawings 1A and 1B, above) and second configurations (Bullington800-Brancazio Drawing 2, below), thus keeping the initial portion of the blood sample backed up (i.e., sequestered) within the chamber (**yellow**) and facilitating the chamber (**yellow**) collecting the first portion of the blood sample. Section XII.B.1.e, above; Ex. 1012, ¶[1114], Fig. 17; *see also* Ex. 1012, ¶¶[1112]-[1113]; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

sample to back up into the chamber following application of the drawing force applied from the outlet port.

169. Claim 3 of the '052 Patent depends from claim 1 and further requires “wherein a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.” Ex. 1001, claim 3. As discussed above, claim 1 is taught by Bullington800-Brancazio. See Sections XII.B.1.a-f, above. As I further explained above, the device taught by Bullington800-Brancazio includes a blood-impermeable membrane (**green**) that prevents the blood in the chamber (**yellow**) from reaching the outlet port (**pink**), keeping the initial portion of the blood sample that was drawn into the chamber (**yellow**) backed up (or sequestered) within the chamber (**yellow**). Section XII.B.2, above.



Bullington800-Brancazio Drawing 1A; Bullington800-Brancazio Drawing 1B

170. As I previously explained, a POSITA would have understood that the backing up caused by the blood-impermeable membrane (**green**) is also consistent with definitions of the term “back up” with which a POSITA would have been familiar. See Ex. 1029, p. 3 (“[t]o accumulate in a clogged state”); Ex. 1030, p. 3 (“an overflow caused by a stoppage, as in water or automobile traffic”).

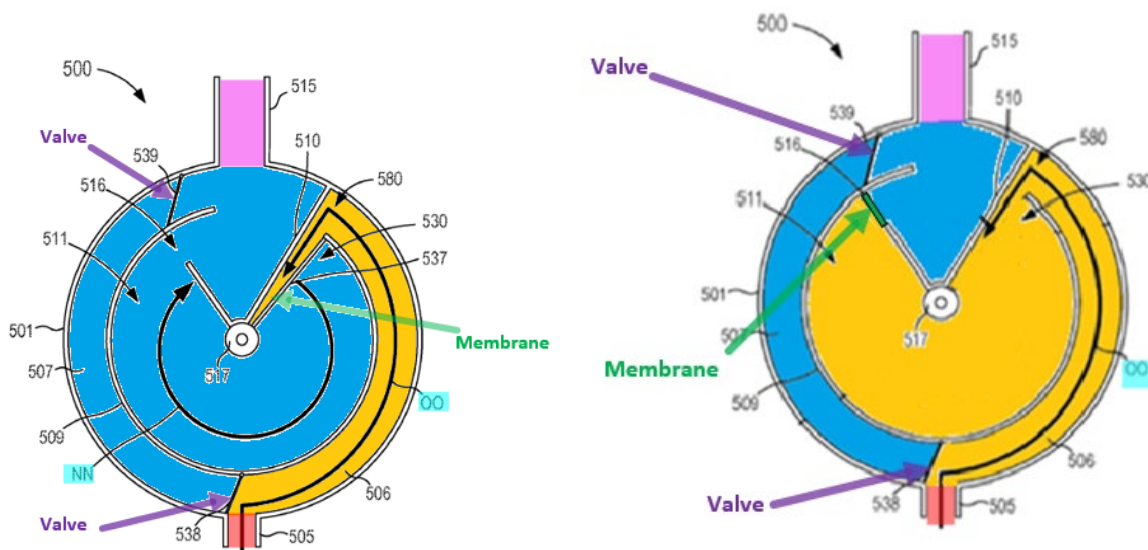
171. Accordingly, it is my opinion that Bullington800-Brancazio teaches the features of claim 3 and renders claim 3 obvious to a POSITA.

4. Dependent Claim 4

The device in accordance with claim 2, wherein the housing is separate from the blood impermeable membrane.

172. Claim 4 of the '052 Patent depends from claim 2 and further requires “wherein the housing is separate from the blood impermeable membrane.” Ex. 1001, claim 4. As discussed above, claim 2 is taught by Bullington800-Brancazio. See Sections XII.B.1.a-f, XII.B.2, above. As I further explained above, Bullington800 discloses and/or renders obvious a housing. Section XII.B.1.f, above. As I discuss in more detail below, Bullington800-Brancazio teaches that its housing is separate from the blood-impermeable membrane (**green**).

173. Bullington800-Brancazio Drawing 1A and Bullington800-Brancazio Drawing 1B, below, both show that the blood-impermeable membrane (**green**) is separate from the housing. First, the blood-impermeable membrane (**green**) is separate from the housing 501 that defines the outer boundary of the device:



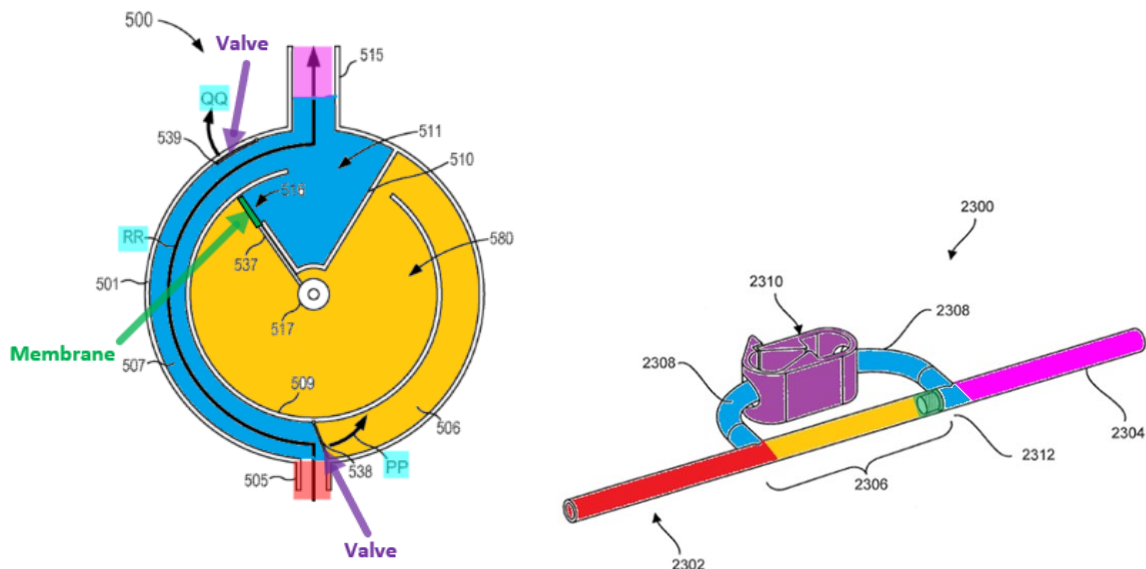
Bullington800-Brancazio Drawing 1A; Bullington800-Brancazio Drawing 1B

Ex. 1012, Figs. 16-17; *see also id.*, ¶¶[1107]-[1114].

174. Second, like Bullington800's first member 537 (the component that, in Bullington800-Brancazio, is constructed from a gas-permeable, blood-impermeable membrane material as taught by Brancazio), the blood-impermeable membrane (**green**) is a component separate from the inner portion of the housing 501 (which includes, the diverter 509 and the wall 510) that may be placed in contact with the housing 501. Sections XII.A.1.f, XII.B.1.f, above; Ex. 1012, ¶[1109], Figs. 16-17.

175. As I previously explained with respect to Bullington800, and as remains the case for Bullington800-Brancazio, the configuration of the blood-impermeable membrane (**green**) is consistent with the disclosures of the '052 Patent. For example, the '052 Patent describes that its sequestration chamber 2306 includes a hydrophobic plug 2312 (i.e., a hydrophobic membrane). Ex. 1001, 21:26-35; *see*

also *id.*, 5:28-47, Figs. 23A-23B. In the comparison of the '052 Patent to Bullington800-Brancazio that I include below, it can be clearly seen that the hydrophobic plug 2312 (green) of the '052 Patent contacts the walls of the sequestration chamber 2306 (yellow) similarly to how the blood-impermeable membrane (green) of Bullington800-Brancazio is placed in contact with the walls of the inner surface of the housing 501 (i.e., the walls of the diverter 509 and wedge-shaped portion 510). Ex. 1001, 5:28-47, 21:26-35, Figs. 23A-23B; Ex. 1012, ¶¶[1107], [1109], Figs. 16-17.



Bullington800-Brancazio Drawing 2; Ex. 1001, Fig. 23A (annotated)

176. Accordingly, it is my opinion that Bullington800-Brancazio teaches “wherein the housing is separate from the blood impermeable membrane.” Ex. 1001, 5:28-47, 21:26-35, Figs. 23A-23B, claim 4; Ex. 1012, ¶¶[1107], [1109], Figs. 16-17.

177. Additionally, the second member 538 of Bullington800-Brancazio (labeled as a “valve” (purple) in the above drawings) would have the same qualities as the second member 538 from Bullington800 in all material respects, and thus the second member 538 also teaches the claimed “blood impermeable membrane” that is separate from the housing for the reasons I previously described with respect to Bullington800. Section XII.A.4, above. For all the above reasons, Bullington800-Brancazio teaches all the features of claim 4 and renders claim 4 obvious to a POSITA.

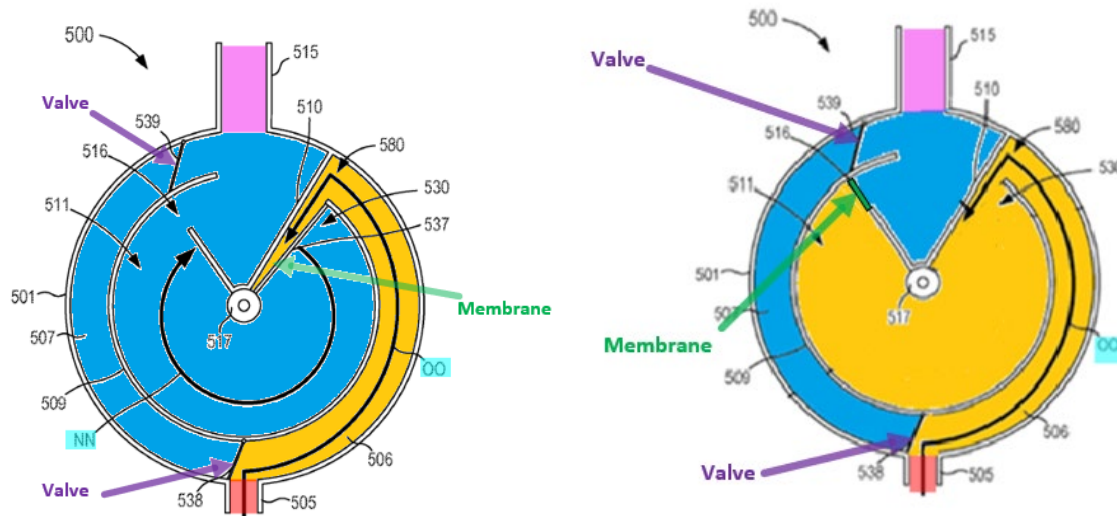
5. Dependent Claim 5

The device in accordance with claim 1, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

178. Claim 5 of the '052 Patent depends from claim 1 and further requires “wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.” Ex. 1001, claim 5. As discussed above, claim 1 is taught by Bullington800-Brancazio. See Sections XII.B.1.a-f, above. As I further explained above, Bullington800 (and thus, Bullington800-Brancazio) teaches a chamber (yellow) that collects a first portion of blood when a drawing force is applied at the outlet port (pink) (i.e., by a sample syringe or the like). Section XII.B.1.c-d, above. Bullington800-Brancazio also teaches claim 5’s

requirement that “when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.” As shown below in Bullington800-Brancazio Drawings 1A and 1B, by arrow **OO**, the flow of the first portion of the blood sample into the chamber (**yellow**) eventually contacts the diverter 509, wedge-shaped portion 510, the exterior wall of housing 501, and the blood-impermeable membrane (**green**).

Ex. 1012, ¶¶[1112]-[1113], Fig. 16; Section XII.B.2, above.



Bullington800-Brancazio Drawing 1A; Bullington800-Brancazio Drawing 1B

179. The blood-impermeable membrane (**green**) is, obviously, constructed of a material that is blood-impermeable (as described in Brancazio). Sections XII.B, XII.B.2, above. Further, as I explained previously, the diverter 509, wedge-shaped portion 510, the exterior wall of housing 501 are also made of a blood-impermeable

material because they keep the blood sequestered in the chamber (yellow). Section XII.A.5, above; Ex. 1012, ¶¶[1112]-[1113], Fig. 16.

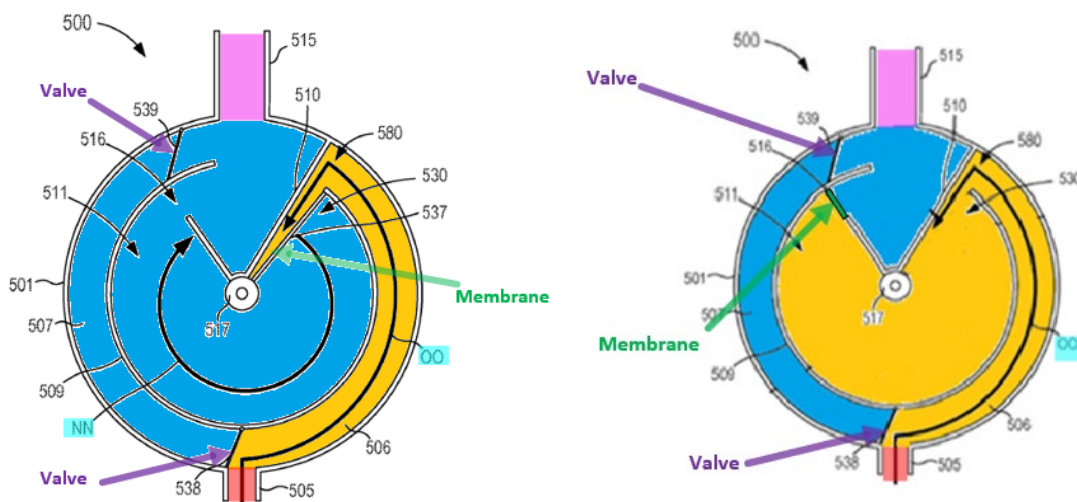
180. Accordingly, for the reasons I explained above, Bullington800-Brancazio teaches all the features of claim 5 and renders claim 5 obvious.

6. Dependent Claim 6

The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel.

181. Claim 6 of the '052 Patent depends from claim 1 and further requires “a valve configured to initially close off the sampling channel.” Ex. 1001, claim 6. As discussed above, claim 1 is taught by Bullington800-Brancazio. See Sections XII.B.1.a-f, above. As I further explained above, Bullington800-Brancazio teaches a sampling channel (blue) that is selectively placed in fluid communication with the outlet port (pink) to convey a subsequent portion of the blood sample to the outlet port (pink). Section XII.B.1.e, above; Ex. 1012, ¶[1108]; *see also* Ex. 1012, ¶¶[1109]-[1111], [1114], Figs. 16-17, above. I also previously explained that Bullington800 discloses that each of the first member 537, the second member 538, and the third member 539 each close off the sampling channel (blue). Section XII.A.6, above; Ex. 1012, ¶[1111], Fig. 16. Bullington800-Brancazio implements (in either the first implementation or the second alternative implementation I described at Section XII.B) the movable first member 537 with a blood-impermeable membrane (green), but as shown below the second member 538 and the third

member 539 (“valves,” **purple**) each render claim 6 obvious for the same reasons that I previously explained for claim 6. Ex. 1012, ¶[1111], Fig. 16; Section XII.A.6, above. Each of second member 538 and third member 539 is “a valve configured to initially close off the sampling channel” as claimed, as is the combination of second member 538 and third member 539.



Bullington800-Brancazio Drawing 1A; Bullington800-Brancazio Drawing 1B

182. Accordingly, it is my opinion that Bullington800-Brancazio teaches the features of claim 6 and thus renders claim 6 obvious.

7. Dependent Claims 7-12

183. As I have previously explained above, Bullington800 discloses or renders obvious claims 7-12. Section XII.A.7-12, above. In Bullington800-Brancazio, a POSITA would merely have implemented the first member 537 with a gas-permeable, blood-impermeable (i.e., hydrophobic) membrane as described in Brancazio (and, in the second, alternative configuration that simplifies the design,

securing Bullington800's first member 537 member in its second configuration (where the volume of the chamber is at its maximum) and. Section XII.B, above. The incorporation of Brancazio's teachings in Bullington800-Brancazio does not change how Bullington800 discloses and/or renders obvious the features of claims 7-12. See Sections XII.A.7-12, above; Ex. 1012, ¶¶[1106]-[1114], Figs. 16-17. Accordingly, it is my opinion that Bullington800-Brancazio teaches claims 7-12 and renders these claims obvious to a POSITA for the reasons that I described above with respect to Bullington800 alone. Sections XII.A.7-12.

8. Independent Claim 13

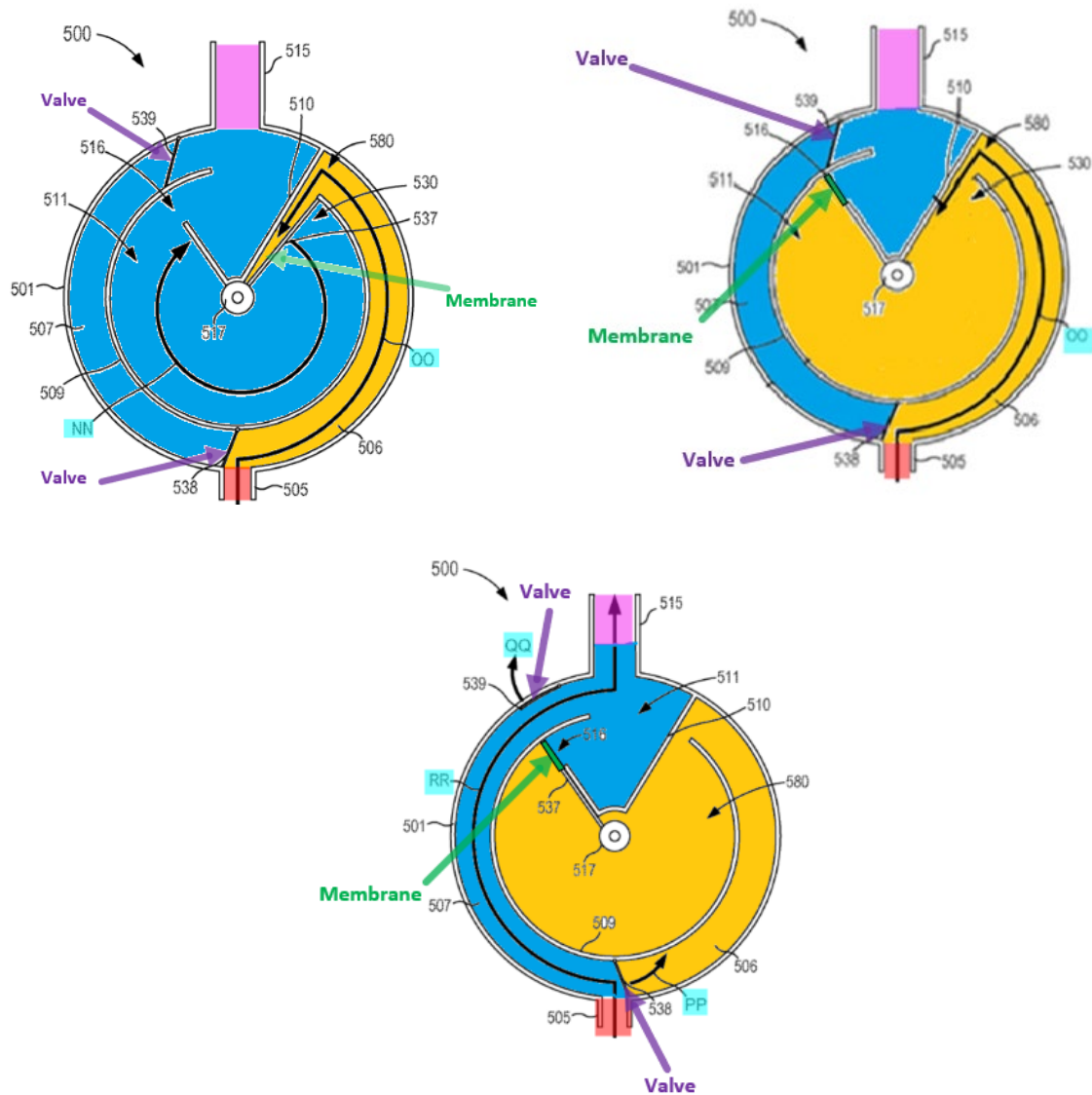
a. [13PRE]: "A device comprising:"

184. This preamble is identical to claim 1, and as I explained, Bullington800-Brancazio renders obvious preamble [1PRE]. Section XII.B.1.a, above. For the reasons I explain in more detail below, Bullington800-Brancazio teaches the remaining elements [13A]-[13E] of claim 13. Sections XII.B.8.b-f, below. Therefore, Bullington800-Brancazio renders obvious [13PRE].

b. [13A]: "an inlet port for receiving blood;"

185. Limitation [13A] is nearly identical to [1A] and, as I explained above, Bullington800-Brancazio teaches "an inlet port for receiving a blood sample" as recited in [1A]. Section XII.B.1.b, above. Specifically, the distal port 505 (**red**) is the claimed "inlet port" and, because this inlet port (**red**) receives blood samples, it is "an inlet port for receiving blood" as claimed. Section XII.B.1.b, above; Ex. 1012,

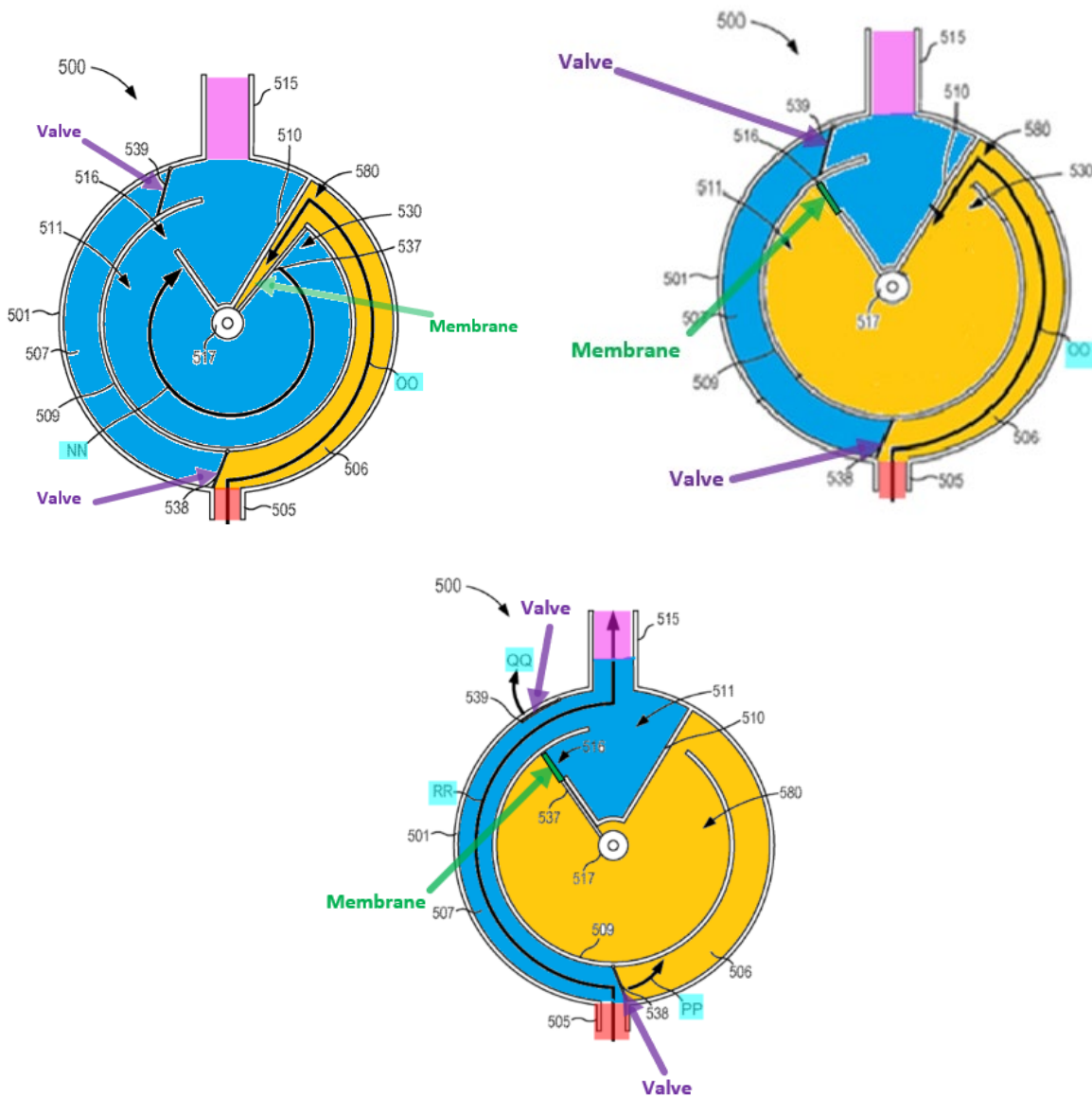
¶¶[1043], [1050], [1055], [1108], [1111]-[1112], [1114], Figs. 16-17. Therefore, Bullington800-Brancazio renders obvious [13A].



Bullington800-Brancazio Drawing 1A (upper right); Bullington800-Brancazio Drawing 1B (upper left); Bullington800-Brancazio Drawing 2 (lower middle)

c. [13B]: “an outlet port;”

186. Limitation [13B] is identical to [1B] and, as I explained above, Bullington800 discloses a proximal port 515 (pink) that is an “outlet port” as claimed. Sections XII.A.1.c, XII.B.1.c, above; Ex. 1012, ¶¶[1108], [1111], [1114], Figs. 16-17.



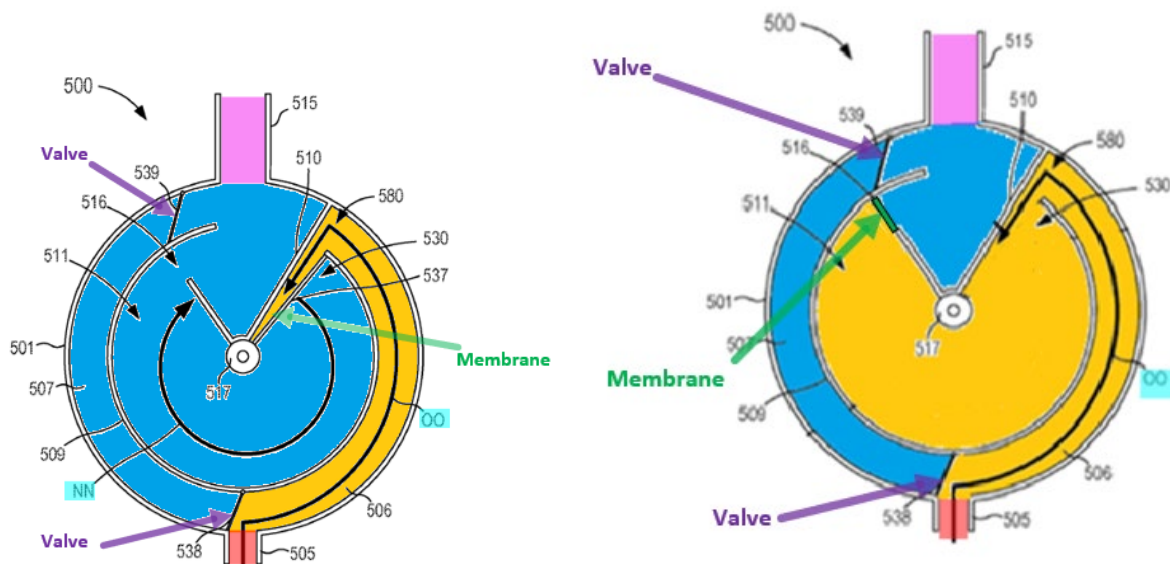
Bullington800-Brancazio Drawing 1A (upper left); Bullington800-Brancazio Drawing 1B (upper right); Bullington800-Brancazio Drawing 2 (lower, middle)

187. Accordingly, Bullington800-Brancazio, which includes the outlet port (**pink**), renders obvious [13B].

- d. **[13C]: “a chamber comprising a flexible material, the chamber connected with the inlet port and configured to collect a first portion of the blood when under a drawing force applied from the outlet port;”**

188. It is my opinion that Bullington800-Brancazio renders [13C] obvious. As I explained above for [1C], Bullington800-Brancazio teaches a device that includes a chamber (**yellow**) that is “in fluid communication with” and connected with the inlet port (**red**). Section XII.B.1.d, above. Bullington800-Brancazio also teaches that its chamber (**yellow**) collects the first portion of a blood sample when under a drawing force applied from the outlet port (**pink**). *Id.* Therefore, for the same reasons as I set forth for [1C] above, Bullington800-Brancazio teaches “the chamber connected with the inlet port and configured to collect a first portion of the blood when under a drawing force applied from the outlet port” as claimed. *Id.* For the reasons I explain below, it is also my opinion that the combination of Bullington800 and Brancazio renders “a chamber comprising a flexible material” obvious.

189. As I previously explained and as shown below, the chamber (yellow) in Bullington800-Brancazio includes a blood-impermeable membrane (green) (that is either movable, in a first implementation, or secured in place, in a second alternative implementation). Section XII.B.1.d, above; Ex. 1013, ¶¶[0042], [0048]-[0049], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.



Bullington800-Brancazio Drawing 1A; Bullington800-Brancazio Drawing 1B

190. Brancazio does not explicitly say whether its blood-impermeable membrane, is “flexible” as recited in [13C]. However, Brancazio does describe that various components can be flexible. Ex. 1013, ¶¶[0222]-[0223]. And it was well-known prior to the ’052 Patent for a membrane, such as the hydrophobic/blood-impermeable membrane of Brancazio, to be made of a flexible material. Section VIII.A, above; Ex. 1015, 1:6-62, 2:13-38; Ex. 1016, 5:52-57, Abstract; Ex. 1017,

Abstract, ¶¶[0064]-[0065]; Ex. 1018, 1:39-49, 4:62-67. Bullington800 also already describes the use of a flexible material in constructing the first member 537. Ex. 1012, ¶[1109]. Therefore, it is my opinion that it would have been obvious to a POSITA that the first member 537 in Bullington800-Brancazio, constructed from a blood-impermeable and air-permeable material as described in Brancazio, would have still been constructed from a flexible material.

191. To any extent it is argued that the blood-impermeable membrane (**green**) in Bullington800-Brancazio is not taught, by Brancazio and Bullington800 and based on what was well-known for such hydrophobic membranes prior to the '052 Patent, to be made of a flexible material, it is my opinion that it still would have been obvious to a POSITA to construct the blood-impermeable membrane (**green**) in Bullington800 and Brancazio out of a flexible material. A POSITA would have been motivated (see Section IV, above, referring to obviousness rationale (G)) to make the blood-impermeable membrane (**green**) out of a flexible material because doing so would advantageously produce an improved seal between the blood-impermeable membrane (**green**) and the portions of the housing 501 that are adjacent to, and in contact with, the blood-impermeable membrane (**green**). A POSITA would have had the mechanical engineering and design experience to understand that flexible materials are better able to seal against a surface, like the housing 501. And, using a flexible material such as flexible fibers or

polytetrafluoroethylene (PTFE) would advantageously increase the likelihood of the blood-impermeable membrane (**green**) working properly in transmitting gas while also preventing the passage of liquid (e.g., blood). Section VIII.A, above; Ex. 1033, 4:46-62, 5:25-30, 6:1-9, 6:17-26, Figs. 4, 11-13; *see also* Ex. 1032, Abstract, 6:14-49, 7:6-12, claims 1, 5; Ex. 1034, 7:43-66, 11:18-42, 15:65-16:12 (describing using a hydrophobic gas-permeable fiber membrane allow gas to pass through the membrane in devices that collect blood). It is my opinion that a POSITA would have known that this type of hydrophobic membrane is also inexpensive to manufacture and would be flexible by nature; I have used such hydrophobic membranes in my experience since at least 1992, all of which were made of non-woven fibers, which are naturally flexible. Ex. 1034, 7:43-66, 11:18-42, 15:65-16:12 (describing using a hydrophobic gas-permeable fiber membrane allow gas to pass through the membrane in devices that collect blood). All of the above flexible materials would be capable of being flexed, bent, stretched, expanded, or compressed under normal conditions. Indeed, because the hydrophobic membranes discussed above are used in devices that require the membrane to withstand liquid pressure caused by prevent blood from flowing through the membrane, the hydrophobic membranes are capable of being flexed, bent, stretched, expanded, or compressed to withstand the increased liquid pressure caused by blood backing up.

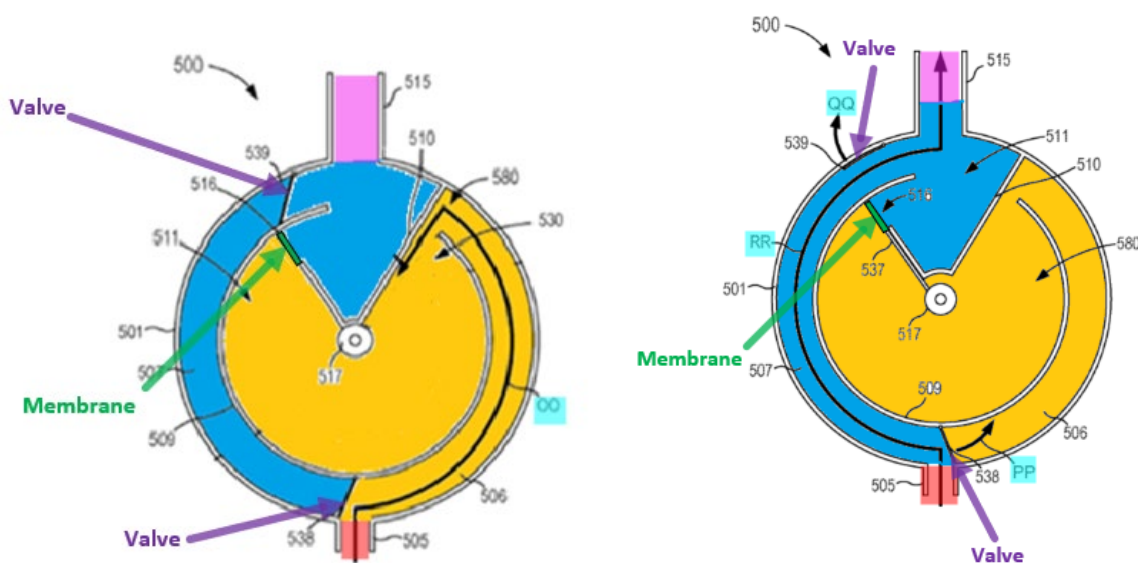
Therefore, any of these membranes would meet the agreed upon definition of “flexible material” described at Section XI, above.

192. There are other rationales that also support my opinion that it would have been obvious to construct the blood-impermeable membrane (green) out of a flexible material. For example, constructing the blood-impermeable (i.e., hydrophobic) membrane (green) would have been obvious to try (Section IV, above (referring to obviousness rationale (E))) because using a flexible material for hydrophobic/blood-impermeable membranes is one of a finite number of identified, predictable solutions for systems utilizing such a membrane. Namely, the use of a flexible material is one of only two options (flexible and inflexible), and as I explained above the use of flexible materials for hydrophobic membranes was an identified and predictable solution for systems utilizing a hydrophobic membrane. Ex. 1014, ¶¶[0007]-[0008], [0052]; Ex. 1015, 1:6-62, 2:13-38; Ex. 1016, 5:52-57, Abstract; Ex. 1017, Abstract, ¶¶[0064]-[0065]; Ex. 1018, 1:39-49, 4:62-67. I also note that Brancazio already describes that “various components of the invention are fabricated from polymeric and/or flexible and/or elastomeric materials.” Ex. 1013, ¶¶[0222]-[0223]. Accordingly, it is my opinion that it would have been obvious to try to construct the hydrophobic/blood-impermeable membrane of Bullington800-Brancazio out of a flexible material.

Bullington800-Brancazio render [13C] obvious.

e. **[13D]: “a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port; and”**

194. Limitation [13D] is nearly identical to [1D] except that [13D] recites “a subsequent portion of the blood” rather than “a subsequent portion of the blood sample.” Ex. 1001, claims 1, 13. As I have previously explained, Bullington⁸⁰⁰-Brancazio renders obvious [1D]. Section XII.B.1.e, above. A POSITA would have understood that the sampling channel (blue) that conveys the subsequent portion of the blood sample to the outlet port (pink) (i.e., as shown by arrow RR) similarly discloses conveying “a subsequent portion of the blood” as claimed in [13D]. See Section XII.A.1.e, above.



Bullington800-Brancazio Drawing 1; Bullington800-Brancazio Drawing 2

195. Accordingly, it is my opinion that Bullington800-Brancazio renders obvious [13D].

f. [13E]: “a housing that defines the inlet port, the sampling channel, and the outlet port.”

196. Limitation [13E] is identical to [1E], which is taught by Bullington800-Brancazio for the reasons I described above. Section XII.B.1.f, above. Accordingly, Bullington800-Brancazio renders obvious [13E] and thus renders all of claim 13 obvious. Sections XII.B.8.a-f, above.

9. Dependent Claims 14-24

197. Each of dependent claims 14-24 corresponds to one of claims 2-12. As such, I have not repeated all of my analysis from above for claims 14-24. Instead, I have prepared the following table to show the claim language side-by-side and to address any minor differences. Specifically, the following tables show how dependent claims 14-24 are taught by Bullington800-Brancazio for the same reasons that claims 2-12 are taught by Bullington800-Brancazio.

Claims 2-12	Claims 14-24	Comparison
[2] The device in accordance with claim 1, wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.	[14] The device in accordance with claim 13, wherein the flexible material is a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood.	Aside from their dependencies, the claims are nearly identical. Claim 14 recites “wherein the flexible material is a blood impermeable membrane...” which is taught by the blood-

		impermeable membrane and/or the second member 538 (also a blood-impermeable membrane) of Bullington800-Brancazio, as discussed for claim 2. See Sections XII.B.2, XII.B.1.c, above. Claim 14 also recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800-Brancazio renders obvious claim 2. Accordingly, Bullington800-Brancazio renders obvious claim 14 for the same reasons Bullington800-Brancazio renders obvious claim 2. See Section XII.B.2, above.
[3] The device in accordance with claim 1, wherein a blood impermeable membrane	[15] The device in accordance with claim 13, wherein the flexible material is a blood	Aside from their dependencies, the claims are nearly identical. Claim 15

causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.	impermeable membrane causes the first portion of the blood to back up into the chamber following application of the drawing force applied from the outlet port.	recites “wherein the flexible material is a blood impermeable membrane...” which is taught by the blood-impermeable membrane (and/or by the second member 538, also a blood-impermeable membrane) of Bullington800-Brancazio, as discussed for claim 3. See Sections XII.B.3, XII.B.1.c, above. Claim 15 also recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800-Brancazio renders obvious claim 15 for the same reasons Bullington800-Brancazio renders obvious claim 3. See Section XII.B.3, above. Thus, claim 15 is disclosed for the same reasons as claim
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		3. See Section XII.B.3, above.
[4] The device in accordance with claim 2, wherein the housing is separate from the blood impermeable membrane.	[16] The device in accordance with claim 14, wherein the housing is separate from the blood impermeable membrane.	Aside from their dependencies and statutory class, the claims are identical. Thus, claim 16 is taught by Bullington800-Brancazio for the same reasons as claim 4. See Section XII.B.4, above.
[5] The device in accordance with claim 1, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.	[17] The device in accordance with claim 13, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.	Aside from their dependencies, the claims are nearly identical. Claim 17 recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800-Brancazio renders obvious claim 17 for the same reasons Bullington800-Brancazio renders obvious claim 5. See Section XII.B.5, above. Thus, claim 17 is disclosed for the same reasons as claim

		5. See Section XII.B.5, above.
[6] The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel.	[18] The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel.	Aside from their dependencies, the claims are identical. Thus, claim 18 is taught by Bullington800-Brancazio for the same reasons as claim 6. See Section XII.B.6, above.
[7] The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.	[19] The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.	Aside from their dependencies, the claims are nearly identical. Claim 19 recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800-Brancazio renders obvious claim 19 for the same reasons Bullington800-Brancazio renders obvious claim 7. See Section XII.B.7, above. Thus, Bullington800-Brancazio renders obvious claim 19. See

		Section XII.B.7, above.
[8] The device in accordance with claim 1, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.	[20] The device in accordance with claim 13, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, follow-on amounts of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.	Aside from their dependencies and minor wording differences (e.g., “the first portion of the blood sample” vs. “the first portion of the blood”) that do not change how Bullington800-Brancazio renders obvious claims 8 and 20, the claims are identical. Thus, claim 20 is taught by Bullington800-Brancazio for the same reasons as claim 8. See Section XII.B.7, above.
[9] The device in accordance with claim 6, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.	[21] The device in accordance with claim 18, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.	Aside from their dependencies, the claims are nearly identical. Claim 21 recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800-Brancazio renders

		obvious claim 21 for the same reasons Bullington800- Brancazio renders obvious claim 9. See Section XII.B.7, above. Thus, Bullington800- Brancazio renders obvious claim 9. See Section XII.B.7, above.
[10] The device in accordance with claim 1, further comprising a patient needle and the blood sample collection device.	[22] The device in accordance with claim 13, further comprising a patient needle and a sample collection device.	Aside from their dependencies, the claims are identical. Thus, claim 22 is taught by Bullington800- Brancazio for the same reasons as claim 10. See Section XII.B.7, above.
[11] The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.	[23] The device in accordance with claim 13, the chamber having a volume sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.	Aside from their dependencies, the claims are nearly identical. Claim 23 recites “the first portion of the blood” rather than “the first portion of the blood sample,” which does not change how Bullington800- Brancazio renders

		obvious claim 23 for the same reasons Bullington800- Brancazio renders obvious claim 11. See Section XII.B.7, above. Thus, Bullington800- Brancazio renders obvious claim 11. See Section XII.B.7, above.
[12] The device in accordance with claim 1, wherein the chamber has a volume of less than 1.5 cubic centimeters.	[24] The device in accordance with claim 13, wherein the chamber has a volume of less than 1.5 cubic centimeters.	Aside from their dependencies, the claims are identical. Thus, claim 24 is taught by Bullington800- Brancazio for the same reasons as claim 12. See Section XII.B.7, above.

C. Bullington800 In View Of Brancazio And Liu

198. I have previously explained how Bullington800-Brancazio renders obvious the features of claim 13, including that the chamber comprises “a flexible material.” See Section XII.B.1.d, above; *see also* Sections XII.B.8.a-c, XII.B.8.e-f, above. I explained that it is my opinion that a POSITA would have been motivated to construct the blood-impermeable (e.g., hydrophobic) membrane in

Bullington800-Brancazio using a flexible material. Section XII.B.8.d, above; Ex. 1015, 1:6-62, 2:13-38; Ex. 1016, 5:52-57, Abstract; Ex. 1017, Abstract, ¶¶[0064]-[0065]; Ex. 1018, 1:39-49, 4:62-67; Ex. 1013, ¶¶[0222]-[0223]. However, I have been asked to consider a scenario where it is argued that it would not have been obvious for Bullington800-Brancazio to include, in the chamber, a blood-impermeable membrane made of a flexible material. To any extent that this argument is made, it is also my opinion that it also would have been obvious to combine Bullington800 and Brancazio with Liu, and that the combination of these references teaches a chamber comprising a flexible material and renders claims 13-24 obvious.

199. As I addressed above, Liu describes the use of a “flexible gas-permeable hydrophobic membrane” to seal an outlet of a fluid channel. Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022]; Section IX.C, above. Liu describes a number of example flexible materials for its hydrophobic membrane. For example, Liu describes that the hydrophobic membrane may be made of a material such as PTFE that flexes under pressure from a fluid source in the fluid channel but, importantly, prevents the fluid from traversing the membrane due to its high hydrophobicity. Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]. Because the materials in Liu are flexible and withstand pressure from a fluid source, they are materials that can be flexed, bent, stretched, expanded, or compressed without breaking under normal

conditions (or even under increased pressure from the fluid) and easily hand-folded, flexed, twisted, and bent. Therefore, Liu’s flexible materials meet the agreed upon construction described at Section XI, above. Liu also describes using the hydrophobic membrane in a system that is similar to the ’052 Patent in that both systems use pressure to cause fluid to flow towards the membrane. *Id.*; See Section XII.B.3, above.

200. A POSITA would have found the combination of Bullington800, Brancazio, and Liu (“Bullington800-Brancazio-Liu”) obvious. In the combination, the device I have described above for Bullington800-Brancazio would continue to operate in the same manner that I described previously, with the blood-impermeable membrane (**green**) being constructed—in either the first implementation of Bullington800-Brancazio where the blood-impermeable membrane (**green**) is movable or the second alternative implementation where the blood-impermeable membrane (**green**) is secured in place—of a flexible gas-permeable hydrophobic material such as described in Liu. Section XII.B, above; Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052].

201. It is my opinion that there are a number of reasons a POSITA would have been motivated to combine the device of Bullington, in view of Brancazio, with Liu’s flexible gas-permeable hydrophobic membrane. See Section IV, above (referring to obviousness rationale (G)). For example, Liu describes that flexible

gas-permeable hydrophobic membranes are made of materials that are known for having a high hydrophobicity. Ex. 1014, ¶[0052]; *see also id.* ¶¶[0007]-[0008], [0021]-[0022]; Ex. 1015, 1:6-62, 2:13-38. Bullington800 and Brancazio both recognized the importance of avoiding contamination, by liquid bodily-fluids such as blood, of medical devices related to drawing blood from patients. Ex. 1012, ¶¶[1002]-[1006], [1030], [1050]-[1051], [1112], [1114]; Ex. 1013, ¶[0103]; *see also* Ex. 1013, ¶¶[0059], [0090], [0111], [0115], [0153]-[0154], [0157]. Therefore, a POSITA would have understood that Liu advantageously provides a material, specifically known for having a high hydrophobicity, that would have been beneficial to use as the material for the blood-impermeable membrane in Bullington800-Brancazio. For example, doing so would have minimized or eliminated any chance of blood traversing the blood-impermeable membrane (**green**) to enter the sampling channel (**blue**) and/or the outlet port (**pink**). Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]; Ex. 1012, ¶¶[1002]-[1006], [1030], [1050]-[1051], [1112], [1114]; Ex. 1013, ¶[0103]; *see also* Ex. 1013, ¶¶[0059], [0090], [0111], [0115], [0153]-[0154], [0157]. Additionally, a POSITA would have understood that Liu's flexible hydrophobic membrane material provides the additional benefit, as I described above, of allowing the membrane to bend, distort its shape, or the like, which would have allowed the blood-impermeable membrane (**green**) to form a complete seal with the adjacent walls of the housing 501 and/or

diverter 509 (which is part of housing 501). And as I have explained previously, a POSITA would have known that the use of flexible hydrophobic membranes can filter air and prevent liquid and blood passage. Flexible fiber-like hydrophobic membranes and/or PTFE membranes are an obvious inexpensive design choice that was well-known in the art. Sections VIII.A, XII.B.1.d, above; Ex. 1033, 4:46-62, 5:25-30, 6:1-9, 6:17-26, Figs. 4, 11-13; *see also* Ex. 1032, Abstract, 6:14-49, 7:6-12, claims 1, 5; Ex. 1034, 7:43-66, 11:18-34, 15:65-16:12; Ex. 1014, ¶¶[0031], [0037], Fig. 1.

202. There are other rationales that further support my opinion that it would have been obvious to combine Bullington800 and Brancazio with Liu. For example, the combination would have been the simple combination of known prior art elements according to known methods in order to yield predictable results. See Section IV, above (referring to obviousness rationale (A)). The known elements are the device of Bullington800 combined with Brancazio, having a first chamber for storing potentially contaminated blood and that is isolated from a second chamber (i.e., for collecting subsequent portions of blood) by a gas-permeable, blood-impermeable membrane, and Liu's gas-permeable, blood-impermeable membrane made from flexible materials (i.e., ones that can be flexed, bent, stretched, expanded, or compressed without breaking under normal conditions and easily hand-folded, flexed, twisted, and bent) with a high hydrophobicity (e.g., PTFE). Ex. 1012,

¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0003], [0013], [0041]-[0042], [0052], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]. The known method for the combination would have been the simple use of a flexible, hydrophobic material such as those taught by Liu when constructing the blood-impermeable membrane for the device produced by Bullington800-Brancazio. Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]. Bullington800-Brancazio-Liu would have yielded predictable results; namely, that the membrane used in the combined device to sequester the chamber from the sampling channel would have been made of a gas-permeable, blood-impermeable, and flexible material that is useful for passing and filtering air and for blocking the flow of liquid such as blood. Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]; *see also* Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

203. Additionally, Bullington800-Brancazio-Liu would have been obvious to try as one of a finite number of identified, predictable solutions for systems (like Bullington800-Brancazio) that utilize a hydrophobic membrane. See Section IV, above (referring to obviousness rationale (E)). Specifically, the use of a flexible material for hydrophobic membranes, such as the flexible materials described by Liu (e.g., PTFE), is one of only two solutions (flexible and inflexible) for selecting a

material to use as/use to construct the blood-impermeable membrane of Bullington800-Brancazio. Accordingly, it is my opinion that a POSITA would have found it obvious, when combining Bullington800 and Brancazio with the motivations I described above (Section XII.B, above), to try Liu's flexible material having a high hydrophobicity as one of a finite number of identified materials for producing a hydrophobic membrane. Ex. 1014, ¶¶[0007]-[0008], [0052].

204. Finally, it is my opinion that a POSITA would have had a reasonable expectation of success in producing Bullington800-Brancazio-Liu. The combination merely involves routine and simple mechanical design techniques with known, predictable results (e.g., using a flexible, hydrophobic material as an air-permeable, blood-impermeable membrane). Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]; *see also* Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. Liu's flexible material is a known material for making hydrophobic membranes. Ex. 1014, ¶¶[0007]-[0008], [0052]. A POSITA would have had the mechanical design skills to implement that material into the device of Bullington800-Brancazio to produce Bullington800-Brancazio-Liu.

1. Independent Claim 13

a. [13PRE]: "A device comprising:"

205. I previously explained that Bullington800-Brancazio renders [13PRE] obvious. Section XII.B.8.a, above. Bullington800-Brancazio-Liu involves the

simple use of Liu's flexible hydrophobic material to construct the blood-impermeable membrane, and thus Bullington800-Brancazio-Liu does not change how Bullington800-Brancazio renders obvious [13PRE]. Section XII.C, above. Therefore, and for the reasons set forth below, Bullington800-Brancazio-Liu renders [13PRE] obvious.

b. [13A]: “an inlet port for receiving blood;”

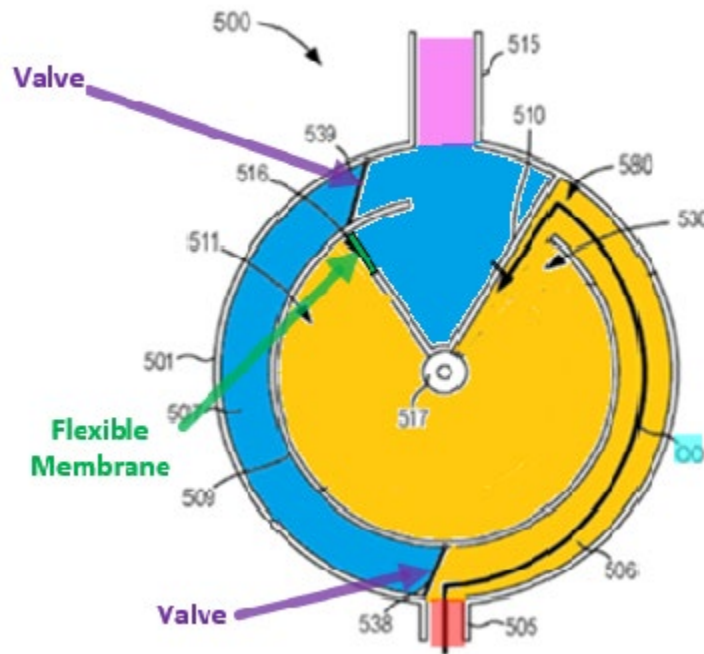
206. I previously explained that Bullington800-Brancazio renders [13A] obvious. Section XII.B.8.b, above. Bullington800-Brancazio-Liu involves the simple use of Liu's flexible hydrophobic material to construct the blood-impermeable membrane, and thus Bullington800-Brancazio-Liu does not change how Bullington800-Brancazio teaches [13A]. Section XII.C, above. Therefore, Bullington800-Brancazio-Liu render [13A] obvious.

c. [13B]: “an outlet port;”

207. I previously explained that Bullington800-Brancazio renders [13B] obvious. Section XII.B.8.c, above. Bullington800-Brancazio-Liu involves the simple use of Liu's flexible hydrophobic material to construct the blood-impermeable membrane, and thus Bullington800-Brancazio-Liu does not change how Bullington800-Brancazio teaches [13B]. Section XII.C.1.b, above. Therefore, Bullington800-Brancazio-Liu render [13B] obvious.

- d. [13C]: “a chamber comprising a flexible material, the chamber connected with the inlet port and configured to collect a first portion of the blood when under a drawing force applied from the outlet port;”

208. As I have previously explained, Bullington800-Brancazio implements the first member 537 with a blood-impermeable membrane as taught by Brancazio (and, in the second, alternative configuration, secures Bullington800’s first member 537 in its second configuration). Sections XII.B.1.d, XII.A.1.d, above. Bullington800-Brancazio-Liu uses this same construction for its device but specifically constructs the blood-impermeable membrane (**green**) out of a flexible material as described in Liu. Section XII.C.1.c, above. Accordingly, Bullington800-Brancazio-Liu teaches the chamber (**yellow**), and that the chamber is “connected with the inlet port and configured to collect a first portion of the blood when under a drawing force applied from the outlet port,” for the same reasons as Bullington800-Brancazio, and further teaches that the chamber comprises “a flexible material” because Liu’s flexible material is used to construct the blood-impermeable membrane (**green**) in the chamber (**yellow**). Sections XII.B.1.d, XII.A.1.d, XII.C.1.c, above; Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052].



Bullington800-Brancazio-Liu Drawing (Ex. 1012, Fig. 17 (modified to show the combination's use of a hydrophobic membrane as disclosed in Brancazio, made of a flexible material as disclosed in Liu, in Bullington800's device)

209. Therefore, Bullington800-Brancazio-Liu renders [13C] obvious.

- e. **[13D]: “a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port; and”**

210. I previously explained that Bullington800-Brancazio renders [13D] obvious. Section XII.B.8.e, above. Bullington800-Brancazio-Liu involves the simple use of Liu's flexible hydrophobic material to construct the blood-impermeable membrane, and thus Bullington800-Brancazio-Liu does not change how Bullington800-Brancazio teaches [13D]. Section XII.C, above. Therefore, Bullington800-Brancazio-Liu render [13D] obvious.

f. [13E]: “a housing that defines the inlet port, the sampling channel, and the outlet port.”

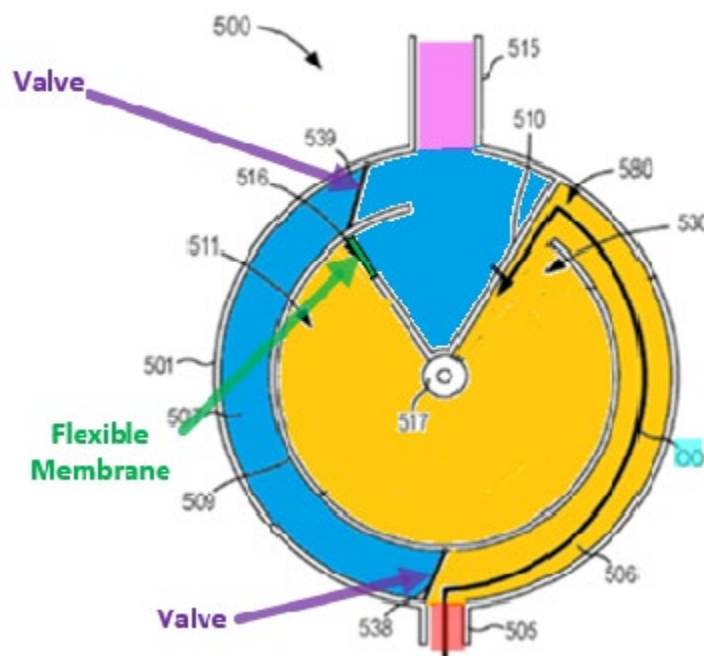
211. I previously explained that Bullington800-Brancazio renders [13E] obvious. Section XII.B.8.f, above. Bullington800-Brancazio-Liu involves the simple use of Liu’s flexible hydrophobic material to construct the blood-impermeable membrane, and thus Bullington800-Brancazio-Liu does not change how Bullington800-Brancazio teaches [13E]. Section XII.C, above. Therefore, Bullington800-Brancazio-Liu renders [13E] obvious. Thus, Bullington800-Brancazio-Liu renders claim 13 obvious.

2. Dependent Claim 14

The device in accordance with claim 13, wherein the flexible material is a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood

212. As I previously explained above, Bullington800-Brancazio isolates the chamber (yellow) from the outlet port (pink) and implements the first member 537 with a gas-permeable, blood-impermeable membrane as taught by Brancazio. Sections XII.B.1.d, XII.A.1.d, above; Ex. 1012, ¶¶[1109], [1111], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. Bullington800-Brancazio-Liu uses a similar construction for its device but specifically constructs the blood-impermeable membrane (green) out of a flexible material as described in Liu. Section XII.C, above; Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]. That is, the “flexible material” in the chamber

(yellow) is the claimed “blood impermeable membrane” (green), because the combination of Bullington, Brancazio, and Liu teaches that the blood-impermeable membrane (green) is made of a material that is known for its flexibility and high hydrophobicity; the membrane remains blood-impermeable. Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]. The blood-impermeable membrane (green) in Bullington800-Brancazio-Liu “is configured to facilitate the chamber collecting the first portion of the blood sample” for the same reasons as I described above with respect to Bullington800-Brancazio. Section XII.B.2, above.



Bullington800-Brancazio-Liu Drawing

3. Dependent Claim 15

213. As I have previously explained, Bullington800-Brancazio-Liu teaches a blood-impermeable membrane (**green**) that is a “flexible material” in the chamber (**yellow**). Section XII.C.2, above; Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]. As I further explained above with respect to Bullington800-Brancazio, this blood-impermeable membrane (**green**) “causes the first portion of the blood to back up into the chamber following application of the drawing force applied from the outlet port” regardless of whether it is flexible, and thus Bullington800-Brancazio-Liu teaches these features for the same reasons. Sections XII.B.3, XII.B.9, above. Therefore, Bullington800-Brancazio-Liu renders claim 15 obvious.

4. Dependent Claims 16-24

214. The construction of the membrane in Bullington800-Brancazio-Liu, using a flexible material, does not change how the device of Bullington800-Brancazio renders obvious claims 4-12. Claims 16-24 are nearly identical to dependent claims 4-12, as I have previously explained, and therefore claims 16-24 are rendered obvious by Bullington800-Brancazio-Liu for the same reasons that these claims are rendered obvious by Bullington800-Brancazio. Sections XII.B.4-7, XII.B.9, above.

XIII. EVIDENCE OF NON-OBVIOUSNESS

215. It is my understanding that in order for evidence of non-obviousness or secondary considerations to be relevant, there must be a nexus between the claimed invention and the evidence. I am not aware of any evidence of non-obviousness or secondary considerations.

XIV. CONCLUSION

216. All of the statements made in this declaration of my own knowledge are true. All statements made based on information and belief are believed to be true. Further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code.

Date: November 12, 2025

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Karl R. Leinsing, MSME, PE

Appendix A

EXHIBITS

- Ex. 1001: U.S. Patent No. 12,138,052 (“the ’052 Patent”)
- Ex. 1002: Expert Declaration of Karl Leinsing
- Ex. 1003: Curriculum Vitae of Karl Leinsing
- Ex. 1004: Certified Prosecution History of U.S. Patent No. 12,138,052 (“ the ’052 Patent”)
- Ex. 1005: Certified Prosecution History of U.S. Patent No. 10,010,282 (“ the ’282 Patent”)
- Ex. 1006: Certified Prosecution History of U.S. Patent No. 10,143,412 (“ the ’412 Patent”)
- Ex. 1007: Certified Prosecution History of U.S. Patent No. 11,185,266 (“ the ’266 Patent”)
- Ex. 1008: Certified Prosecution History of U.S. Patent No. 11,963,769 (“ the ’796 Patent”)
- Ex. 1009: Certified Prosecution History of U.S. Patent No. 11,832,944 (“ the ’944 Patent”)
- Ex. 1010: Certified Prosecution History of U.S. Patent No. 12,357,209 (“ the ’209 Patent”)
- Ex. 1011: Certified Prosecution History of U.S. Patent No. 12,390,137 (“ the ’137 Patent”)
- Ex. 1012: WO Pub. No. 2014/085800 (“Bullington800”)
- Ex. 1013: U.S. Patent App. Pub. No. 2014/0336536 (“Brancazio”)
- Ex. 1014: U.S. Patent App. Pub. No. 2012/0245042 (“Liu”)
- Ex. 1015: U.S. Patent No. 5,286,279 (“Wu”)

Ex. 1016: U.S. Patent No. 6,103,271 (“Morrison”)

Ex. 1017: U.S. Patent App. Pub. No. 2014/0208978 (“Sunder”)

Ex. 1018: U.S. Patent No. 7,923,053 (“Kitching”)

Ex. 1019: U.S. Patent No. 10,039,483 (“Bullington483”)

Ex. 1020: --

Ex. 1021: --

Ex. 1022: U.S. Patent No. 7,087,047 (“Kraus”)

Ex. 1023: --

Ex. 1024: --

Ex. 1025: U.S. Patent No. 12,357,209 (“the ’209 Patent”)

Ex. 1026: U.S. Patent App. Pub. No. 2014/0155782 (“Bullington782”)

Ex. 1027: U.S. Patent App. Pub. No. 2015/0032067 (“Bullington067”)

Ex. 1028: U.S. Patent App. Pub. No. 2014/0039348 (“Bullington348”)

Ex. 1029: The American Heritage Dictionary, Office Edition, Houghton Mifflin Company, (4th Ed. 2001)

Ex. 1030: The New Oxford American Dictionary, Oxford University Press (2001)

Ex. 1031: Defendant’s Second Amended Answer and Counterclaims, *Magnolia Medical Techs. v. Kurin, Inc.*, C.A. No. 24-1124-CFC, Dkt. 95 (D. Del. Nov. 21, 2024)

Ex. 1032: U.S. Patent No. 3,882,026 (“McPhee”)

Ex. 1033: U.S. Patent No. 9,694,304 (“Perreault”)

Ex. 1034: U.S. Patent No. 4,832,034 (“Pizziconi”)

- Ex. 1035: Joint Claim Construction Brief, *Magnolia Medical Techs. v. Kurin, Inc.*, C.A. No. 24-1124-CFC, Dkt. 153 (D. Del. Mar. 10, 2025)
- Ex. 1036: Letter to Deputy Clerk, District of Delaware regarding construction of term “housing that defines”, *Magnolia Medical Techs. v. Kurin, Inc.*, C.A. No. 24-1124-CFC, Dkt. 339 (D. Del. Jul. 9, 2025)
- Ex. 1037: Hackh’s Chemical Dictionary (McGraw-Hill, Inc. 1969)
- Ex. 1038: Random House Webster’s College Dictionary (Random House, Inc. 2005)
- Ex. 1039: Membrane, Cambridge Advanced Learner’s Dictionary (Cambridge Univ. Press), archived at <https://web.archive.org/web/20150914225839/https://dictionary.cambridge.org/dictionary/english/membrane>

Appendix B

CLAIM LISTING APPENDIX

U.S. Patent No. 12,138,052

Designation	Claim Language
Claim 1	
[1pre]	1. A device comprising:
[1A]	an inlet port for receiving a blood sample;
[1B]	an outlet port;
[1C]	a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device;
[1D]	a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port; and
[1E]	a housing that defines the inlet port, the sampling channel, and the outlet port.
Claim 2	
2	2. The device in accordance with claim 1, wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.
Claim 3	
3	3. The device in accordance with claim 1, wherein a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.
Claim 4	
4	4. The device in accordance with claim 2, wherein the housing is separate from the blood impermeable membrane.
Claim 5	
5	5. The device in accordance with claim 1, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

Designation	Claim Language
Claim 6	
6	6. The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel.
Claim 7	
7	7. The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.
Claim 8	
8	8. The device in accordance with claim 1, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.
Claim 9	
9	9. The device in accordance with claim 6, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.
Claim 10	
10	10. The device in accordance with claim 1, further comprising a patient needle and the blood sample collection device.
Claim 11	
11	11. The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.
Claim 12	
12	12. The device in accordance with claim 1, wherein the chamber has a volume of less than 1.5 cubic centimeters.
Claim 13	
[13pre]	13. A device comprising:
[13A]	an inlet port for receiving blood;
[13B]	an outlet port;
[13C]	a chamber comprising a flexible material, the chamber connected with the inlet port and configured to collect a first

Designation	Claim Language
	portion of the blood when under a drawing force applied from the outlet port;
[13D]	a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port; and
[13E]	a housing that defines the inlet port, the sampling channel, and the outlet port.
Claim 14	
14	14. The device in accordance with claim 13, wherein the flexible material is a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood.
Claim 15	
15	15. The device in accordance with claim 13, wherein the flexible material is a blood impermeable membrane causes the first portion of the blood to back up into the chamber following application of the drawing force applied from the outlet port.
Claim 16	
16	16. The device in accordance with claim 14, wherein the housing is separate from the blood impermeable membrane.
Claim 17	
17	17. The device in accordance with claim 13, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.
Claim 18	
18	18. The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel.
Claim 19	
19	19. The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.
Claim 20	
20	20. The device in accordance with claim 13, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, follow-on

Designation	Claim Language
	amounts of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.
Claim 21	
21	21. The device in accordance with claim 18, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.
Claim 22	
22	22. The device in accordance with claim 13, further comprising a patient needle and a sample collection device.
Claim 23	
23	23. The device in accordance with claim 13, the chamber having a volume sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.
Claim 24	
24	24. The device in accordance with claim 13, wherein the chamber has a volume of less than 1.5 cubic centimeters.

Appendix C

MAGNOLIA FAMILY TREE BASED ON US 12,138,052

