

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

**PETITION FOR *INTER PARTES* REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.***

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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”)
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- 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”)
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- 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>

MANDATORY NOTICES

Real Parties in Interest (37 C.F.R. § 42.8(b)(1))

The real party-in-interest for this petition is Magnolia Medical Technologies, Inc. No unnamed entity is funding, controlling, or directing this Petition for *inter partes* review (IPR) of U.S. Patent No. 12,138,052 (“the ’052 Patent”), or otherwise has an opportunity to control or direct this Petition or Petitioner’s participation in any resulting IPR.

Related Matters (37 C.F.R. § 42.8(b)(2))

This is the first petition for *inter partes* review filed by Petitioner against the ’052 Patent. No other Office proceedings (e.g., *inter partes* review, post-grant review, covered business method, or *ex parte* reexamination) have been filed against the ’052 Patent.

Patent Owner has asserted the ’052 Patent in its counterclaims in *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. The earliest date of service of any complaint alleging infringement of the ’052 Patent by any of the real parties-in-interest was November 21, 2024. *Id.*

According to the Office’s records, the ’052 Patent is a continuation of application Ser. No. 18/494,622, filed Oct. 25, 2023, now U.S. Pat. No. 12,357,209 (“the ’209 Patent”), which is a continuation of application Ser. No. 18/113,710, filed

Feb. 24, 2023, now U.S. Pat. No. 11,832,944 (“the ’944 Patent”), which is a continuation of application Ser. No. 17/538,990, filed Nov. 30, 2021, now U.S. Pat. No. 11,963,769 (“the ’769 Patent”), which is a continuation of application Ser. No. 16/208,559, filed Dec. 4, 2018, now U.S. Pat. No. 11,185,266 (“the ’266 Patent”), which is a continuation of application Ser. No. 15/994,559, filed May 31, 2018, now U.S. Pat. No. 10,143,412 (“the ’412 Patent”), which is a continuation of application Ser. No. 15/140,448, filed Apr. 27, 2016, now U.S. Pat. No. 10,010,282 (“the ’282 Patent”), which claims priority to U.S. Prov. App. Nos. 62/318,194 (filed Apr. 4, 2016), 62/238,636 (filed Oct. 7, 2015), and 62/196,797 (filed Jul. 24, 2015). According to the Office’s records, the ’052 Patent is also to the parent of application Ser. No. 18/898,239, filed Sept. 26, 2024, now U.S. Pat. No. 12,390,137, and the grandparent to application Ser. No. 19/294,063, filed Aug. 7, 2025, which is currently pending.

Other than the Corresponding District Court Litigation, the ’052 Patent or its related patents have not been subject to district court litigation.

Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3))

Petitioner designates counsel listed below. A power of attorney for counsel is being concurrently filed.

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I. INTRODUCTION

Magnolia Medical Technologies, Inc. (“Petitioner”) petitions for *inter partes* review of claims 1-24 of U.S. Patent No. 12,138,052 (“the ’052 Patent”).

II. SUMMARY OF ARGUMENT

The ’052 Patent generally claims a device that sequesters a portion of blood, and that draws a subsequent portion of blood to the outlet port via a channel. A valve initially closes off the channel, allowing blood into the chamber, and subsequently bypasses the chamber, allowing blood through the channel. During prosecution, the Examiner found that the art of record disclosed all these features except for a housing that defines an inlet port, channel, and outlet port.

However, the ’052 Patent’s claim elements, including the housing, are disclosed and/or rendered obvious by prior art that was not considered by the Examiner as shown herein. For example, WO2014/085800 (“Bullington800”) discloses a device with a sequestration chamber, a sampling channel bypassing the chamber, and associated valves to direct the flow of blood. Bullington800 also discloses a similar mechanism of using a suction force from the outlet to draw an initial portion of blood into the sequestration chamber. And, Bullington800 discloses and/or renders obvious the housing that defines the inlet port, channel, and outlet port, that the Examiner mistakenly thought was missing from the prior art.

§VI.A.

As set forth below (§VI.B, *infra*), to any extent Bullington800's use of a suction force from the outlet does not disclose or render obvious the claims of the '052 Patent, they are rendered obvious by Bullington800 in view of Brancazio. Brancazio teaches applying a vacuum to an air-permeable blood-impermeable membrane to draw blood into a collection chamber.

As set forth herein, claims 1-24 of the '052 Patent are unpatentable and should be cancelled.

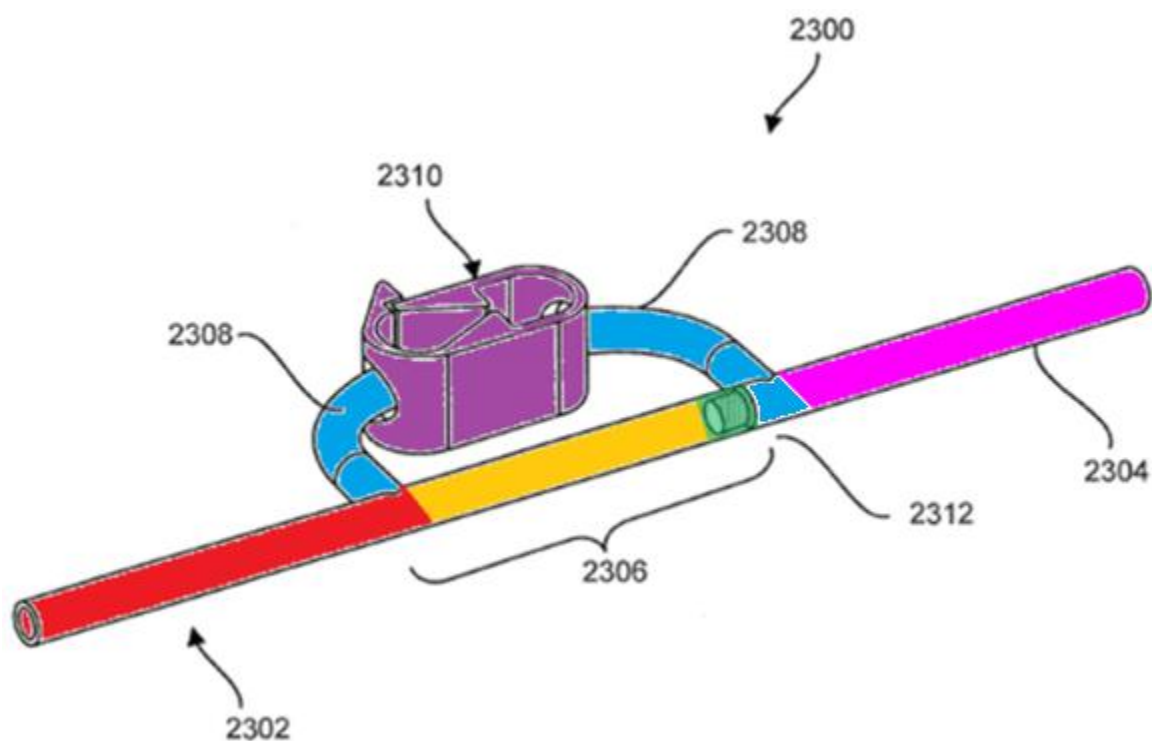
III. OVERVIEW OF THE '052 PATENT

A. Summary

The '052 Patent 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, 21:19-26. The device includes “a sequestration chamber...” *Id.*, Abstract, 5:47-51, 21:19-26. A sampling channel then “bypasses the sequestration chamber” to convey uncontaminated blood to the outlet. *Id.*, Abstract, 5:50-55, 21:19-26; Ex. 1002, ¶¶25-26.

Figures 23A and 23B illustrate a representative implementation “that uses a vacuum force from a blood collection device” to draw “blood into the inlet port...and directly into the sequestration chamber....” Ex. 1001, 5:29-31, 21:19-51, Figs. 23A, 23B. The device of Figure 23A, annotated below, includes an **inlet port 2302** “to

connect with a patient needle,” an **outlet port 2304** “to connect with a blood sample collection device,” a **sequestration chamber 2306**, and a **sampling channel 2308** “that bypasses the sequestration chamber 2306 once the sequestration chamber is filled [with] an initial aliquot of potentially contaminated blood to be sequestered.” Ex. 1001, 21:19-26, Figs. 23A, 23B; Ex. 1002, ¶27.



Ex. 1001, Fig. 23A (annotated)

The **sequestration chamber** includes a **hydrophobic plug 2312** “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.*; Ex. 1002, ¶28.

The drawing of the blood by the vacuum or other drawing force applied from the outlet port is facilitated by a **valve**¹ which initially closes off the **sampling channel**. Ex. 1001, 21:35-37, Figs. 23A, 23B; Ex. 1002, ¶¶29-30. 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.

B. Prosecution History

During prosecution, claims 1, 6-9, 11-12, 14, 19-22, and 24-25 were rejected as anticipated by U.S. Patent App. Pub. No. 2008/0145933 to Patton (“Patton”). Ex. 1004, pp. 5571-76. Among other things, Patton disclosed “to collect a first potion

¹ The ’052 Patent references a “valve 2308,” but this conflicts with its previous description of “the sampling channel 2308” and the labeling in Figures 23A and 23B of the sampling channel as element 2308. Ex. 1001, 21:19-47, Figs. 23A, 23B.

of the blood sample...when under a drawing force applied from the outlet port from a blood sample collection device...” of claim 1. *Id.*, pp. 5573-76. Claims 2-5 and 15-18 were rejected as obvious over Patton in view of U.S. Patent App. Pub. No. 2006/0009713 to Flaherty et al. (“Flaherty”), and claims 13 and 26 were rejected as obvious over Patton alone. *Id.*, pp. 5577-79. The Office allowed dependent claims 10 and 23. *Id.*, p. 5579. The Applicant then amended independent claims 1 and 14 to incorporate “a housing that defines the inlet port, the sampling channel, and the outlet port.” *Id.*, pp. 5825-32. The ensuing Notice of Allowability 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.*, pp. 5899-5906.

None of the art relied upon herein was applied or cited during prosecution.

C. Earliest Priority Date for the Claims

The earliest possible effective filing date is July 24, 2015, the filing date of Provisional Application No. 62/196,797. Ex. 1001, cover. The references cited herein constitute prior art, even assuming the claims are entitled to this date.²

² However, the '052 Patent claims appear to be supported by Figure 23, which was first included in Provisional Application No. 62/318,194, filed April 4, 2016. Ex. 1002, ¶26.

IV. STATE OF THE ART

A. Technical Background

All technical aspects of the claims were well-known, including specimen (e.g., blood, bodily-fluid) collection using a vacuum force, sequestration of samples, and the use of flexible, blood-impermeable membranes/hydrophobic materials. Ex. 1002, ¶¶44-48.

B. Prior Art

1. Bullington800

Bullington800 (Ex. 1012) was filed December 2, 2013, and published June 5, 2014; it is prior art under AIA 35 U.S.C. §102(a)(1). Ex. 1002, ¶49. Bullington800 relates to parenterally-procuring blood samples with reduced contamination from microbes or other exterior contaminants and is analogous art to the '052 Patent. Ex. 1012, ¶[1002]; Ex. 1002, ¶¶49-53.

Like the '052 Patent, Bullington800 describes a device that sequesters an initial (potentially contaminated) portion 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. 1002, ¶50. 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]-

channel 507 “can be selectively placed in fluid communication with the proximal port 515 and the distal port 505....” Ex. 1012, ¶[1108].

Bullington800 also discloses a flow control mechanism 530 comprising a **first member 537**, a **second member 538**, and a **third member 539** that “can be valves or the like....” *Id.*, ¶[1109], Figs. 16-17. The **first member 537** 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**, either alone or in combination with the remaining **portion of the inner volume 511** in fluid communication with the **proximal port 515**). Ex. 1012, ¶¶[1109], [1111], Figs. 16-17; Ex. 1002, ¶52.

Figure 16 illustrates a first position of the flow control mechanism 530 where 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, ¶[1111], Fig. 16; Ex. 1002, ¶53. In operation, a negative pressure (e.g., at the **proximal port 515**) exerts a suction force that rotates the **first member 537** 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** and the **distal port 505** to urge a flow of blood from a patient through the **first channel 506** and into the **fluid reservoir 580** to be sequestered. Ex. 1012, ¶¶[1111]-

[1114], Figs. 16-17; Ex. 1002, ¶53. Figure 17 illustrates a second position of the flow control mechanism 530 where the **second member 538** and the **third member 539** operate as **valves** that are opened to place the **second channel 507** in fluid communication with the **distal port 505** and the **proximal port 515** in order to urge a flow of blood that is substantially free from contaminants into, e.g., a syringe. Ex. 1012, ¶[1114], Fig. 17; Ex. 1002, ¶53. This flow bypasses the **fluid reservoir 580** and **first channel 506**, which are now fluidically isolated from the **distal port 505** and the **proximal port 515** by the **first member 537** and the **second member 538**, thereby sequestering the initial volume of blood. Ex. 1012, ¶[1114], Fig. 17; Ex. 1002, ¶53.

2. Brancazio

Brancazio (Ex. 1013) was filed July 10, 2014, and published November 13, 2014; it is prior art under AIA 35 U.S.C. §102(a)(1). Ex. 1013, cover; Ex. 1002, ¶54. Like the '052 Patent, Brancazio relates to extracting blood from a subject using a reduced pressure or vacuum chamber (e.g., a Vacutainer) to draw the blood into a collection chamber. Ex. 1013, Abstract, ¶¶[0003], [0013], [0041]-[0042], [0048]-[0049], [0052], [0059], [0087]-[0120], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1002, ¶54. Further, both 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. Brancazio is analogous to the '052 Patent. Ex. 1002, ¶¶54-57.

3. Liu

Liu (Ex. 1014) was filed February 16, 2012 and published September 27, 2012; it is prior art under AIA 35 U.S.C. §102(a)(1). Ex. 1014, cover; Ex. 1002, ¶58. Liu relates to the use of hydrophobic membranes in the field of fluid mechanics and devices that utilize pressure within a fluid channel to move fluids. Ex. 1014, Abstract, ¶¶[0003], [0007]-[0008], [0021]-[0022], [0031], [0037]-[0038], [0052]; Ex. 1002, ¶58. Liu and the '052 Patent both describe the use of a hydrophobic membrane that acts as a barrier to liquid (e.g., blood) in a fluid flow path of a system that utilizes pressure to move liquid towards the membrane while allowing gas (e.g., air) to be displaced. Ex. 1001, 6:24-47, 13:58-63, 21:20-48, claims 2-4, 14-16, Figs. 23A-23B; Ex. 1014, ¶¶[0003], [0007]-[0008], [0021]-[0022], [0031], [0037]-[0038], [0052]. Liu is analogous to the '052 Patent. Ex. 1002, ¶¶58-59.

V. IDENTIFICATION OF CHALLENGE PURSUANT TO 37 C.F.R. § 42.104(B)

A. Claims for Which Review is Requested and Grounds on Which Challenge Is Based

Petitioner requests review of claims 1–24 on the following grounds.

Ground	References	Basis	Claims Challenged
A	Bullington800	§102	1-24
B	Bullington800	§103	1-24
C	Bullington800-Brancazio	§103	1-24
D	Bullington800-Brancazio-Liu	§103	13-24

This petition is supported by the expert testimony of Karl R. Leinsing and Exhibits 1001-1036. Ex. 1002, ¶¶1-216. Mr. Leinsing is at least a POSITA as defined below. *Id.*, ¶¶4-12, 60-64; Ex. 1003.

B. Level of Ordinary Skill

A POSITA at the time of the alleged invention 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. Additional education may substitute for professional experience, and significant work experience may substitute for formal education. Ex. 1002, ¶¶60-64.

C. Claim Construction

The parties to the Corresponding District Court Litigation stipulated that “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. The parties also stipulated that “a housing that defines” means “a casing that fixes or marks the limits of.” Ex. 1036, p. 1. This Petition applies these constructions. Petitioner first proposed that “flexible material” is a “[m]aterial that is easily hand-folded, flexed, twisted, and bent.” See Ex. 1035, p. 7. All other claim terms herein should be given their ordinary and customary meaning to a POSITA, as they would be given in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b). For the reasons discussed herein, the art teaches the claim limitations under any reasonable construction, including any of the above constructions proposed by the parties.

VI. SPECIFIC GROUNDS FOR UNPATENTABILITY

A. Grounds A-B: Claims 1-24 are Anticipated and/or Rendered Obvious by Bullington800

As set forth below, Bullington800 anticipates and/or renders obvious claims 1-24. Ex. 1002, ¶¶66-139.

1. Independent Claim 1

a. [1PRE] “A device comprising:”

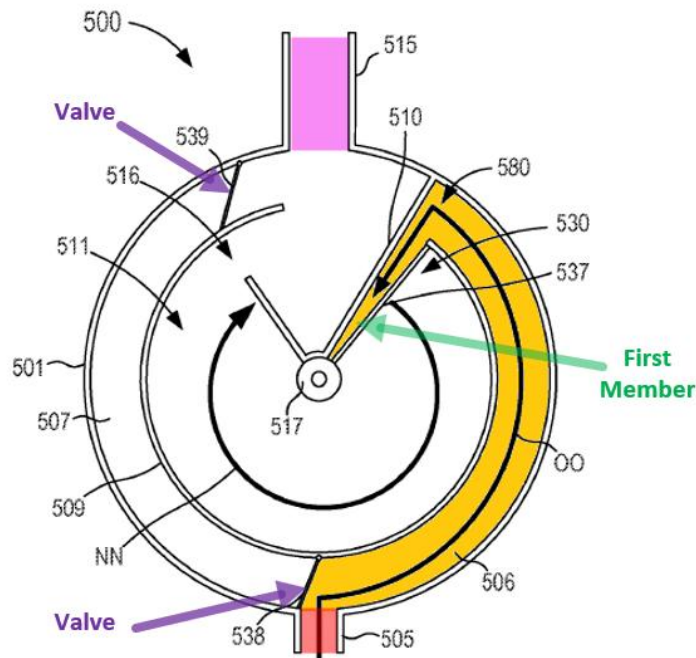
Bullington800 discloses “a device” as recited in claim 1. Ex. 1012, ¶¶[1006], [1107]-[1114], Figs. 1, 11-17. Specifically, Bullington800 describes a device that sequesters an initial aliquot of blood in a sequestration chamber and that uses a

sampling channel to then bypass the sequestration chamber. *Id.*; Ex. 1002, ¶71; §§II, IV.B.1, *supra*.

As set forth below, Bullington800 discloses and/or renders obvious the remaining elements [1A]-[1E], and therefore discloses and/or renders obvious [1PRE]. See §§VI.A.1.b-f, *infra*; Ex. 1002, ¶¶72-89.

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

Bullington800 discloses [1A]. Bullington800’s device is configured for the “procurement of bodily-fluid samples” such as blood samples. Ex. 1012, ¶¶[1002], [1037], [1030], [1107]-[1108], [1111]-[1112]; Ex. 1002, ¶73. Bullington800’s device has housing 501 “includ[ing] a distal port 505” coupled to a needle. Ex. 1012, ¶¶[1108], [1111], Figs. 16-17. The needle can be disposed within a patient. *Id.*



Ex. 1012, Fig. 16 (annotated)

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 blood is eventually collected in a sample reservoir. *Id.*, ¶[1114], Figs. 16-17; Ex. 1002, ¶74. The **distal port 505** is thus “an inlet port for receiving a blood sample” as claimed. Ex. 1002, ¶74. Therefore, Bullington800 discloses [1A]. *Id.*

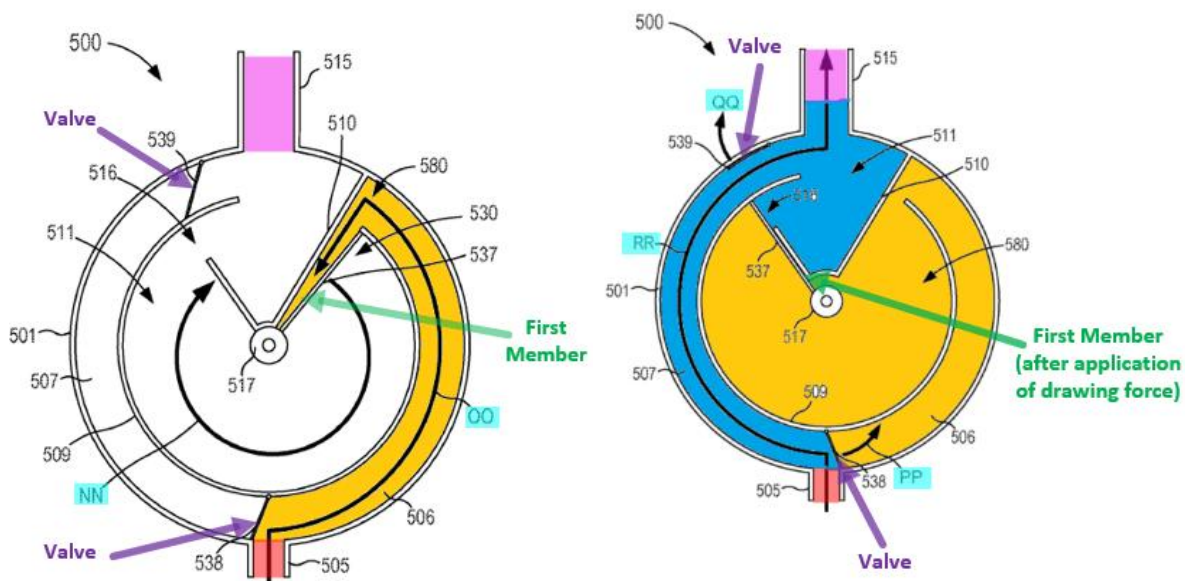
c. [1B] “an outlet port”

Bullington800 discloses “an outlet port.” Bullington800’s **distal port 505** (“**inlet port**”) may be in fluid communication with a **proximal port 515** (“**outlet port**”). Ex. 1012, ¶[1108], Figs. 16-17. A user physically and fluidically couples the **outlet port** “to a syringe or the like” that “can form a sample reservoir ... configured to receive a flow of bodily-fluid...” *Id.*, ¶[1111]. The blood flows through the **outlet port** and into the sample reservoir defined by the syringe. *Id.*, ¶¶[1108], [1111], [1114], Figs. 16-17; Ex. 1002, ¶76. Thus, Bullington800 discloses [1B]. Ex. 1002, ¶¶75-76.

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;”

Bullington800 discloses [1C]. As shown below, Bullington800’s device comprises a **first channel 506** that is “in fluid communication with” a **fluid**

reservoir 580 (the fluid reservoir, either alone or in combination with the first channel, is the “chamber” recited in element [1C]). Ex. 1012, ¶¶[1112],[1107]-[1108], [1113]-[1114], Figs. 16-17.



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

Both the **fluid reservoir 580** and the **first channel 506** of Bullington800's device are fluidically isolated from a portion of the inner volume 511 in fluid communication with the **outlet port**. *Id.*, ¶¶[1108]-[1109], Figs. 16-17.

In an initial configuration, shown in Figure 16, the **first channel 506** and the **fluid reservoir 580** are in fluid communication with the **inlet port**. *Id.*, ¶¶[1111], [1108], [1112], Fig. 16. Specifically, Bullington800's **first channel 506** connects the **fluid reservoir 580** to the **inlet port**, and the **fluid reservoir 580**, alone or in combination with the **first channel 506**, is “a chamber connected with the inlet port” as claimed. *Id.*, ¶¶[1107]-[1109], [1111]-[1112], Figs. 16-17; Ex. 1002, ¶78.

Bullington800's **fluid reservoir 580** is configured to receive a first portion of a blood sample, via the **first channel 506**. Ex. 1012, ¶¶[1112]-[1114], Figs. 16-17. Bullington800's **fluid reservoir 580** alone, or with the **first channel 506** is thus "configured to collect a first portion of the blood sample" as claimed. *Id.*; Ex. 1002, ¶79.

Bullington800 discloses that its **fluid reservoir 580** alone, or with the **first channel 506** ("**chamber**"), receives the first portion of the blood sample after the **outlet port** is "coupled to a syringe or the like" that "define[s] a fluid reservoir...that can receive a flow of bodily fluid" (claimed "blood sample collection device"). Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17. When coupled to the **outlet port**, the syringe "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." *Id.*, ¶¶[1112], [1107], Fig. 16. The rotation of the **first member 537** increases a volume of the **chamber** thus causing the negative pressure to be exerted within the **chamber**. *Id.* 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.* Thus, the **chamber** (claimed "chamber connected with the inlet port and configured to collect a first portion of the blood sample") draws a flow of blood from the patient when the suction force introduced by the syringe coupled to the **outlet port** pulls the **first member 537**

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

Ex. 1012, ¶[1111], Fig. 16.

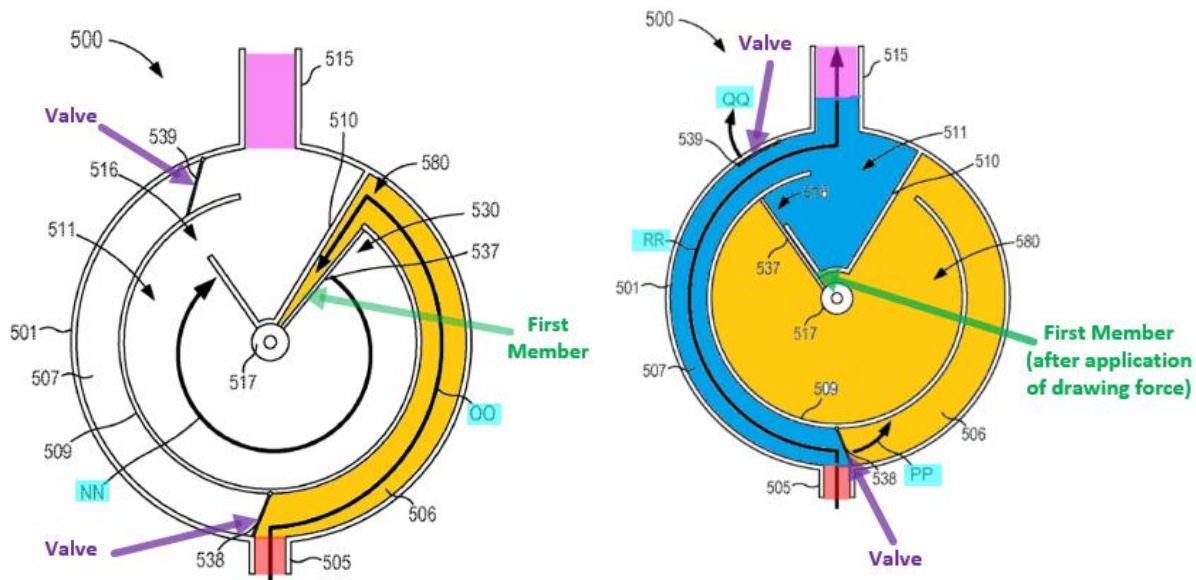
As shown in Figure 17, once a predetermined amount of blood is transferred to the **chamber**, Bullington800's device is moved to a configuration where the **second member 538** and a **third member 539** (“**valves**”) are rotated (as shown by arrows **PP** and **QQ**) such that “the fluid reservoir 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], [1112]-[1113], Fig. 17. In this configuration the **second channel 507** is in fluid communication with the **inlet port** and, adjacent to a **wedge-shaped portion of the inner volume 511**, the **outlet port**, as shown by arrow **RR**. *Id.*, ¶[1114], Fig. 17; Ex. 1002, ¶84. The **inlet port**, via the **second channel 507** (alone, or in combination with the **wedge-shaped portion of the inner volume 511**, constituting the claimed “**sampling channel**”), is thus placed in fluid communication with the sample syringe, which is coupled to the **outlet port**. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17. The 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]....” *Id.*, ¶[1114], Fig. 17; Ex. 1002, ¶84. Thus, when the syringe exerts the suction force through the **sampling channel** to urge blood to the sample syringe, the

blood flow also goes to the **outlet port**. Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17; Ex. 1002, ¶84. Accordingly, the **sampling channel** is “a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port” and Bullington800 discloses [1D]. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1002, ¶¶82-84.

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

Bullington800 discloses and/or renders obvious [1E]. The device described in Bullington800 includes a housing. Ex. 1012, ¶¶[1006], [1030], [1044], [1053]-[1054], [1107]-[1112], [1114], Figs. 1-2, 16-17. Housing 501 is described as including (and thus fixing or marking the limits of) the **outlet port** and **inlet port**. *Id.*, ¶¶[1107]-[1108], Figs. 16-17; §§VI.A.1.b-c, *supra*. The housing 501 also includes diverter 509 that “can be a set of walls that...direct a fluid of bodily-fluid within the inner volume 511.” Ex. 1012, ¶[1108], Figs. 16-17. Bullington800 states 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....” *Id.*, ¶[1108]. 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, also fixes or marks the limits of the **wedge-shaped portion of the inner volume 511** that is in fluid communication with the **outlet port** in the Figure 17 configuration. *Id.*, ¶[1108],

Figs. 16-17; Ex. 1002, ¶¶85-86. Thus, regardless of whether the **second channel 507** alone, or in combination with the **wedge-shaped portion of the inner volume 511**, constitutes the claimed “**sampling channel**,” the housing 501 fixes or marks the limits of each of the **outlet port**, **inlet port**, and **sampling channel**:

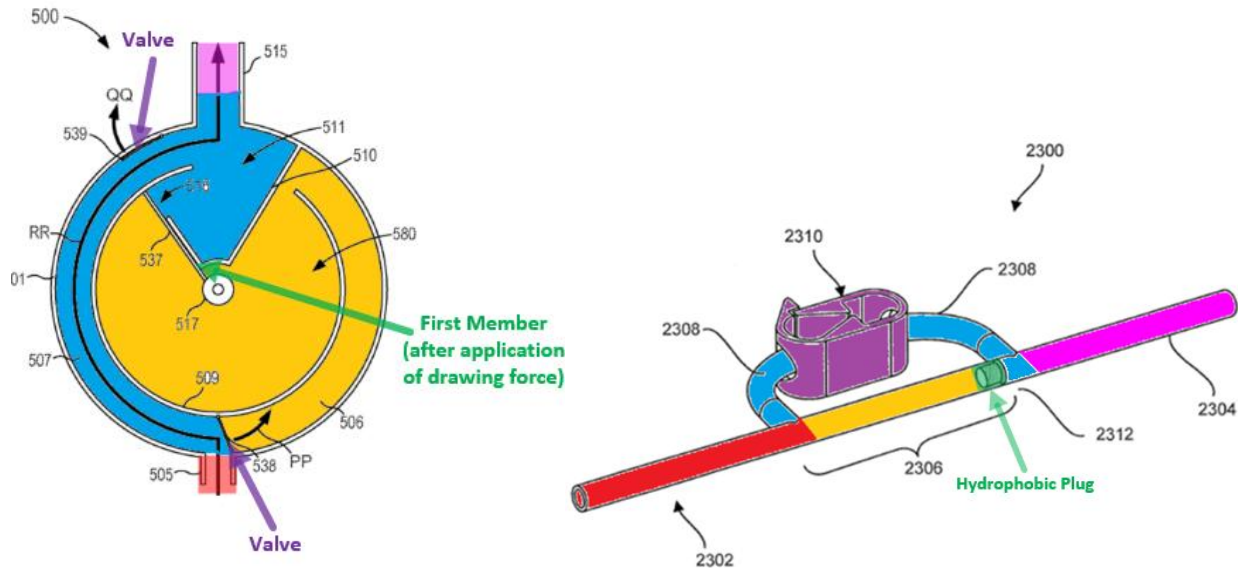


Ex. 1012, Figs. 16 & 17 (annotated)

Ex. 1012, ¶¶[1107]-[1108], [0114], Figs. 16-17 (see arrow **RR** passing through each of the distal port 505, second channel 507, the wedge-shaped portion of the inner volume 511 and proximal port 515); Ex. 1002, ¶86.

To any extent that Patent Owner argues that Bullington800 does not expressly disclose that its housing 501 “defines the inlet port, the sampling channel, and the outlet port,” a POSITA would have found that Bullington800 renders these features obvious. Ex. 1002, ¶87. For example, to any extent that Patent Owner argues Bullington800’s description of its housing 501 “including” the **inlet port** and the

outlet port does not disclose that the housing 501 defines these elements, Bullington800 at least renders obvious [1E] because, as shown above, a POSITA would understand that 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**. *Id.*; Ex. 1012, ¶¶[1006], [1030], [1044], [1053]-[1054], [1107]-[1112], [1114], Figs. 1-2, 16-17. Bullington800's housing is consistent with the description of the '052 Patent. As shown in Figure 17, the housing 501 (including diverter 509 with wedge-shaped portion 510) nearly completely composes the boundaries of each of the **outlet port**, **inlet port**, and **sampling channel**. Ex. 1012, ¶¶[1107]-[1108], [0114], Figs. 16-17; Ex. 1002, ¶87. The **first member 537** provides the border for a small portion of the **sampling channel** near the **outlet port** while keeping the **sampling channel** fluidically isolated from the **chamber**. Ex. 1012, ¶¶[1109]-[1111], [1114], Figs. 16-17; Ex. 1002, ¶87. Thus, to the extent the '052 Patent describes a housing as claimed, Bullington800 is consistent with it, where both include a set of walls that substantially forms the boundaries of each of the **outlet port**, **inlet port**, and **sampling channel** and the back side of the **hydrophobic plug** delineates a small portion of the **sampling channel** near the **outlet port** while keeping the **sampling channel** fluidically isolated from the **chamber**:



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

Ex. 1001, 21:19-48, Figs. 1, 23A-23B. Thus, Bullington800's housing (a casing) substantially forms the bordering structure that walls off (i.e., fixes or defines the limits of) the **sampling channel** taking blood from the **inlet port** to the **outlet port** ("a housing that defines the inlet port, the sampling channel, and the outlet port").

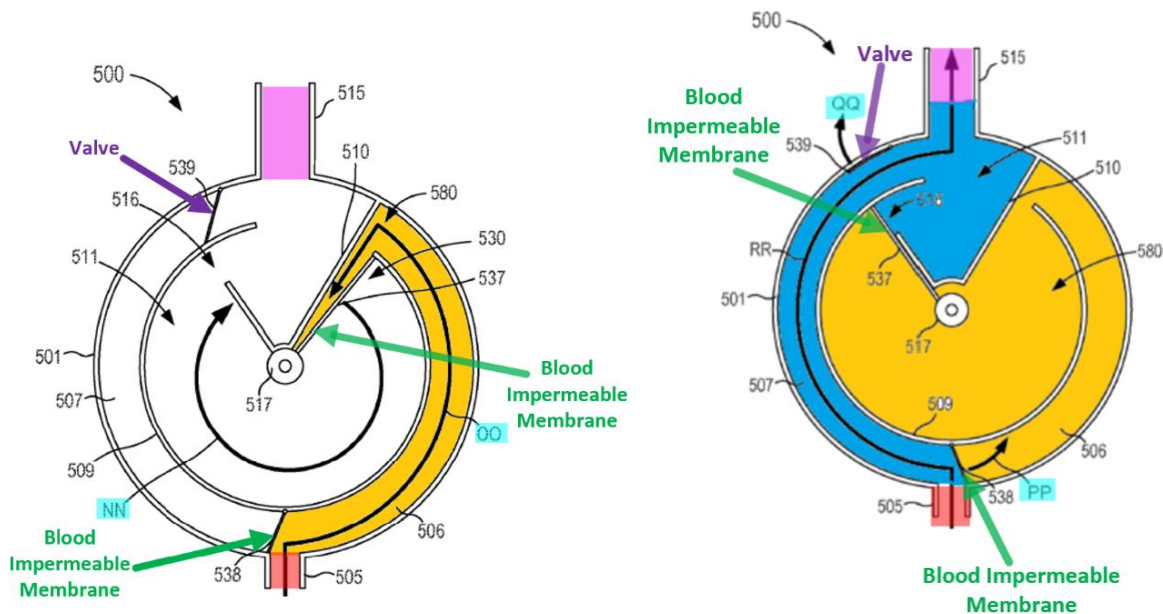
Id.; Ex. 1012, ¶¶[1107]-[1108], [0114], Figs. 16-17; Ex. 1002, ¶¶87-88.

Accordingly, Bullington800 discloses and/or renders obvious [1E]. For the foregoing reasons, Bullington800 discloses and/or renders obvious claim 1. Ex. 1002, ¶¶85-89; §§VI.A.1.a-f, *supra*.

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.

As discussed above, Bullington800 discloses a **chamber** that collects a first portion of a blood sample. §VI.A.1.d, *supra*; Ex. 1012, ¶¶[1107]-[1114], Figs. 16-17; Ex. 1002, ¶¶90-91. Bullington800 also describes that its device includes a flow control mechanism 530 comprising a **first member 537**. Ex. 1012, ¶[1109], Figs. 16-17. The **first member 537** “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.” *Id.*, ¶¶[1109], [1111], Figs. 16-17; Ex. 1002, ¶91.



Further, as previously described at §VI.A.1.d above, rotation of the **first member** **537** caused by negative pressure from a syringe “increases a volume of the fluid

reservoir 580” thus allowing a negative pressure to further be exerted within (and fill) the **chamber**. *Id.*, ¶[1112], Fig. 16. 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.*

Bullington800 additionally describes **second member 538** that selectively places the **chamber** in fluid communication with the **inlet port**. *Id.*, ¶[1111], Figs. 16-17. In the initial configuration shown in Figure 16, the **second member 538** places the **chamber** in fluid communication with the **inlet port** to facilitate collection of the first portion of the blood sample in the **chamber**, and in the configuration shown in Figure 17 the **second member 538** is positioned to fluidically isolate the **chamber** from the **inlet port** to sequester the first portion of the blood sample. *Id.*, ¶¶[1109]-[1111], [1114], Figs. 16-17.

Accordingly, because the **first member 537** and **second member 538** each facilitates the flow of the first portion of the blood sample into the **chamber** and/or fluidically isolates the **chamber** to sequester the first portion of the blood sample, the **first member 537** and the **second member 538** (each alone or in combination a blood-impermeable “**membrane**”) teach “wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood

sample” as recited in claim 2. *Id.*, ¶¶[1107], [1109], [1111]-[1114], Figs. 16-17; Ex. 1002, ¶94.

First member 537 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. Ex. 1012, ¶¶[1109], Figs. 16-17. Furthermore, Bullington800 describes that fluidically isolating **second member 538** is similar to the **first member 537**. *Id.*, ¶¶[1109]-[1110]. Thus, A POSITA would understand the **first member 537** and/or the **second member 538** to be “membranes.” Ex. 1002, ¶94; Ex. 1030, p. 4; Ex. 1037, p. 3; Ex. 1038, p. 3; Ex. 1039, p. 1.

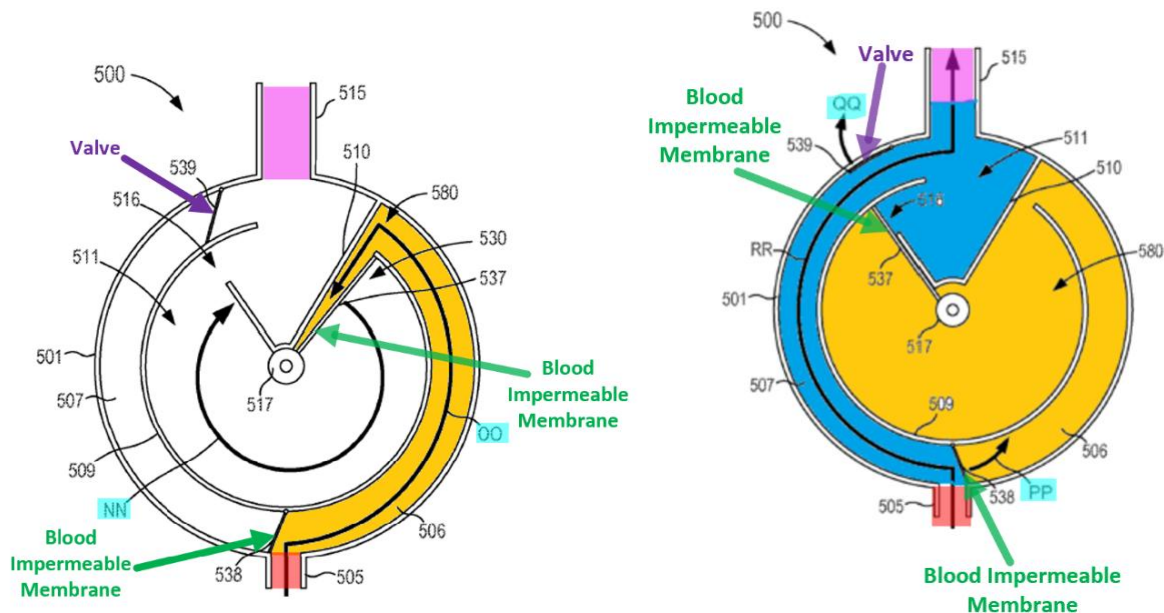
Thus, Bullington800 discloses and/or renders obvious claim 2. Ex. 1002, ¶¶90-95.

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.

Bullington800’s device includes at least one **membrane** that is configured to isolate the **chamber** from the **outlet port**. §VI.A.2, *supra*; Ex. 1012, ¶¶[1109], [1111], Figs. 16-17; Ex. 1002, ¶96. Bullington800 also describes a sample syringe coupled to the **outlet port**, the sample syringe “introduc[ing] 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. Following application of the suction force from the **outlet port**, rotation of the **first member 537** increases a volume of the **chamber** and causes flow of the first portion of the blood into the **chamber**. *Id.*; §VI.A.1.d, *supra*. This flow is further facilitated by the positioning of the **second member 538**, directing blood into the **chamber**. *Id.* The **first member 537** fluidically isolates the **chamber** from the **outlet port**. §VI.A.2, *supra*; Ex. 1012, ¶[1109], Figs. 16-17. Similarly, when Bullington800’s device transitions from its Figure 16 configuration to its Figure 17 configuration, the **second member 538** is positioned to fluidically isolate the **chamber** from the **inlet port** (and thus, the **sampling channel** and **outlet port**). §VI.A.2, *supra*; Ex. 1012, ¶¶[1109]-[1111], [1114], Figs. 16-17; Ex. 1002, ¶97.



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

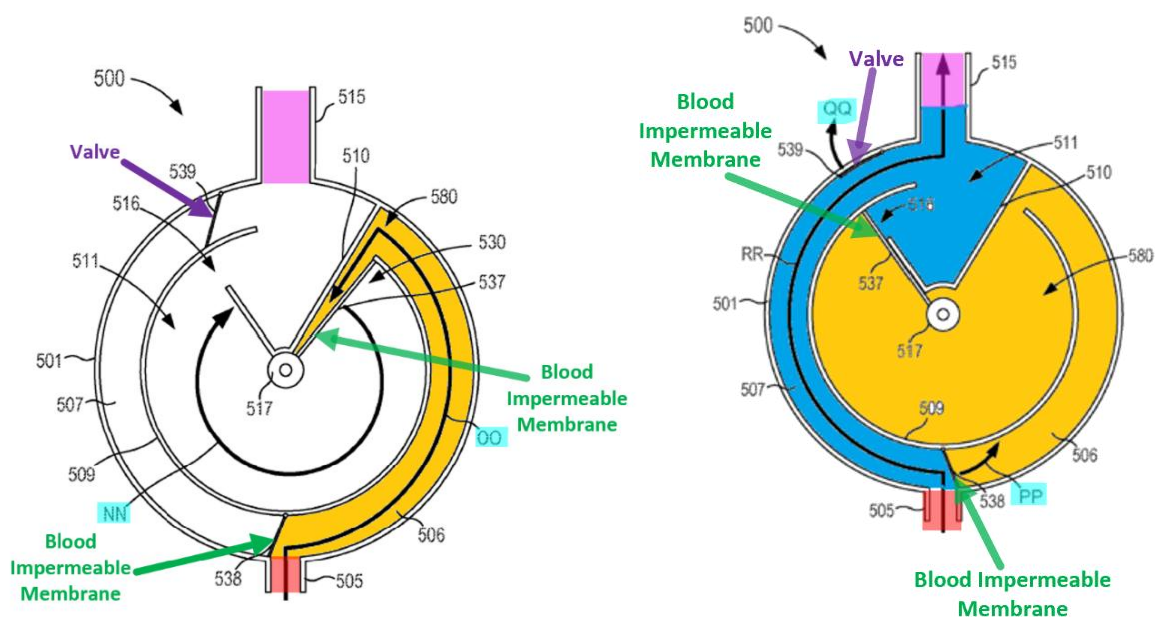
Because the **membrane** (i.e., the **first member 537** and/or the **second member 538**) prevents the first portion of the blood from reaching the sample syringe and the **outlet port**, the **membrane** functions as a barrier that causes the first portion of the blood to back up into (i.e., fill) the **chamber** (claimed “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, ¶¶[1109], [1112], Fig. 16; Ex. 1002, ¶98.

For the foregoing reasons, Bullington800 discloses and/or renders obvious claim 3. Ex. 1002, ¶¶96-99.

4. Dependent Claim 4

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

Bullington800 discloses claim 2 and discloses a **membrane** that is configured to isolate the **chamber** from the **outlet port**. §VI.A.2, *supra*; Ex. 1002, ¶¶100-101. Bullington800’s device also “includes a housing 501.” §VI.A.1.f, *supra*; Ex. 1012, ¶[1107], Figs. 16-17. The **membrane** is separate from the housing 501:

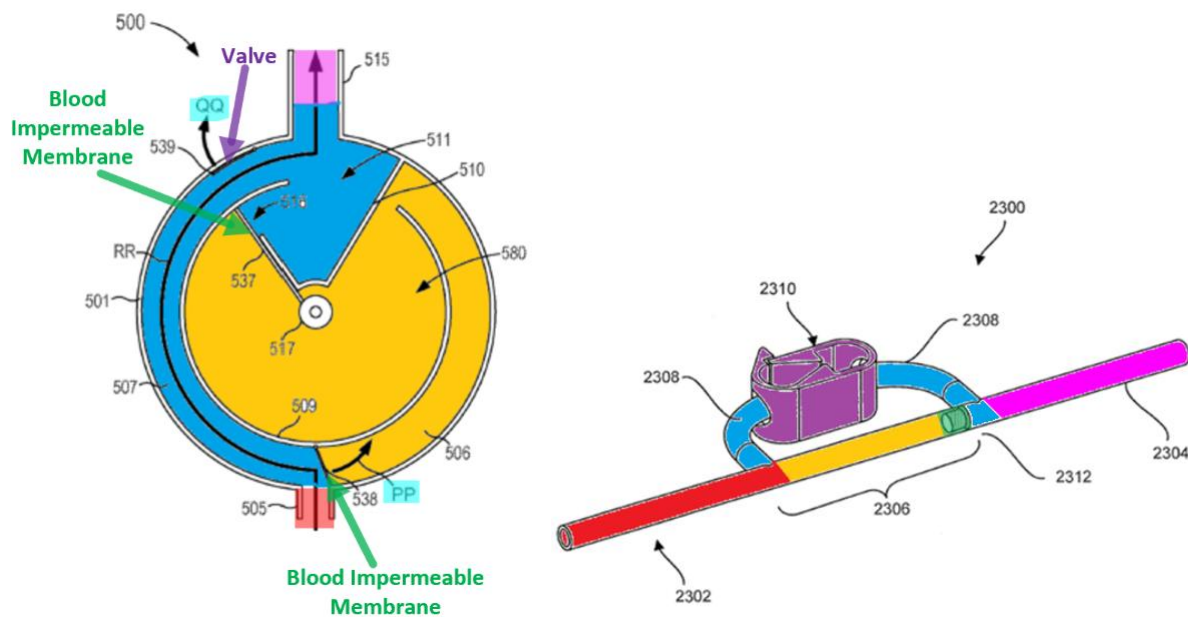


Ex. 1012, Figs. 16 & 17 (annotated)

The **first member 537** “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** “can be rotatably coupled to an outer surface of the annular wall defining a portion of the diverter 509. *Id.* The **first member 537** also “can be selectively placed in contact with an inner surface of the housing 501” *Id.* Thus, the **membranes** are a component separate from the housing 501 that may be placed in contact with and/or coupled to the housing 501. *Id.*; Ex. 1002, ¶101.

To the extent the '052 Patent discloses a housing, the configuration of the **membranes** relative to the housing 501 mirrors the disclosures in 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, 5:28-47, Figs. 23A-23B. As depicted in the comparison of Figure 23A of the '052 Patent and Figure 17 of Bullington800, below, the **hydrophobic plug 2312** contacts the walls of the **sequestration chamber 2306** in the '052 Patent in the same manner that Bullington800's **membranes** are selectively placed in contact with and/or coupled to an inner surface of the housing 501:



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

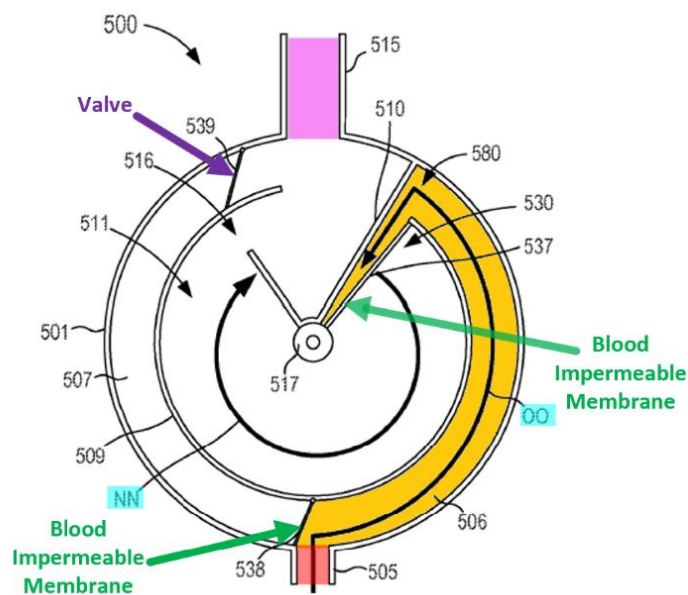
Thus, Bullington800 discloses “wherein the housing is separate from the blood impermeable membrane.” Ex. 1001, 5:28-47, 21:26-35, Figs. 23A-23B; Ex. 1012, ¶¶[1107], [1109], Figs. 16-17; Ex. 1002, ¶¶102-103.

Accordingly, Bullington800 discloses and/or renders obvious claim 4. Ex. 1002, ¶¶100-104.

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.

As explained above, Bullington800 discloses a **chamber** that receives a first portion of a blood sample from a patient, and further explains that this blood sample is drawn into the **chamber** by a drawing force generated by, e.g., a syringe at the **outlet port**. §§VI.A.1.c-d, VI.A.2-3, *supra*; Ex. 1002, ¶¶105-106. As shown in Figure 16, below, by arrow **OO**, the first portion of the blood sample contacts the diverter 509, the wall 510, the exterior wall of the housing, and the **membrane** (**first member 537** and/or **second member 538**). Ex. 1012, ¶¶[1112]-[1113], Fig. 16; Ex. 1002, ¶106.



Ex. 1012, Fig. 16 (annotated)

As previously explained, the **membranes** fluidically isolate the **chamber** and thus are a blood-impermeable material. §VI.A.2, *supra*; Ex. 1002, ¶107. Additionally, it would have been obvious to a POSITA that the **membranes** and the housing material (e.g., the diverter 509, and/or wedge-shaped portion 510 and the exterior wall) that the blood contacts in the **chamber** would be blood-impermeable in order to prevent the blood from leaving the **chamber**. Ex. 1012, ¶¶[1108]-[1114]; Ex. 1002, ¶107. In short, any or all of the aforementioned materials that the first portion of blood contacts when drawn into the **chamber** are disclosed to be, and obviously would be, blood-impermeable.

Accordingly, Bullington800 discloses or renders obvious claim 5. Ex. 1002, ¶¶105-108.

6. Dependent Claim 6

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

Bullington800 discloses “a valve configured to initially close off the sampling channel.” As previously explained, Bullington800 describes a **sampling channel** that “can be selectively placed in fluid communication with the proximal port 515 and the distal port 505” and which can be initially configured to be “fluidically isolated from the distal port 505 and the proximal port 515....” Ex. 1012, ¶¶[1108], [1109]-[1111], [1114], Figs. 16-17; §VI.A.1.e, *supra*. Figure 16 of Bullington800

1002, ¶¶109-112.

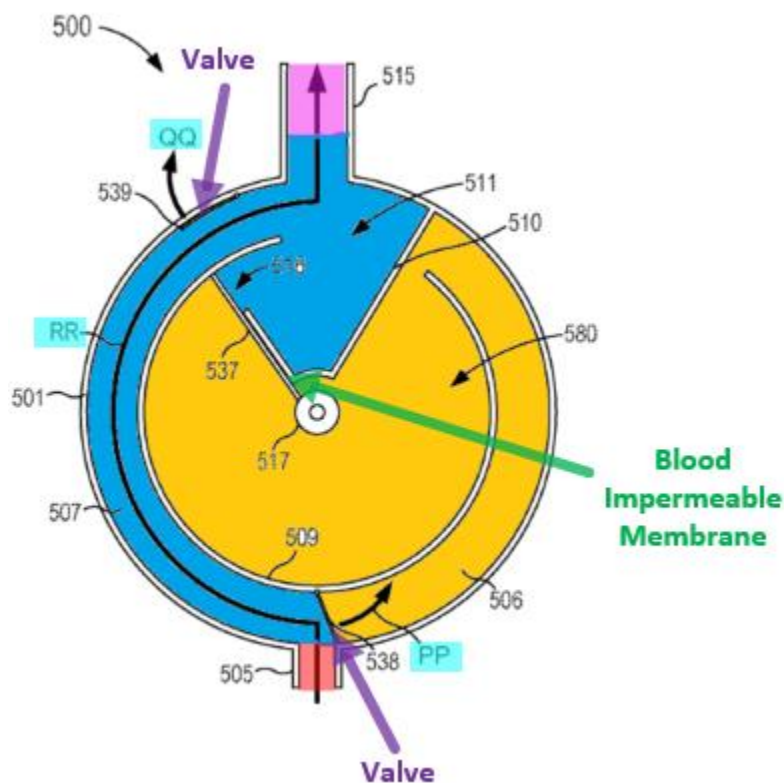
7. Dependent Claim 7

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.

As previously explained, Bullington800 discloses that at least the **second member 538** and the **third member 539** (alone or in combination) are “a valve configured to initially close off the sampling channel” as claimed. §VI.A.6, *supra*. These **valves** close off the **sampling channel** “until the first portion of the blood sample is in the chamber” because the **valves** are configured to open (and thus no longer close off the **sampling channel**) when the **chamber** is filled with the first portion of the blood sample, as shown in Figures 16 and 17. Ex. 1012, Figs. 16-17; Ex. 1002, ¶¶113-114. This opening of these **valves** allows the remainder of the blood sample (follow-on amounts of the blood sample) to then pass through the **sampling channel** toward the **outlet port** and into the syringe, bypassing the **chamber** as shown by arrow **RR** in Figure 17. §VI.A.6, *supra*; Ex. 1012, ¶¶[1108]-[1111], Fig. 16; Ex. 1002, ¶114. More particularly, once a first portion of a sample is transferred to the **chamber**, these **valves** are opened (as shown by arrows **PP** and **QQ**) such that the **sampling channel** is placed in fluid communication with the **inlet port** and the **outlet port**:

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

For the reasons explained above and with respect to claims 6 and 7, Bullington800 also discloses claim 8’s requirement of “a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber” that is “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.” §§VI.A.6-7, IV.B.1, *supra*. The “release” recited in claim 8 is the movement of the **valves** 538 and 539 from their first configuration to their second configuration, as shown by arrows **PP** and **QQ** in Figure 17. Ex. 1002, ¶117.



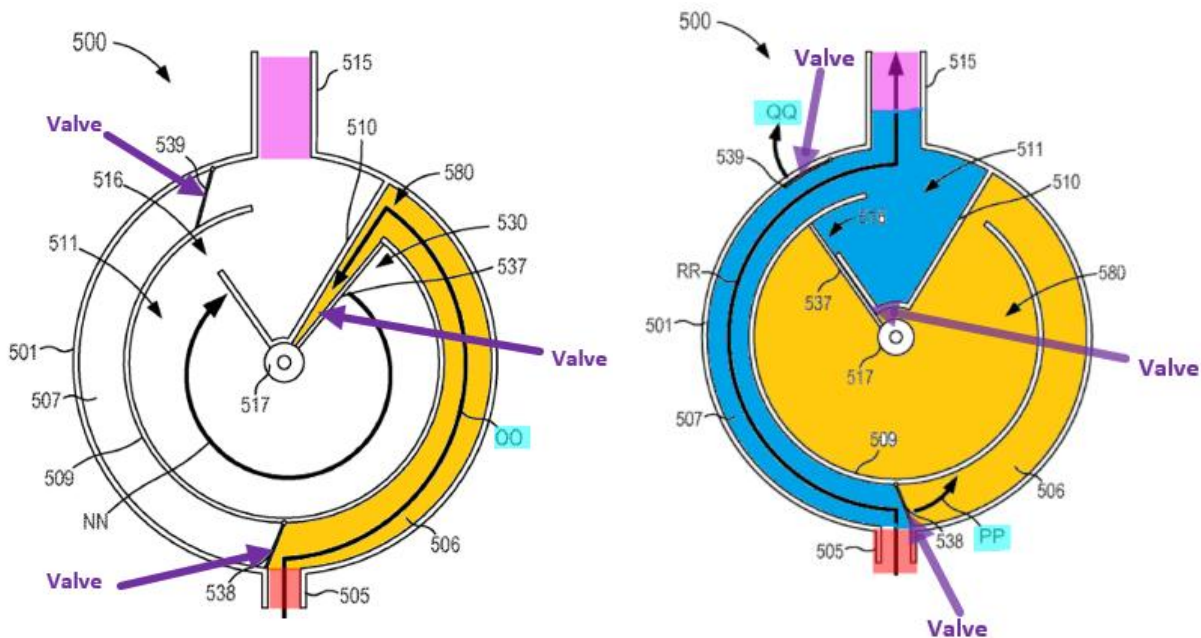
Ex. 1012, Fig. 17 (annotated)

In this configuration, the suction force from the sample syringe urges “follow-on amounts of the blood sample” toward the **outlet port** (i.e., along arrow **RR**), bypassing the **chamber**. §§VI.A.6-7, IV.B.1, *supra*. For the reasons set forth above, Bullington800 discloses and/or renders obvious claim 8. Ex. 1002, ¶¶116-118.

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.

Bullington800 discloses the valve as claimed in claim 6. §VI.A.6, *supra*. Bullington800 explains that, before the first portion of the blood sample is drawn into the **chamber** and as shown in Figures 16-17, the **valves** 537, 538, and 539 (alone or in any combination) close off the region that is the **sampling channel** in Figure 17 (i.e., the **valves** are in their “first position”) “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, Figs. 16 & 17 (annotated)

Ex. 1012, ¶¶[1111], [1109], [1112]-[1113], Fig. 16; Ex. 1002, ¶120.

Accordingly, Bullington800 discloses and/or renders obvious claim 9. Ex. 1002, ¶¶119-121.

10. Dependent Claim 10

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

Bullington800 describes that its device for collecting blood from a patient includes an **inlet port** “coupled to a proximal end portion of a lumen-defining device such as, for example, a butterfly needle...or the like.” Ex. 1012, ¶¶[1111], [1043], [1108], Figs. 1, 16-17. The **outlet port** is coupled to a blood sample collection device, such as a syringe. Ex. 1012, ¶¶[1107]-[1108], [1043], [1111], Figs. 1, 16-

17; §VI.A.1.d, *supra*; Ex. 1002, ¶122.

Accordingly, Bullington800 discloses and/or renders obvious claim 10. Ex. 1002, ¶¶122-123.

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.

Bullington800 discloses a **chamber** that collects “the first portion of the blood sample.” §VI.A.1.d, *supra*; Ex. 1002, ¶124. This sequestered blood “can contain undesirable microbes such as ... dermally-residing microbes and/or other external contaminants” (Ex. 1012, ¶[1112]), and sequestering it keeps the later flow of blood from the patient to the sample reservoir substantially free from contaminants. Ex. 1012, ¶[1114]; Ex. 1002, ¶125. Because the contaminants are “dermally-residing” and “external,” they will be contained within the first portion of blood because the contaminants will be introduced into the collection needle as it punctures the skin or port. Ex. 1012, ¶¶[1004]-[1006], [1030], [1112], [1114]. Any later amount of blood (e.g., blood collected through the sampling channel after the first portion is sequestered in the chamber) is less prone to contamination because the needle has already punctured the skin or port. Bullington800 thus discloses that the sequestered volume of blood is “the first portion of the blood sample that is more prone to

contamination” as claimed. *Id.*; Ex. 1002, ¶125. Indeed, Bullington800 repeatedly describes its device being used to reduce 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], [1112], [1114]; Ex. 1002, ¶125.

Bullington800 also describes the various volumes that may be used for its **chamber** to minimize contamination. For example, it 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]. Thus, Bullington800 teaches that these volumes are sufficient to collect the first portion of blood that is more prone to contamination. This is consistent with what a POSITA would expect in any event; it was 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; Ex. 1002, ¶126.

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. 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.” *Id.*, 9:8-10. The smaller ranges of volumes that Bullington800 discloses, e.g., “from about 0.1 ml to about 3.0 ml,” by virtue of being smaller than the other ranges it discloses, minimize the amount of blood being sequestered. Ex. 1002, ¶126. And, these volumes fall within the range of volumes described in the ’052 Patent. Ex. 1001, 9:8-10, 6:20-23. Further, because the first portion of blood is more likely to be contaminated than later portions, even these smaller **chambers** still collect the first portion of blood that is more prone to contamination.³ A POSITA would have thus understood that Bullington800 discloses a **chamber** having a volume 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. 1002, ¶126; Ex. 1012, ¶¶[1002], [1005]-[1006], [1030]-[1033], [1050], [1112]-[1114].

Accordingly, Bullington800 discloses and/or renders obvious claim 11. Ex. 1002, ¶¶124-127.

³ The claim does not require that the follow-on amounts of blood be free from contamination, or even that the chamber contain blood that is more contaminated than the follow-on blood.

12. Dependent Claim 12

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

As described above, Bullington800 discloses a **chamber**. §VI.A.1.d, *supra*; Ex. 1002, ¶128. As discussed for claim 11, the **chamber** 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.” §VI.A.11, *supra*; Ex. 1012, ¶[1113].

Accordingly, Bullington800 discloses and/or renders obvious claim 12. Ex. 1002, ¶¶128-129.

13. Independent Claim 13

a. [13PRE] “A device comprising:”

As discussed above for [1PRE], Bullington800 discloses “a device” as recited in claim 13. §VI.A.1.a, *supra*. For the reasons set forth below, Bullington800’s device discloses and/or renders obvious the remaining elements [13A]-[13E] of claim 13, and therefore discloses [13PRE]. §§VI.A.13.a-f, *infra*; Ex. 1002, ¶130.

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

As explained above, Bullington800 discloses “an inlet port for receiving a blood sample.” §VI.A.1.b, *supra*. Because Bullington800’s **distal port 505** receives blood samples, it is “an inlet port for receiving blood” as claimed. See §VI.A.1.b, *supra*; Ex. 1002, ¶131.

Therefore, Bullington800 discloses [13A]. Ex. 1002, ¶131.

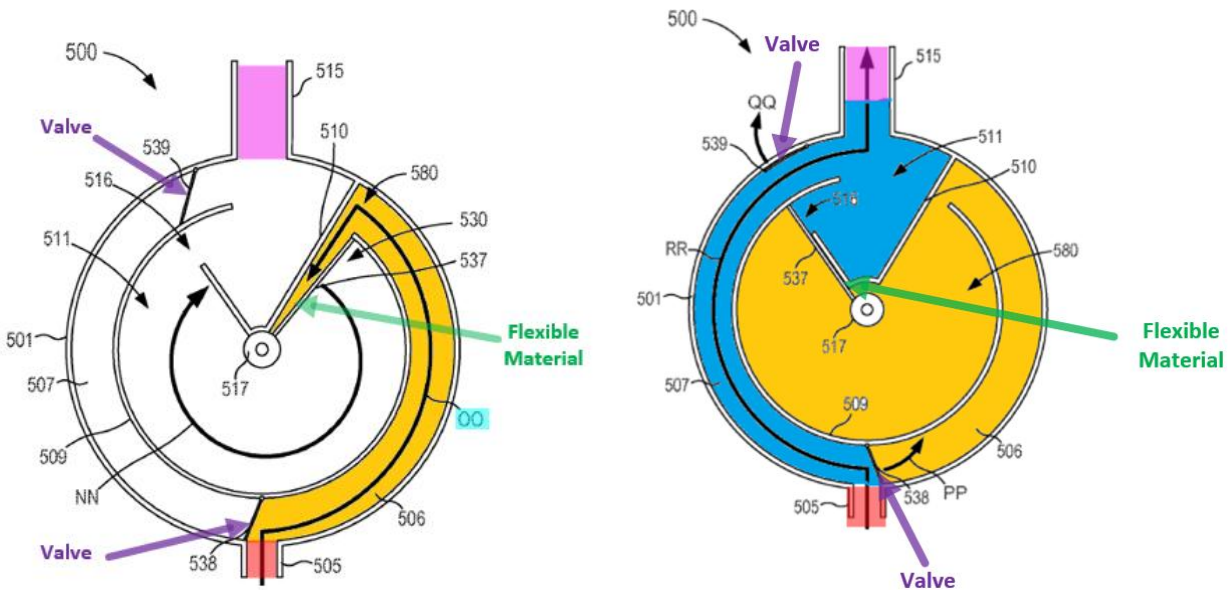
c. [13B] “an outlet port;”

As explained above, Bullington800 discloses a **proximal port 515** that is an “outlet port” as claimed. §VI.A.1.c, *supra*. Thus, Bullington800 discloses [13B]. Ex. 1002, ¶¶132-133.

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;”

Bullington800 discloses [13C]. As explained for [1C], Bullington800’s device comprises a **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. §VI.A.1.d, *supra*; Ex. 1002, ¶134.

Bullington800 also discloses that the **chamber** includes a **first member 537** that can be a “relatively **flexible and/or compressible material**”:



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

§VI.A.2, *supra*; Ex. 1012, ¶¶[1109], [1111], Figs. 16-17; Ex. 1002, ¶135. A flexible and/or compressible material fits the plain and ordinary meaning of a “flexible material” noted above (i.e., “a material that can be flexed, bent, stretched, expanded, or compressed without breaking under normal conditions”) and is also consistent with Petitioner’s first proposed construction (*see* §V.C). Ex. 1012, ¶¶[1109], [1111], Figs. 16-17; Ex. 1002, ¶135. Accordingly, Bullington800 discloses “a chamber comprising a flexible material.” §VI.A.2, *supra*.

For the foregoing reasons, Bullington800 discloses [13C]. Ex. 1002, ¶¶134-135.

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”

Other than reciting “a subsequent portion of the blood” rather than “a subsequent portion of the blood sample,” [13D] is identical to [1D]. As described above, Bullington800 discloses [1D]. §VI.A.1.e, *supra*. Accordingly, Bullington800 discloses [13D]. Ex. 1002, ¶¶136-137.

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

Element [13E] is identical to element [1E], which is disclosed and/or rendered obvious by Bullington800 for the reasons discussed above. §VI.A.1.f, *supra*. Accordingly, Bullington800 discloses and/or renders obvious [13E], and thus Bullington800 discloses and/or renders obvious claim 13. Ex. 1002, ¶138; §§VI.A.13.a-f, *supra*.

14. Dependent Claims 14-24

Dependent claims 14-24 are nearly identical to dependent claims 2-12, and are unpatentable for the same reasons. §§VI.A.2-12, *supra*. The minor wording differences (e.g., “blood” instead of “blood sample”) between some of the terms have no impact on the patentability of the claims, and all features of dependent claims 14-24 are disclosed and/or rendered obvious by Bullington800’s device. *Id.*; Ex. 1002, ¶139.

B. Ground C: Claims 1-24 Are Rendered Obvious By Bullington800 In View Of Brancazio

To any extent that Patent Owner argues Bullington800 does not disclose a “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), Bullington800 in view of Brancazio teaches these features. Ex. 1002, ¶¶140-152. For the reasons set forth below, a POSITA would have found it obvious to combine Bullington800 with Brancazio (“Bullington800-Brancazio”), and such a combination would render claims 1-24 obvious. *Id.*

Brancazio collects a blood sample using a device housing a **vacuum chamber** that applies negative pressure, transmitted through a gas-permeable **membrane**, to draw blood into a **collection/storage chamber**. §IV.B.2, *infra*; Ex. 1013, ¶¶[0042], [0048]-[0049], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. To prevent blood from entering the **vacuum chamber** from the **collection chamber**, the **membrane** is made of a “material permeable to gas but not to...blood.” Ex. 1013, ¶¶[0153]-[0154], Fig. 4; §IV.B.2, *infra*.

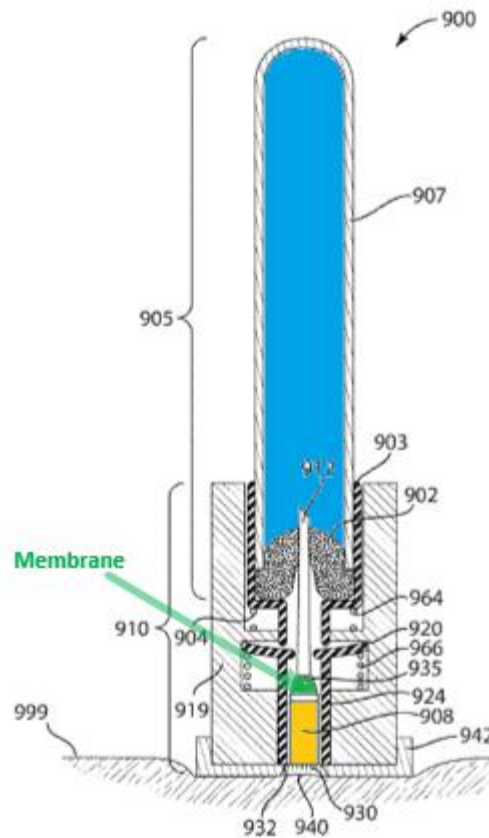
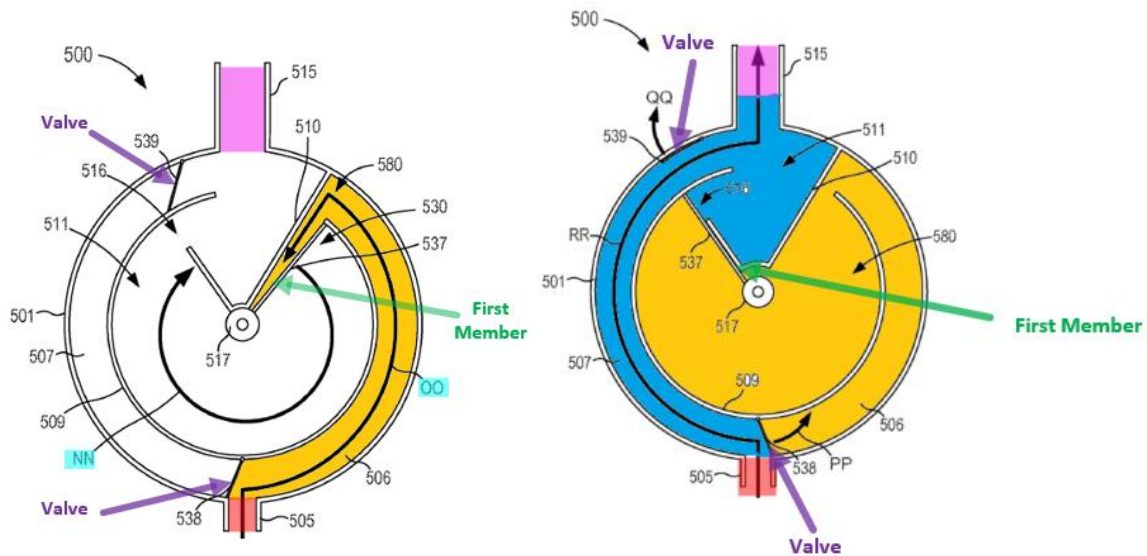


Fig. 13B

Ex. 1013, Fig. 13B (annotated)

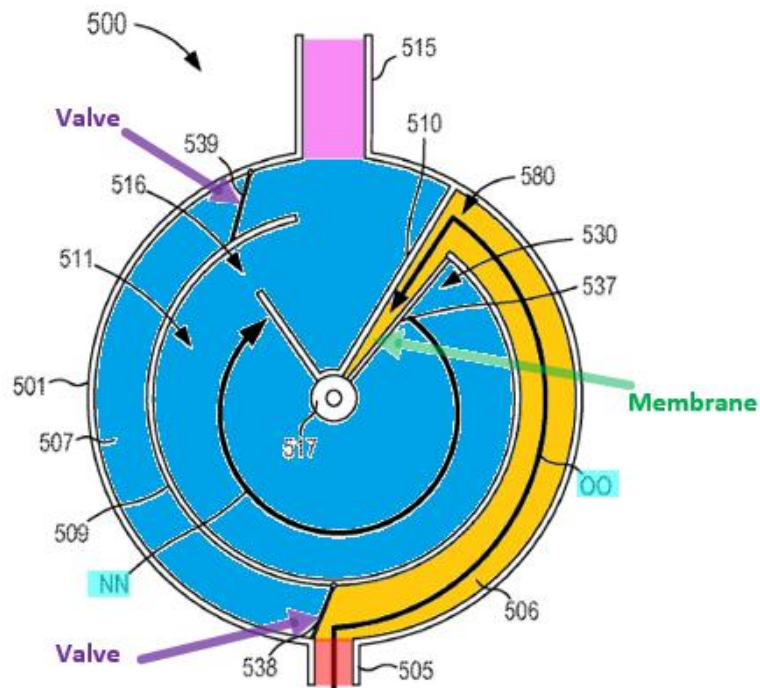
This is similar to how Bullington800 uses negative pressure to collect the initial portion of a blood sample into its **chamber**, although in Bullington800 the negative pressure causes Bullington800's **first member 537** to rotate from a first configuration to a second configuration, thereby increasing the volume of the **chamber** and draw blood into the **chamber**. Ex. 1012, ¶¶[1108]-[1112], Figs. 16-17; Ex. 1002, ¶¶142-143.



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

An advantage provided by the membrane in Brancazio is that it is air-permeable while remaining blood-impermeable. Ex. 1013, ¶¶[0042], [0048]-[0049], [0059], [0088]-[0090], [0099], [0103], [0111], [0115], [0124], [0153]-[0154], [0157], Figs. 4-5, 13A-13E. It would have been obvious to modify Bullington800's device by constructing the **first member 537** out of a "material permeable to gas but not to...blood" as taught by Brancazio because doing so would allow for any air that is in the **chamber** and/or the patient needle to be pulled through the now air-permeable **first member 537** (labeled as a **membrane** in Bullington-Brancazio Drawing 1A, below) as blood from the patient enters the **chamber**, preventing the air from compressing inside the chamber. *Id.*; Ex. 1002, ¶144. For example, constructing the **membrane** from a blood-impermeable, air-permeable material as disclosed in Brancazio would transmit the negative pressure being applied by the

vacuum chamber through the **membrane** to draw a flow of blood from the patient into the **chamber** until it contacts the **membrane** (e.g., as shown by arrow **OO** below), while the negative pressure also pulls any air in the **chamber** through the **membrane**. *Id.* The blood would contact the **membrane** and, due to the negative pressure pulling the blood towards the **outlet port**, the blood would push the **membrane** to move (e.g., as shown by arrow **NN**, below) in the same manner that the **first member 537** in Bullington800 moves to transition from a first configuration to a second configuration. *Id.*; Ex. 1012, ¶¶[1114], [1112]-[1113], Fig. 17.

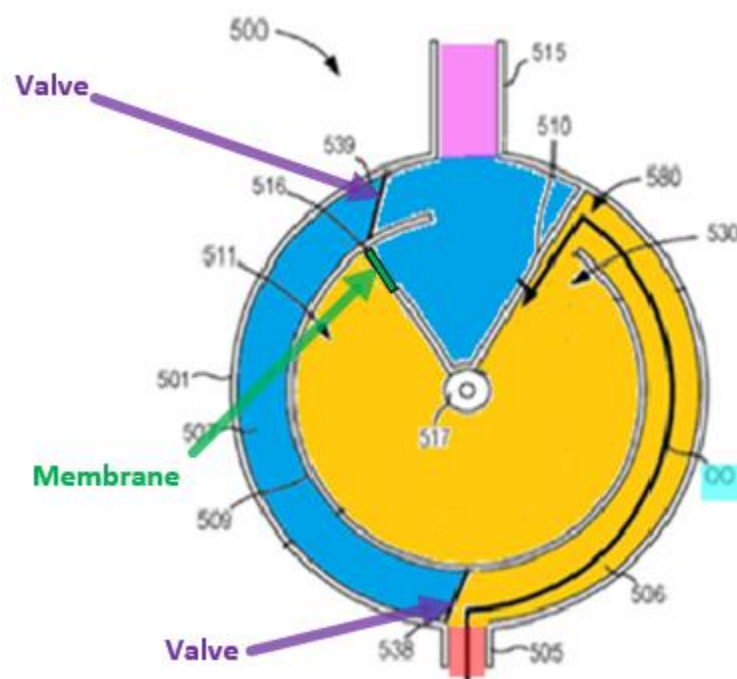


Bullington800-Brancazio Drawing 1A (Ex. 1012, Fig. 16 (modified to show Bullington-Brancazio's membrane))

In an alternative obvious implementation of Bullington800-Brancazio, a POSITA would have been motivated to modify Bullington800's device by permanently positioning **first member 537** in its second configuration (as shown in Figure 17 above) and having it be constructed of a "material permeable to gas but not to...blood" as taught by Brancazio. Ex. 1002, ¶145. The **membrane** in Brancazio is advantageously simpler than the membrane of Bullington800, in that it does not move; Brancazio's **membrane** transmits the negative pressure being applied by the vacuum chamber simply by virtue of being constructed of a gas-permeable material. *Id.* Accordingly, it would have been obvious to produce the alternative implementation of Bullington800-Brancazio to achieve this same advantage in Bullington800's device.

In Bullington800-Brancazio, this modification 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], Figs. 16-17; Ex. 1002, ¶146. In Bullington800-Brancazio, the **membrane** would simply begin in the "second configuration," where the volume of the **chamber** is at its maximum, and the negative pressure from the syringe would be exerted within the **chamber** through the **membrane**, which is made of a material permeable to gas (but not to blood). Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1012, ¶¶[1111]-[1113], Figs.

16-17; Ex. 1002, ¶146. As shown in the modified Figure 16 of Bullington800 below, in Bullington800-Brancazio the introduction of the negative pressure by the syringe located at the **outlet port** results in a suction force exerted through the **membrane**, the **chamber**, and the **inlet port** to draw a flow of blood from the patient into the **chamber** (e.g., as shown by arrow **OO**).



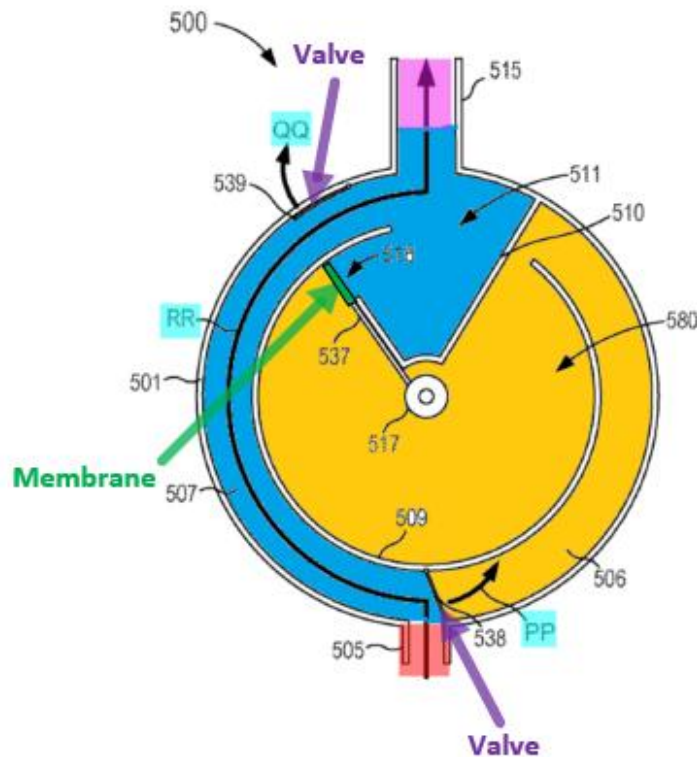
Bullington800-Brancazio Drawing 1B (Ex. 1012, Fig. 16 (modified to show Bullington-Brancazio's membrane that does not move))

Ex. 1002, ¶146; Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

Regardless of whether Bullington800's first member 537 is movable (as shown in Bullington800-Brancazio Drawing 1A) or secured in place (as shown in

Bullington800-Brancazio Drawing 1B), the Bullington800-Brancazio **membrane**, which is blood-impermeable, would prevent the blood entering the **chamber** from entering the **outlet port** in the same way that Brancazio's blood-impermeable 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; Ex. 1002, ¶147.

Once the **chamber** is filled with the initial portion of the blood sample, regardless of which implementation of Bullington800-Brancazio is used, the Bullington800-Brancazio device would operate in essentially the same manner as previously described with respect to Bullington800's Figure 17, *i.e.*, the **second member 538** and the **third member 539** ("valves") would be rotated to place the **sampling channel** in fluid communication with the **inlet port** and the **outlet port** to collect the remaining blood sample. §VI.A.1.e, *supra*; Ex. 1012, ¶¶[1114], [1107]-[1108], [1111]-[1113], Fig. 17; Ex. 1002, ¶148. As shown below, the **second member 538** and the blood-impermeable **membrane** isolate the sequestered contaminated blood in the **chamber**. Ex. 1012, ¶¶[1114], [1107]-[1108], [1111]-[1113], Fig. 17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1002, ¶148.



Bullington800-Brancazio Drawing 2 (Ex. 1012, Fig. 17 (annotated to show Bullington-Brancazio's use of a blood-impermeable air-permeable membrane in Bullington800's device))

A POSITA would have been motivated to produce the first Bullington800-Brancazio implementation (e.g., as shown in Bullington800-Brancazio Drawing 1A above) because doing so allows any air that is in the **chamber** to be drawn, by the negative pressure at the **outlet port**, through the **membrane**, so that the air does not compress in the **chamber**. Ex. 1002, ¶149. A POSITA would also have been motivated to produce the second Bullington800-Brancazio implementation (e.g., as shown in Bullington800-Brancazio Drawing 1B) because doing so has the same

benefit of preventing air from compressing in the **chamber** and also yields a simpler 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. *Id.* Bullington800-Brancazio provides the benefits described above to Bullington800's device while still providing the benefits of avoiding contamination of blood samples. Ex. 1002, ¶149; Ex. 1012, ¶¶[1002]-[1006], [1030], [1050]-[1051], [1112], [1114]; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157].

Either implementation of Bullington800-Brancazio would have been obvious to a POSITA because they merely combine known prior art elements according to known methods in order to yield predictable results. Ex. 1002, ¶150. The known elements are Bullington800's device that has a first chamber for storing the first portion of a blood sample that is isolated from an outlet yet allows a drawing force from the outlet to draw fluid into the first chamber via a moveable membrane, and Brancazio's teaching of a 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. *Id.* The known method of combination is constructing Bullington800's first member 537 using a gas-permeable, blood-impermeable material as described in Brancazio (and, in the second alternative implementation as shown in Bullington800-Brancazio Drawing 1B, securing the

membrane in place). Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1002, ¶150.

Bullington800-Brancazio would have yielded the predictable result of drawing (using a suction force exerted from the outlet port through the gas-permeable, blood-impermeable membrane) potentially contaminated blood into the chamber where it could be sequestered (by the gas-permeable, blood-impermeable membrane). Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1002, ¶¶150-152. The combination also is the simple substitution of one known element (a gas-permeable, blood-impermeable membrane) with another (Bullington800's moveable first member) to achieve the above-described predictable result. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1002, ¶151.

A POSITA would have expected success in producing Bullington800-Brancazio because it involves routine and simple mechanical design techniques with known, predictable results. Ex. 1002, ¶152. And, a POSITA would have had the mechanical design skills to implement Bullington800-Brancazio. *Id.*

1. Independent Claim 1

a. [1PRE] “A device comprising:”

For the reasons set forth below, the Bullington800-Brancazio’s device renders obvious the remaining elements [1A]-[1E] of claim 1, and therefore renders obvious [1PRE]. §§VI.B.1.b-f, *infra*; §VI.A.1.a, *supra*; Ex. 1002, ¶153.

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

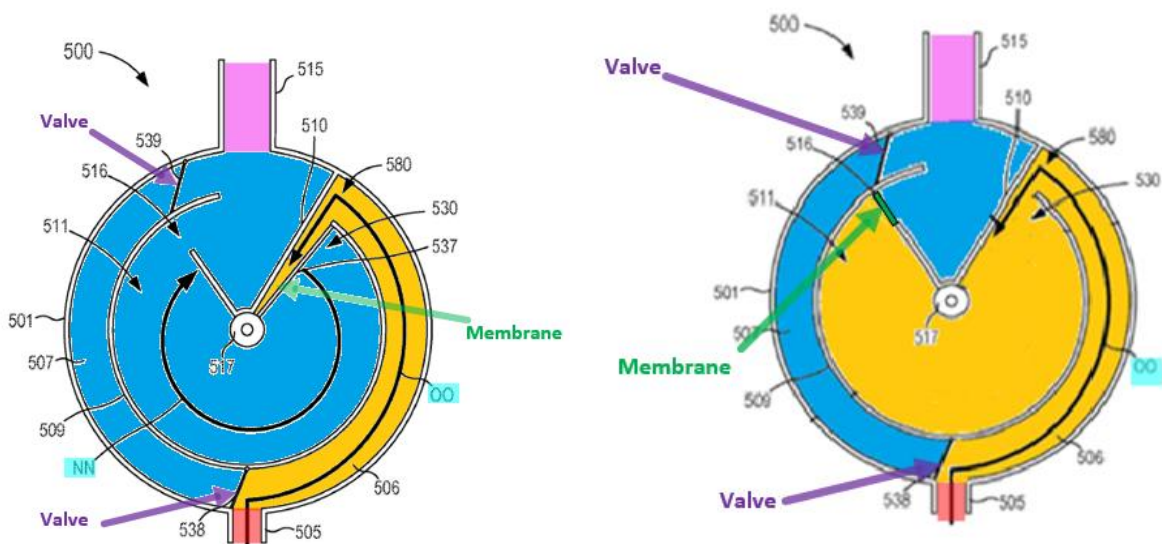
As previously explained, Bullington800 teaches “an inlet port for receiving a blood sample.” Specifically, the **distal port 505** is “an **inlet port** for receiving a blood sample” as claimed. §VI.A.1.b, *supra*; Ex. 1002, ¶154. Bullington800-Brancazio includes the **inlet port** and does not change how Bullington800 teaches [1A]. §VI.B, *supra*. Therefore, Bullington800-Brancazio renders obvious [1A]. §VI.A.1.b, *supra*; Ex. 1002, ¶154.

c. [1B] “an outlet port;”

As previously explained, Bullington800 teaches “an outlet port.” Specifically, the **proximal port 515** is “an **outlet port**” as claimed. §VI.A.1.c, *supra*; Ex. 1002, ¶155. Bullington800-Brancazio includes the **outlet port** and does not change how Bullington800 teaches [1B]. §VI.B, *supra*. Therefore, Bullington800-Brancazio renders obvious [1B]. *Id.*; Ex. 1002, ¶155.

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;”

Bullington800-Brancazio renders obvious [1C]. As shown below, Bullington800-Brancazio’s device (like Bullington800) comprises a **first channel 506** that is “in fluid communication with” a **fluid reservoir 580** (the fluid reservoir, either alone or in combination with the first channel, constitutes the “**chamber**”) that occupies a portion of the inner volume 511 of the device and that is isolated from other portions of the inner volume. Ex. 1012, ¶¶[1107]-[1109], [1112]-[1114], Figs. 16-17; Ex. 1002, ¶156.



Bullington800-Brancazio Drawings 1A and 1B

As seen above, in either implementation of Bullington800-Brancazio, the device is initially configured so that the **chamber** is connected to the **inlet port**. §§VI.A.1.c, VI.B, *supra*; Ex. 1012, ¶¶[1107]-[1109], [1111]-[1112], Figs. 16-17;

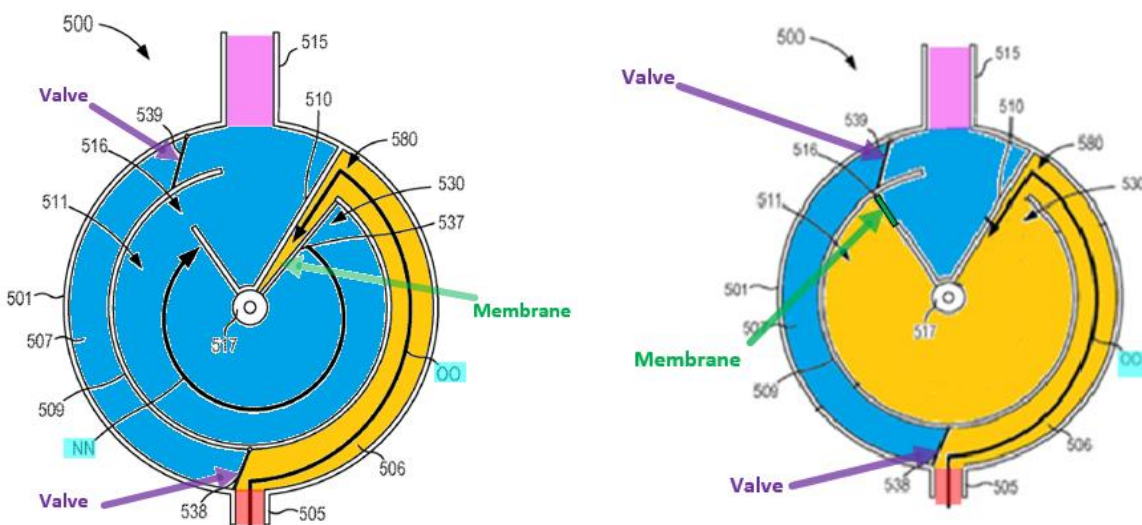
Ex. 1002, ¶157. As previously explained, the **chamber** is configured to receive a first portion of a blood sample from a patient. §§VI.A.1.c, VI.B *supra*; Ex. 1012, ¶¶[1112]-[1114], Figs. 16-17.

Like in Bullington800, in order for the **chamber** of Bullington800-Brancazio to receive the first portion of the blood sample, the **outlet port** is coupled to a sample syringe (claimed “blood sample collection device”). Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17; Ex. 1002, ¶158. When coupled to the **outlet port**, the syringe 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, blood-impermeable **membrane** in Bullington800-Brancazio’s **chamber**, which separates the **chamber** from the **outlet port** as shown in the Bullington800-Brancazio Drawings 1A and 1B above, would transmit the suction force produced by the negative pressure of the syringe (claimed “drawing force applied from the outlet port from a blood sample collection device”) to draw blood from the patient into the **chamber**. §VI.B, *supra*; 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; Ex. 1002, ¶158. The **membrane** would also prevent the blood in the **chamber** from reaching the **outlet port**, thus collecting the blood in the **chamber**. Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154],

[0157], Figs. 4-5, 13A-13E; Ex. 1002, ¶158. Accordingly, Bullington800-Brancazio renders obvious [1C]. Ex. 1002, ¶¶156-159.

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”

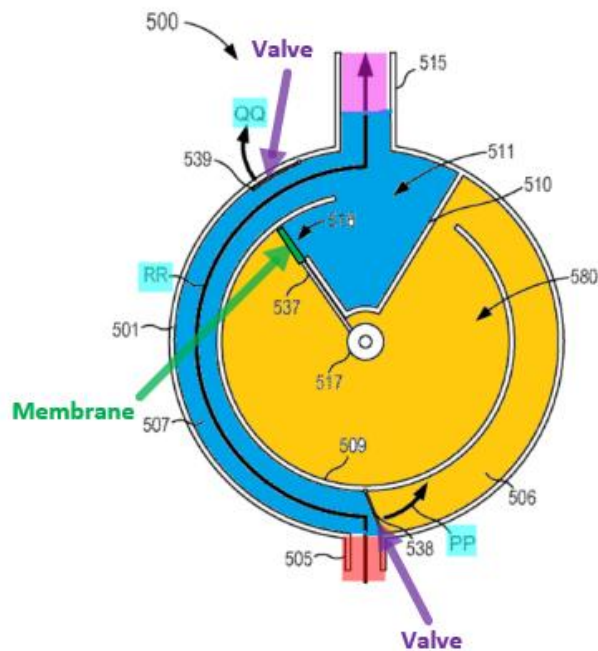
As previously explained, Bullington800 discloses [1D]. §VI.A.1.e, *supra*. Bullington800-Brancazio includes Bullington800’s **second channel 507** (alone or with the **wedge-shaped portion of the inner volume 511** the claimed “**sampling channel**”) that “can be selectively placed in fluid communication with the proximal port 515 and the distal port 505....” Ex. 1012, ¶[1108]; Ex. 1002, ¶160; §VI.A.1.e, *supra*. As shown in Bullington800-Brancazio Drawing 1A and Bullington800-Brancazio Drawing 1B (below), the device is initially configured such that **sampling channel** is isolated from the **inlet port** and the **outlet port** when the **chamber** is in fluid communication with the **inlet port**:



Bullington800-Brancazio Drawings 1A and 1B

Ex. 1012, ¶[1111], Fig. 16; Ex. 1002, ¶160.

As shown in Bullington800-Brancazio Drawing 2 (below), once the initial portion of the blood sample is transferred to the **chamber** (e.g., as shown by arrow **OO** in Bullington800-Brancazio Drawings 1A and 1B) Bullington800-Brancazio's **second member 538** and **third member 539** ("valves") are rotated (as shown by arrows **PP** and **QQ**) such that the **chamber** is isolated from the **inlet port** and the **outlet port** by a **valve** and the blood-impermeable **membrane** to sequester the predetermined volume of blood in the **chamber**. Ex. 1012, ¶¶[1112]-[1114], Fig. 17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1002, ¶161.



Bullington800-Brancazio Drawing 2

As with Bullington800's Figure 17 configuration, the **sampling channel** is placed in fluid communication with the **inlet port** and the **outlet port**. Ex. 1012, ¶[1114], Fig. 17; Ex. 1002, ¶161. The **inlet port** is thus placed in fluid communication with the syringe at the **outlet port**, through the **sampling channel**, 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; Ex. 1002, ¶161. When the syringe exerts the suction force to draw the subsequent blood through the **sampling channel** to the syringe, the blood travels through the **outlet port**. Ex. 1012, ¶¶[1107], [1111]-[1114], Figs. 16-17; Ex. 1002, ¶161. Accordingly, Bullington800-Brancazio renders obvious [1D]. Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1002, ¶¶160-162.

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

As previously explained, Bullington800 discloses and/or renders obvious [1E]. §VI.A.1.f, *supra*. Bullington800-Brancazio includes the same housing in all material respects and does not change how Bullington800 discloses and/or renders obvious [1E]. §VI.B, *supra*. Accordingly, Bullington800-Brancazio renders obvious [1E]. Ex. 1002, ¶163.

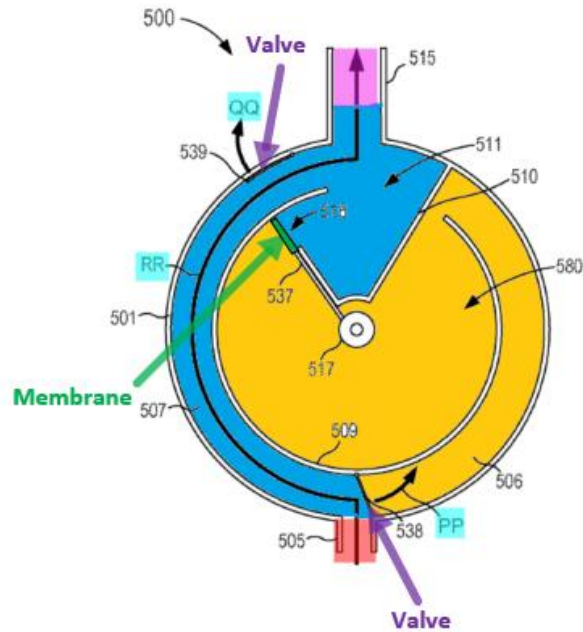
For the foregoing reasons, Bullington800-Brancazio renders obvious claim 1.
Ex. 1002, ¶¶153-163; §§VI.B.1.a-f, *supra*.

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.

As discussed above, Bullington800-Brancazio secures Bullington800's first member 537 that isolates the **chamber** from the **outlet port** into its second configuration and constructs it from the material of Brancazio's membrane (claimed "blood impermeable membrane"). §VI.B, *supra*; Ex. 1002, ¶¶164-165.

Bullington800-Brancazio's **membrane** "is configured to facilitate the chamber collecting the first portion of the blood sample" in at least two ways. First, as previously described, the blood-impermeable **membrane** is gas-permeable (Ex. 1013, ¶[0059]) and thus transmits the negative pressure of the syringe exerted through the **outlet port** so that it draws the blood (claimed "first portion of the blood sample") into the **chamber**, as shown by arrow **OO** in the Bullington800-Brancazio Drawings 1A and 1B (below). §VI.B.1.d, *supra*; Ex. 1002, ¶166.



Bullington800-Brancazio Drawing 2

Additionally, the second member 538 of Bullington800-Brancazio (labeled a “**valve**” above) teaches the claimed “blood impermeable membrane” for the same reasons as previously described. §VI.A.2, *supra*.

Thus, Bullington800-Brancazio renders obvious claim 2. Ex. 1002, ¶¶164-168.

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.

As described above (§VI.B.2, *supra*), Bullington800-Brancazio’s device includes a blood-impermeable **membrane** that prevents the blood in the **chamber**

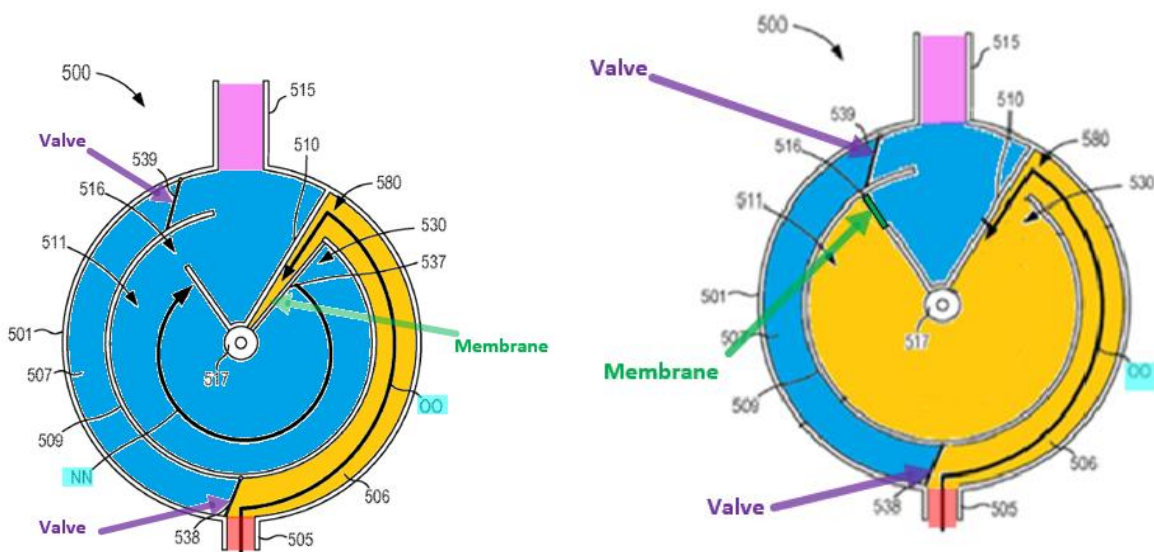
from reaching the **outlet port**, keeping the initial portion of the blood sample that was drawn into the **chamber** backed up (sequestered) within the **chamber**. Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1002, ¶169.

For the reasons set forth above, Bullington800-Brancazio renders obvious claim 3. Ex. 1002, ¶¶170-171.

4. Dependent Claim 4

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

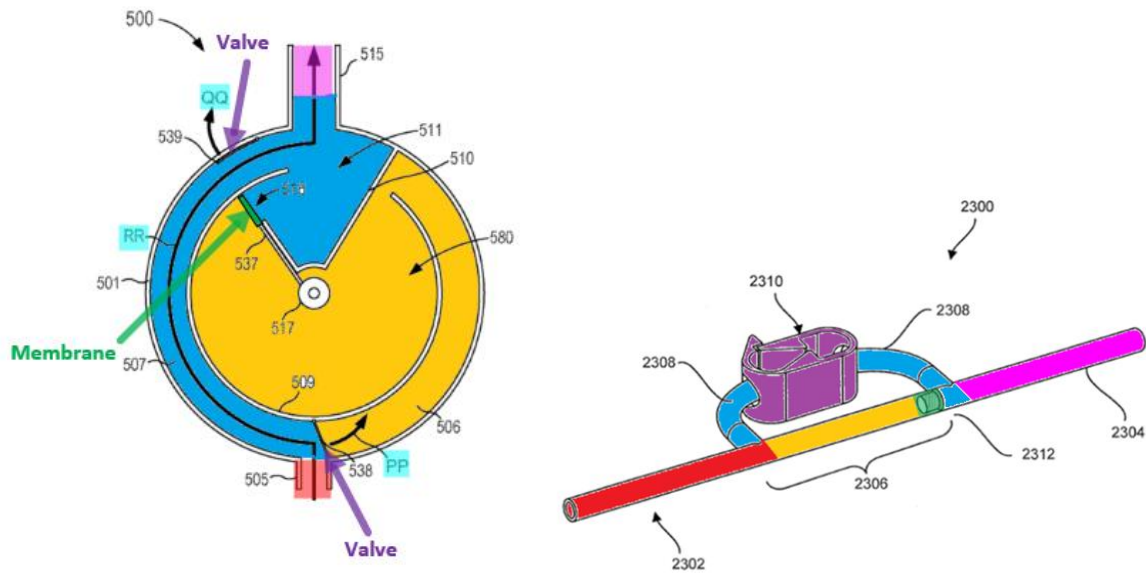
As described above, Bullington800-Brancazio renders obvious claim 2 and includes a blood-impermeable **membrane**. §VI.B.2, *supra*; Ex. 1002, ¶¶172-173. As further discussed, Bullington800-Brancazio also includes a housing 501. §VI.B.1.f, *supra*; Ex. 1012, ¶[1107], Figs. 16-17. As shown below, the **membrane** is separate from the housing 501 that defines the outer boundary of the device:



Bullington800-Brancazio Drawings 1A and 1B

Ex. 1012, Figs. 16-17, ¶¶[1107]-[1114]. Like Bullington800's first member 537, the **membrane** is a component separate from the housing 501 that may be placed in contact with the housing 501. §VI.A.1.f, above; Ex. 1002, ¶174.

The configuration of the **membrane** relative to the housing 501 is consistent with the disclosures of the **hydrophobic plug** in the '052 Patent. Ex. 1002, ¶175. 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, 5:28-47, Figs. 23A-23B. As depicted in the comparison below, the **hydrophobic plug 2312** of the '052 Patent contacts the walls of the **sequestration chamber 2306** similarly to how Bullington800-Brancazio's **membrane** is placed in contact with an inner surface of the housing 501:



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

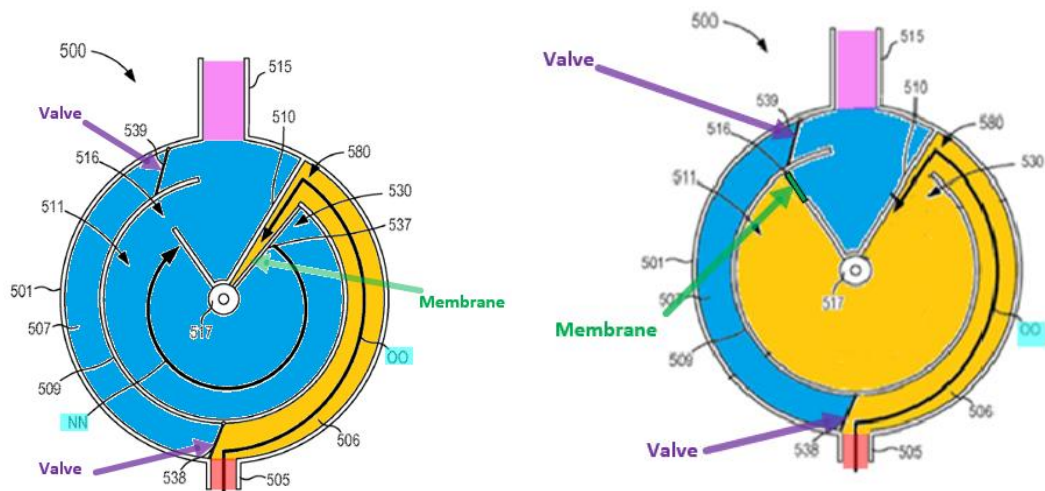
Additionally, the second member 538 of Bullington800-Brancazio (labeled a “**valve**” above) teaches the claimed “blood impermeable membrane” that is separate from the housing for the same reasons as previously described. §VI.A.4, *supra*. Thus, Bullington800-Brancazio teaches “wherein the housing is 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; Ex. 1002, ¶¶175-176.

Accordingly, Bullington800-Brancazio renders obvious claim 4. Ex. 1002, ¶¶172-177.

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.

As explained above, Bullington800-Brancazio teaches a **chamber** to receive a first portion of a blood sample from a patient, drawn into the **chamber** by a drawing force generated by, e.g., a syringe at the **outlet port**. §§VI.B.1.c-d, VI.B.2-3, *supra*. As shown in Bullington800-Brancazio Drawings 1A and 1B, below, by arrow **OO**, the flow of the first portion of the blood sample contacts the blood-impermeable **membrane**, as well as diverter 509, wall 510, and the exterior wall of the housing (which are all also blood-impermeable, see §VI.A.5, *supra*). Ex. 1012, ¶¶[1112]-[1113], Fig. 16; §VI.B.2, *supra*; Ex. 1002, ¶¶178-179.



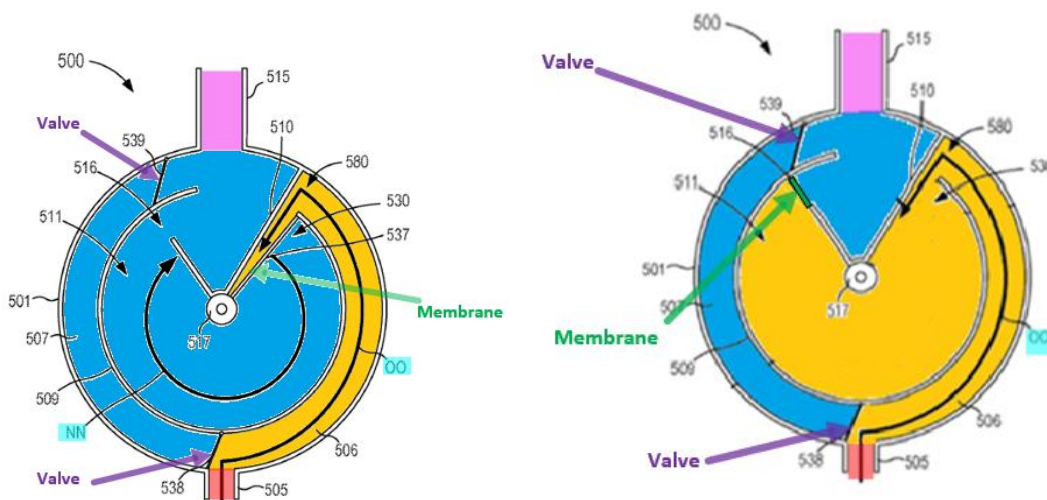
Bullington800-Brancazio Drawings 1A and 1B

Accordingly, Bullington800-Brancazio renders obvious claim 5. Ex. 1002, ¶¶178-180.

6. Dependent Claim 6

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

As previously explained, Bullington800 discloses that at least the **second member 538** and the **third member 539** (“**valves**”) each close off the **sampling channel**. §VI.A.6, *supra*; Ex. 1012, ¶[1111], Fig. 16; Ex. 1002, ¶181. Each of 538 and 539 is “a valve configured to initially close off the sampling channel” as claimed, as is the combination of 538 and 539. As shown below, Bullington800-Brancazio includes these same features and thus renders obvious claim 6.



Bullington800-Brancazio Drawings 1A and 1B

§VI.A.6, *supra*; Ex. 1012, ¶[1111], Fig. 16; Ex. 1002, ¶¶181-182.

7. Dependent Claims 7-12

As previously explained, Bullington800 discloses or renders obvious claims 7-12. §§VI.A.7-12, *supra*. Constructing first member 537 with a gas-permeable, blood-impermeable membrane as taught by Brancazio in Bullington800-Brancazio does not change how Bullington800 discloses the features of claims 7-12. *Id.*; Ex.

1012, ¶¶[1106]-[1114], Figs. 16-17; Ex. 1002, ¶183. Accordingly, Bullington800-Brancazio renders obvious claims 7-12. Ex. 1002, ¶183.

8. Independent Claim 13

a. [13PRE] “A device comprising:”

As discussed above for [1PRE], Bullington800-Brancazio renders obvious “[a] device” as recited in claim 13. §VI.B.1.a, *supra*. For the reasons set forth below, Bullington800-Brancazio’s device renders obvious the remaining elements [13A]-[13E] of claim 13, and therefore renders obvious [13PRE]. §§VI.B.8.b-f, *infra*; Ex. 1002, ¶184.

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

As explained above, Bullington800-Brancazio teaches “an inlet port for receiving a blood sample.” §VI.B.1.b, *supra*. Because Bullington800-Brancazio’s **inlet port** receives blood samples, it is “an inlet port for receiving blood” as claimed. §VI.B.1.b, *supra*; Ex. 1002, ¶185.

Therefore, Bullington800-Brancazio renders obvious [13A]. Ex. 1002, ¶185.

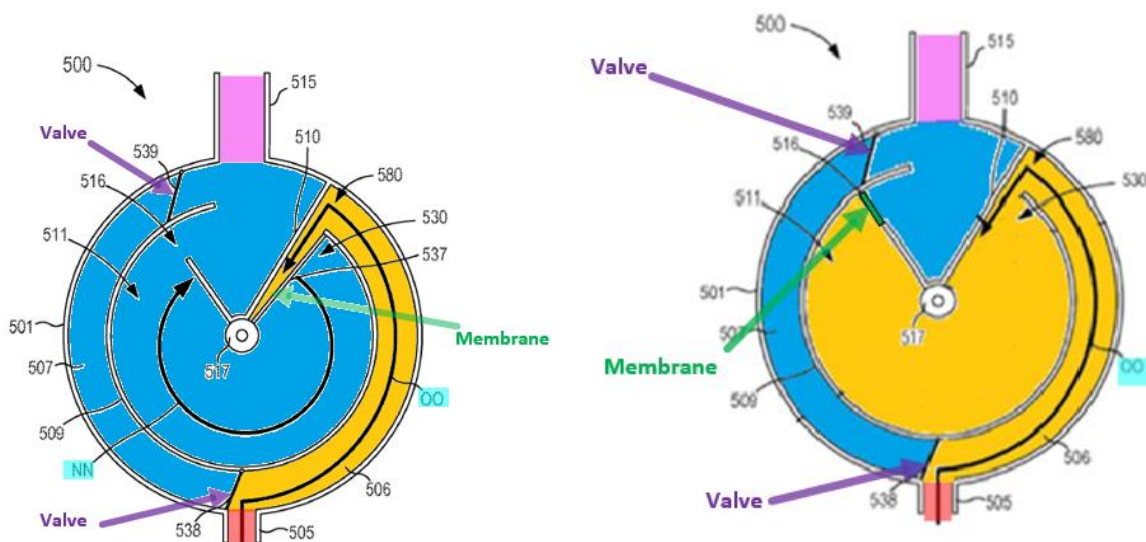
c. [13B] “an outlet port;”

As explained above, Bullington800-Brancazio teaches a **proximal port 515** (claimed “an outlet port”). §VI.B.1.c, *supra*. Thus, Bullington800-Brancazio renders obvious [13B]. Ex. 1002, ¶¶186-187.

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;”

Bullington800-Brancazio renders obvious [13C]. As explained for [1C], Bullington800-Brancazio's device comprises a **chamber** that is "in fluid communication with" and connected with **distal port 505** ("the inlet port"). §VI.B.1.d, *supra*. Further, Bullington800-Brancazio's **chamber** collects the first portion of a blood sample when under a drawing force applied from the **proximal port 515** ("the outlet port"). *Id.* Accordingly, for the reasons set forth for [1C], 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.*; Ex. 1002, ¶188.

As previously explained, Bullington800-Brancazio’s **chamber** includes a **membrane**. §VI.B.1.d, *supra*; Ex. 1002, ¶189.



Bullington800-Brancazio Drawings 1A and 1B

While Brancazio does not explicitly say whether its **membrane** is flexible, it was well-known for a membrane (e.g., a hydrophobic membrane as described in Brancazio) to be made of a flexible material, and Bullington800 teaches the use of a flexible material. Ex. 1002, ¶¶44-45, 190-191; Ex. 1012, ¶[1109]; Ex. 1015, 1:6-62, 2:13-38; Ex. 1016, Abstract, 5:52-57; Ex. 1017, Abstract, ¶¶[0064]-[0065]; Ex. 1018, 1:39-49, 4:62-67. Constructing Bullington800-Brancazio's hydrophobic **membrane** out of a flexible material would have been obvious to try as one of a finite number (i.e., two—flexible and inflexible) of identified, predictable solutions for systems utilizing a hydrophobic membrane. Ex. 1002, ¶192. Specifically, a POSITA would have found it obvious to try a flexible material having a high hydrophobicity as one of a finite number of identified materials for producing a hydrophobic membrane. *Id.*; Ex. 1014, ¶¶[0007]-[0008], [0052]; Ex. 1015, 1:6-62, 2:13-38; Ex. 1016, Abstract, 5:52-57; Ex. 1017, Abstract, ¶¶[0064]-[0065]; Ex. 1018, 1:39-49, 4:62-67. Brancazio also already describes that “various components of the invention are fabricated from polymeric and/or flexible and/or elastomeric materials.” Ex. 1013, ¶¶[0222]-[0223]. Further, it was known that hydrophobic membranes, made of materials that can be flexed, bent, twisted, stretched, expanded, easily hand-folded, and/or compressed, such as fibers or polytetrafluoroethylene (PTFE), allow for gas to pass through the membrane while preventing liquid (e.g.,

blood) from passing. Ex. 1002, ¶¶44-45, 190-191; Ex. 1033, 4:46-62, 5:25-30, 6:1-9, 6:17-26, Figs. 4, 11-13; Ex. 1032, Abstract, 6:14-49, 7:6-12, claims 1, 5; Ex. 1034, 7:43-66, 11:18-34, 15:65-16:12. Thus, it would have been obvious to try constructing the hydrophobic membrane, implemented in Bullington800-Brancazio, out of a flexible material. Ex. 1002, ¶¶191-192. Additionally, a POSITA would have been motivated to construct the **membrane** out of a flexible material because a flexible material would result in an improved seal between the **membrane** and adjacent housing 501. *Id.*, ¶191.

For the foregoing reasons, Bullington800-Brancazio renders obvious [13C]. *Id.*, ¶¶188-193.

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”

Other than reciting “a subsequent portion of the blood” rather than “a subsequent portion of the blood sample,” [13D] is identical to [1D]. As described above, Bullington800-Brancazio renders obvious [1D]. Accordingly, Bullington800-Brancazio renders obvious [13D]. Ex. 1002, ¶¶194-195.

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

Element [13E] is identical to element [1E], which is taught by Bullington800-Brancazio for the reasons discussed above. §VI.B.1.f, *supra*. Accordingly,

Bullington800-Brancazio renders obvious [13E], and thus Bullington800-Brancazio renders obvious claim 13. Ex. 1002, ¶196; §§VI.B.13.a-f, *supra*.

9. Dependent Claims 14-24

Dependent claims 14-24 are nearly identical to dependent claims 2-12, and are unpatentable for the same reasons. §§VI.B.2-7, *supra*. The minor wording differences (e.g., “blood” instead of “blood sample”) between some of the terms have no impact on the patentability of the claims, and all features of dependent claims 14-24 are rendered obvious by Bullington800-Brancazio’s device. *Id.*; Ex. 1002, ¶197.

C. Ground D: Claims 13-24 Are Rendered Obvious By Bullington800 In View Of Brancazio and Liu

As explained above, a POSITA would have been motivated to construct Bullington800-Brancazio’s hydrophobic membrane using a flexible material. §VI.B.8.d, *supra*; 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]. But to any extent that Patent Owner argues that it would not have been obvious for Bullington800-Brancazio’s membrane to be made of a flexible material, Bullington800-Brancazio in further view of Liu teaches this feature. Ex. 1002, ¶¶198-204. A POSITA would have found it obvious to combine Bullington800-

Brancazio with Liu (“Bullington800-Brancazio-Liu”), and such a combination would render claims 13-24 obvious. *Id.*, ¶¶198-214.

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]. Liu provides an example where the hydrophobic membrane is made of a material such as polytetrafluoroethylene (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. *Id.*, ¶[0052]; Ex. 1002, ¶199. Liu uses its membrane in a system that, like the ’052 Patent, uses pressure to cause the fluid to flow towards the membrane. §IV.B.3, *supra*.

In Bullington800-Brancazio-Liu, Bullington800-Brancazio’s device would continue to operate as described above, with the **membrane** being made of a flexible gas-permeable hydrophobic material such as described in Liu. §VI.B, *supra*; Ex. 1002, ¶200. A POSITA would have been motivated to combine Bullington800-Brancazio with Liu’s flexible gas-permeable hydrophobic membrane because such materials are known for having a high hydrophobicity. Ex. 1014, ¶¶[0052], [0007]-[0008], [0021]-[0022]; Ex. 1015, 1:6-62, 2:13-38. Bullington800 and Brancazio each recognize the importance of avoiding contamination, by liquid bodily-fluids (e.g., blood), of certain portions of a medical device. Ex. 1012, ¶¶[1002]-[1006], [1030], [1050]-[1051], [1112], [1114]; Ex. 1013, ¶¶[0103], [0059], [0090], [0111],

[0115], [0153]-[0154], [0157]; Ex. 1002, ¶201. A POSITA would thus have recognized the benefits of selecting a material specifically known for having a high hydrophobicity for the hydrophobic membrane in Bullington800-Brancazio, in order to minimize or eliminate any chance of blood traversing the **membrane** to enter the **sampling channel** and/or **outlet port**. Ex. 1002, ¶201; Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]. A POSITA would also have recognized the further benefit provided by Liu's *flexible* hydrophobic membrane material of improving the seal between the **membrane** and surrounding housing 501. Ex. 1002, ¶201; Ex. 1014, ¶¶[0031], [0037], Fig. 1. A POSITA would also have recognized that flexible hydrophobic membranes were one well-known example of materials that can filter air and prevent liquid/blood passage. Ex. 1002, ¶201; Ex. 1033, 4:46-62, 5:25-30, 6:1-9, 6:17-26, Figs. 4, 11-13; Ex. 1032, Abstract, 6:14-49, 7:6-12, claims 1, 5; Ex. 1034, 7:43-66, 11:18-34, 15:65-16:12.

Additionally, Bullington800-Brancazio-Liu would have been obvious to a POSITA because it merely combines known prior art elements according to known methods in order to yield predictable results. Ex. 1002, ¶202. The known elements are Bullington800-Brancazio's device that has a first chamber for storing blood that is isolated from a second chamber by a gas-permeable, blood-impermeable membrane, and Liu's disclosure of such a membrane that is made of a flexible material (e.g., one that can be easily hand-folded, flexed, twisted, and bent, and/or

stretched, expanded, or compressed without breaking under normal conditions) with a high hydrophobicity (e.g., PTFE). *Id.*; 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 of combination was simply to use a flexible, hydrophobic material as taught by Liu when constructing the membrane of Bullington800-Brancazio. Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]; Ex. 1002, ¶202.

Bullington800-Brancazio-Liu would have yielded the predictable result that the membrane would be gas-permeable, blood-impermeable, and flexible. Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]; Ex. 1002, ¶202; Ex. 1012, ¶¶[1107]-[1108], [1111]-[1114], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E.

Further, Bullington800-Brancazio-Liu would have been obvious to try as one of a finite number (i.e., two – flexible and inflexible) of identified, predictable solutions for systems utilizing a hydrophobic membrane. Ex. 1002, ¶203. Specifically, when combining Bullington800-Brancazio with the motivations described above (§VI.B, *supra*; Ex. 1002, ¶¶149-152), a POSITA would have found it obvious to try Liu’s flexible material as one of a finite number of identified

materials for producing a hydrophobic membrane. Ex. 1002, ¶203; Ex. 1014, ¶¶[0007]-[0008], [0052].

A POSITA would have expected success in producing Bullington800-Brancazio-Liu because it involves routine and simple techniques with known, predictable results. Ex. 1002, ¶204. Liu’s flexible material is a known material for making hydrophobic membranes. Ex. 1014, ¶¶[0007]-[0008], [0052]. And, a POSITA would have had the skills to implement Bullington800-Brancazio-Liu. Ex. 1002, ¶204.

1. Independent Claim 13

a. [13PRE]-[13B]

The construction of the membrane in Bullington800-Brancazio-Liu using a flexible material does not otherwise change how the device of Bullington800-Brancazio (and thus Bullington800-Brancazio-Liu) renders obvious [13PRE]-[13B]. §§VI.B.8.a-c, *supra*; Ex. 1002, ¶¶205-207.

b. [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;”

Bullington800-Brancazio-Liu renders obvious [13C]. As explained for Ground C, Bullington800-Brancazio’s device renders [13C] obvious. To the extent that Patent Owner argues Bullington800-Brancazio fails to render obvious the use

c. [13D]-[13E]

The construction of the membrane in Bullington800-Brancazio-Liu using a flexible material does not otherwise change how the device of Bullington800-Brancazio (and thus Bullington800-Brancazio-Liu) renders obvious [13D]-[13E]. §§VI.B.8.e-f, *supra*; Ex. 1002, ¶¶210-211.

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.

As discussed above, Bullington800-Brancazio secures Bullington800's first member 537 that isolates the **chamber** from the **outlet port** and constructs it from a gas-permeable, blood-impermeable **membrane** as taught by Brancazio. §VI.B, *supra*; Ex. 1012, ¶¶[1109], [1111], Figs. 16-17; Ex. 1013, ¶¶[0059], [0090], [0103], [0111], [0115], [0153]-[0154], [0157], Figs. 4-5, 13A-13E; Ex. 1002, ¶212. In Bullington800-Brancazio-Liu, the **membrane** (recited "flexible material") is made of a material known for its flexibility and high hydrophobicity and the membrane remains blood-impermeable. Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]. As further discussed above, a POSITA would have understood that Bullington800-Brancazio's **membrane** (and thus, Bullington800-Brancazio-Liu's **membrane**) "is configured to facilitate the chamber collecting the first portion of the blood sample."

§VI.B.2, *supra*. Thus, Bullington800-Brancazio-Liu renders obvious claim 14. Ex. 1002, ¶212.

3. Dependent Claim 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.

Bullington800-Brancazio-Liu renders obvious a blood-impermeable **membrane** (“flexible material”) in the **chamber**. §VI.C.2, *supra*; Ex. 1014, ¶¶[0007]-[0008], [0021]-[0022], [0052]. As explained above, this **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.” §§VI.B.3, VI.B.9, *supra*; Ex. 1002, ¶213. Thus, Bullington800-Brancazio-Liu renders obvious claim 15. Ex. 1002, ¶213.

4. Dependent Claims 16-24

Dependent claims 16-24 are nearly identical to dependent claims 4-12, and are unpatentable over Bullington-Brancazio-Liu for the same reasons they are unpatentable over Bullington-Brancazio. §§VI.B.4-7, VI.B.9, *supra*. The construction of the membrane in Bullington800-Brancazio-Liu using a flexible material does not otherwise change how the device of Bullington800-Brancazio (and

thus Bullington⁸⁰⁰-Brancazio-Liu) renders obvious claims 16-24. *Id.*; Ex. 1002, ¶214.

VII. GROUNDS FOR STANDING & FEE PAYMENT

Petitioner hereby certifies that the '052 Patent is available for, and Petitioner is not barred or estopped from requesting, *inter partes* review challenging claims 1-24.

Pursuant to 37 C.F.R. §42.103, the undersigned authorizes the charge of any required fees to Deposit Account No. 19-0733.

VIII. THE DIRECTOR SHOULD NOT DISCRETIONARILY DENY INSTITUTION

Pursuant to the USPTO's March 26, 2025 Memorandum and FAQs⁴ regarding its interim processes for discretionary denial, Petitioner does not address such issues herein. Petitioner reserves all rights to address any discretionary denial issues.

In view of the USPTO's October 16, 2025, Notice of Proposed Rulemaking, Petitioner stipulates that if the PTAB institutes this IPR (and does not subsequently vacate institution), Petitioner and any real party in interest or privy of the Petitioner

⁴ https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management?utm_campaign=subscriptioncenter&utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=.

will not raise in the trial currently scheduled to begin on December 8, 2025 in the Corresponding District Court Litigation (*Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, 1-24-cv-01124 (D. Del. filed Mar. 4, 2024)), grounds of invalidity or unpatentability to the challenged patent under 35 U.S.C. §§ 102 or 103. This stipulation does not apply to any subsequent trials regarding the '052 Patent that may or may not occur.

IX. CONCLUSION

Inter partes review should be instituted and claims 1-24 canceled.

Dated: November 12, 2025

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for Inter Partes Review totals 13,980, which is less than the 14,000 allowed under 37 CFR § 42.24(a)(1)(i). This total includes words as counted by the Word Count feature of Microsoft Word and 235 words used in annotations.

Pursuant to 37 C.F.R. § 42.24(a)(1), this count does not include the table of contents, the table of authorities, mandatory notices under § 42.8, the certificate of service, this certification of word count, the claim listing appendix, or appendix of exhibits.

BANNER & WITCOFF, LTD

Dated: November 12, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.105, I hereby certify that I caused a true and correct copy of this Petition for *Inter Partes* Review in connection with U.S. Patent No. 12,138,052 and supporting evidence to be served via U.S.P.S. Priority Mail Express on November 12, 2025, on the following:

PILLSBURY WINTHROP SHAW PITTMAN LLP
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Dated: November 12, 2025

By: /Frederic M. Meeker/

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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.