

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: De Becdelievre et al. Attorney Docket No.: 58498-0005IP1
U.S. Patent No.: 11,806,454
Issue Date: Nov. 7, 2023
Appl. Serial No.: 18/148,864
Filing Date: December 30, 2022
Title: WEARABLE BREAST PUMP SYSTEM

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PETITION FOR *INTER PARTES* REVIEW OF U.S. PAT. NO. 11,806,454
PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBITS

EX1001	U.S. Patent No. 11,806,454 to De Becdelievre et al. (“the ’454 Patent”)
EX1002	Excerpts from the Prosecution History of the ’454 Patent (“the ’454 Prosecution History”)
EX1003	Declaration and Curriculum Vitae of Ryan Bauer
EX1004	U.S. Patent No. 10,149,929 to Furrer et al. (“Furrer”)
EX1005	U.S. Patent Application Pub. No. 2015/0283311 to Alvarez et al. (“Alvarez”)
EX1006	U.S. Patent Application Pub. No. 2015/0217035 to Pollen et al. (“Pollen”)
EX1007	U.S. Patent Application Pub. No. 2004/0087898 to Weniger (“Weniger”)
EX1008	U.S. Patent Application Pub. No. 2018/0021491 to Rigert et al. (“Rigert”)
EX1009	PCT Application Pub. No. WO2016/186452 to Park
EX1010	Certified English translation of PCT Application Pub. No. WO2016/186452 to Park (“Park”)
EX1011	U.S. Patent Application Pub. No. 2011/0071466 to Silver et al. (“Silver”)
EX1012	U.S. Patent No. 7,677,423 to Kasting et al. (“Kasting”)
EX1013	U.S. Patent No. 8,187,227 to Luzbetak et al. (“Luzbetak”)
EX1014	U.S. Patent No. 10,046,097 to Thompson et al. (“Thompson”)
EX1015	U.S. Patent Application Pub. No. 2018/0333523 to Chang et al. (“Chang”)

- EX1016 Docket of *Shenzhen Root Technology Co., Ltd., v. Chiaro Technology, Ltd.*, Case No. 2:23-cv-631-KKE (W.D. Wash.), as of August 13, 2024
- EX1017 Order on Motion to Continue Pretrial Deadlines and Strike Trial Date, *Shenzhen Root Technology Co., Ltd., v. Chiaro Technology, Ltd.*, Case No. 2:23-cv-631 (W.D. Wash.), issued June 28, 2024
- EX1018 Momcozy’s Motion to Continue Pre-Trial Deadlines and Strike Trial Date, *Shenzhen Root Technology Co., Ltd., v. Chiaro Technology, Ltd.*, Case No. 2:23-cv-631 (W.D. Wash.), issued June 4, 2024
- EX1019 U.S. Patent No. 6,379,327 to Lundy (“Lundy”)
- EX1020 PCT Application Pub. No. WO2002/102437 to Myers et al.
- EX1021 PTC Application Pub. No. WO2008/137678 to Myers et al.
- EX1022 U.S. Patent Application Pub. No. 2016/0082166 to Guthrie et al.

LISTING OF CLAIMS

Claim 17	
[17pre]	A breast pump system comprising:
[17a-1]	a control unit comprising:
[17a-2]	a battery, and
[17a-3]	a pump configured to be powered by the battery and to generate negative air pressure; and
[17b]	a wearable milk collection hub configured to connect to the control unit via an air line, the wearable milk collection hub comprising:
[17c-1]	a breast shield comprising:
[17c-2]	a breast flange; and
[17c-3]	a nipple tunnel extending from the breast flange;
[17d]	a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel;
[17e]	an outer shell comprising a rear end configured to removably attach to the breast shield and, an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk; and
[17f]	a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end, the diaphragm cap forms a central region on a front surface of the outer shell.
Claim 18	
[18]	The breast pump system of claim 17, wherein the breast shield comprises an outer edge configured to be received by the rear end of the outer shell.
Claim 19	

[19]	The breast pump system of claim 17, wherein the interior volume is bounded by the rear end of the outer shell and a front end of the breast shield.
Claim 21	
[21]	The breast pump system of claim 17, further comprising a milk port through which the expressed milk flows into the chamber.
Claim 22	
[22]	The breast pump system of claim 21, wherein the diaphragm is configured to extend over and adjacent to the milk port in a relaxed state.
Claim 23	
[23]	The breast pump system of claim 21, further comprising a non-return valve configured to be mounted to the milk port.
Claim 24	
[24]	The breast pump system of claim 17, wherein the diaphragm cap comprises an air port configured to receive an end of the air line.
Claim 25	
[25]	The breast pump system of claim 24, wherein the diaphragm cap is configured such that the air port can be located above the nipple tunnel.
Claim 26	
[26]	The breast pump system of claim 17, wherein the diaphragm cap comprises a pair of recessed finger grip features.
Claim 27	
[27]	The breast pump system of claim 17, wherein at least a part of the diaphragm is arranged concentric with the nipple tunnel.
Claim 28	
[28pre]	A breast pump system comprising:
[28a-1]	a control unit comprising:

[28a-2]	A battery, and
[28a-3]	a pump configured to be powered by the battery and to generate negative air pressure; and
[28b]	a wearable milk collection hub configured to connect to the control unit via an air line, the wearable milk collection hub comprising:
[28c-1]	a breast shield comprising:
[28c-2]	a breast flange; and
[28c-3]	a nipple tunnel extending from the breast flange;
[28d]	a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel, at least a part of the diaphragm is arranged concentric with the nipple tunnel;
[28e]	an outer shell comprising a rear end configured to removably attach to the breast shield, an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk; and
[28f]	a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end.
Claim 29	
[29]	The breast pump system of claim 28, wherein the interior volume is bounded by the rear end of the outer shell and a front end of the breast shield.
Claim 30	
[30]	The breast pump system of claim 28, wherein the diaphragm cap forms a central region on a front surface of the outer shell.
Claim 31	
[31]	The breast pump system of claim 28, further comprising a milk port through which the expressed milk flows into the chamber, wherein the diaphragm is configured to extend over and adjacent to the milk port in a relaxed state.

Claim 32	
[32]	The breast pump system of claim 28, wherein the diaphragm cap comprises an air port configured to receive an end of the air line.
Claim 33	
[33]	The breast pump system of claim 28, wherein the diaphragm cap comprises a pair of recessed finger grip features.

Petitioner Shenzhen Root Technology Co., Ltd. (“Petitioner”) *requests inter partes* review (“IPR”) of claims 17-19 and 21-33 (“the Challenged Claims”) of U.S. Patent No. 11,806,454 (“the ’454 Patent”).

I. REQUIREMENTS FOR IPR

A. Grounds for Standing

Petitioner certifies that the ’454 Patent is available for IPR. Petitioner is not barred or estopped from requesting review of the Challenged Claims on the below-identified grounds.

B. Challenge and Relief Requested

Petitioner requests IPR on the following grounds. A skilled expert in the field, Mr. Ryan Bauer, provides supporting Declaration testimony (EX1003, ¶¶1-297).

Ground	Claim(s)	35 U.S.C. § 103
1A	17-18, 21-22, 24-25, 27-28, 30-32	Furrer
1B	17-18, 21-22, 24-25, 27-28, 30-32	Furrer + Alvarez
1C	17-19, 21-25, 27-32	Furrer + Alvarez + Pollen
1D	22, 31	Furrer + Alvarez + Pollen + Weniger
1E	25	Furrer + Alvarez + Pollen + Rigert

Ground	Claim(s)	35 U.S.C. § 103
1F	26, 33	Furrer + Alvarez + Pollen + Kasting
2A	17-19, 21, 23-24, 27-30, 32	Park + Silver
2B	22, 31	Park + Silver + Weniger
2C	25, 27-30, 32	Park + Silver + Rigert
2D	31	Park + Silver + Rigert + Weniger
2E	26, 33	Park + Silver + Kasting
2F	33	Park + Silver + Rigert + Kasting

Each reference pre-dates the filing of the earliest claimed priority application filed on March 26, 2020. The applied references qualify as prior art under §102:

Reference	Filing Date	Publication Date
US 10,149,929 (Furrer)	Dec. 12, 2013	Dec. 1, 2018
US 2015/0283311 (Alvarez)	Feb. 6, 2015	Oct. 8, 2015
US 2015/0217035 (Pollen)	Apr. 14, 2015	Aug. 6, 2015
US 2004/0087898 (Weniger)	Nov. 1, 2002	May 6, 2004
US 2018/0021491 (Rigert)	Feb. 9, 2016	Jan. 25, 2018
US 7,677,423 (Kasting)	Feb. 14, 2006	Mar. 16, 2010
PCT WO2016/186452 (Park)	May 18, 2016	Nov. 24, 2016
US 2011/0071466 (Silver)	Sep. 17, 2010	Mar. 24, 2011

Park (EX1010) is a certified English Translation of PCT Publication No. WO2016/186452 and is cited through the petition to identify relevant aspects of Park (EX1009).

C. Claim Construction

All claim terms should be construed according to the *Phillips* standard. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005); 37 C.F.R. §42.100. In this proceeding, and given the noticeable overlap between the components of the preferred embodiment of the '454 Patent and the prior art/predictable combinations articulated in Grounds 1A-2F, Petitioner submits that no formal claim constructions are necessary for purposes of resolving controversies in this proceeding. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011); *Google Inc. v. Intellectual Ventures II LLC*, 701 Fed. Appx. 946, 956 (Fed. Cir. 2017) (“do not require construction” for purposes of “resolv[ing] the parties’ patentability arguments”); EX1003, ¶60.

D. Level of Ordinary Skill in the Art

A person of ordinary skill in the art (“POSITA”) as of the Critical Date (March 26, 2020) would have had at least a bachelor’s degree in mechanical engineering or a similar field and at least two years of experience designing human breast pump equipment. EX1003, ¶¶30-33. More education could substitute for

experience and vice versa. *Id.*

II. THE '454 PATENT

A. Brief Description

The '454 patent describes a wearable breast pump system. EX1001, 1:17-18, 2:16-51, 5:3-67, FIGS. 1A-8, Abstract. In one embodiment, as shown in Figure 6, the breast pump includes a breast shield 21 having a nipple tunnel for receiving the user's breast:

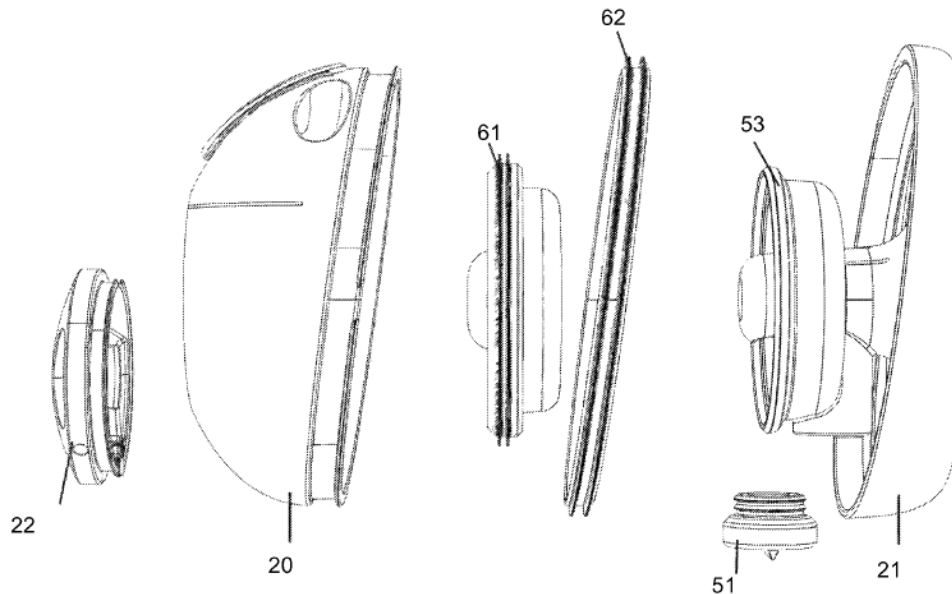
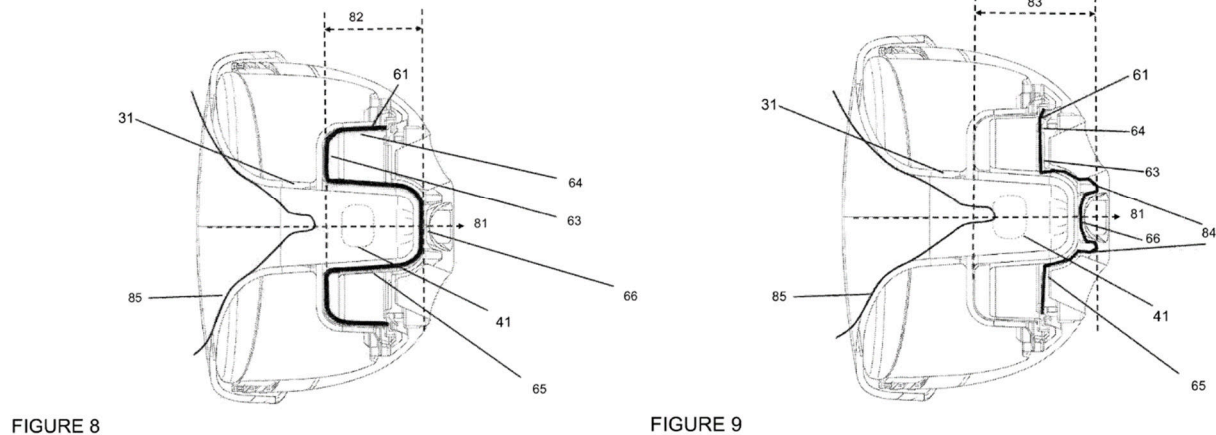


FIGURE 6

EX1001, FIG. 6, 6:23-29. The breast shield is connected to a diaphragm housing 53 for receiving diaphragm 61. *Id.*, 8:1-11. The breast pump further includes an outer shell 20 that engages the breast shield and a removable seal member 62 for forming “[a]n air tight seal between the breast shield 21 and outer shell 20.” *Id.*, 5:40-67, 8:22-29. The diaphragm 61 is covered by “a removable diaphragm cap

22.” *Id.*, 5:54-6:12. A non-return valve 51 “enables milk to pass into the milk container in one direction.” *Id.*, 7:62-67.

Figure 8 shows the assembled breast pump with the diaphragm 61 in a relaxed state (no negative air pressure is applied) while FIG. 9 shows the diaphragm 61 flexed to the right under negative air pressure to draw milk from the breast:



EX1001, FIGs. 8-9, 7:32-43, 9:30-42.

B. Prosecution History

The '454 patent was filed as US Patent Application No. 18/148,864 (the “'864 application”) on Dec. 30, 2022 with 20 claims. EX1001, cover; EX1002, 49-52. In a first non-final rejection, the Examiner rejected all claims based on several prior art combinations. EX1002, 164-183. In response to this rejection, the applicant made several amendments to the pending claims, including amending original claim 16 (issued claim 17) to additionally recite “a diaphragm cap

configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end.” EX1002, 263-268. The applicant also submitted nine new claims. *Id.* In requesting reconsideration of the rejection, the applicant argued that the amendments to the claims differentiated over the cited art because the “cover 400” in the cited primary reference “is not positioned at a front end of the outer shell.” *Id.*, 274.

The Examiner ultimately allowed the claims after making an examiner’s amendment to original 16 (issued claim 17) to include the additional recitation of “*the diaphragm cap forms a central region on a front surface of the outer shell.*” *Id.*, 282-283 (emphasis added), 287 (“Applicant authorized the examiner to amend claim 16 to incorporate the subject matter of claim 22 to allow the application”). The Examiner allowed original claim 16 based on the mistaken belief that the prior art failed to teach “the diaphragm cap forms a central region on a front surface of the outer shell.” *Id.*, 285.

This material error during examination should be reviewed here. As articulated below, Furrer, Silver, and other known references demonstrate that such a configuration for a diaphragm cap of a breast pump was surely known and that, when predictably combined with other prior art, at least issued claims 17-19 and 21-33 would have been obvious. EX1003, ¶¶63, 81-83, 44-48 106-107, 110-116, 239, 241-245.

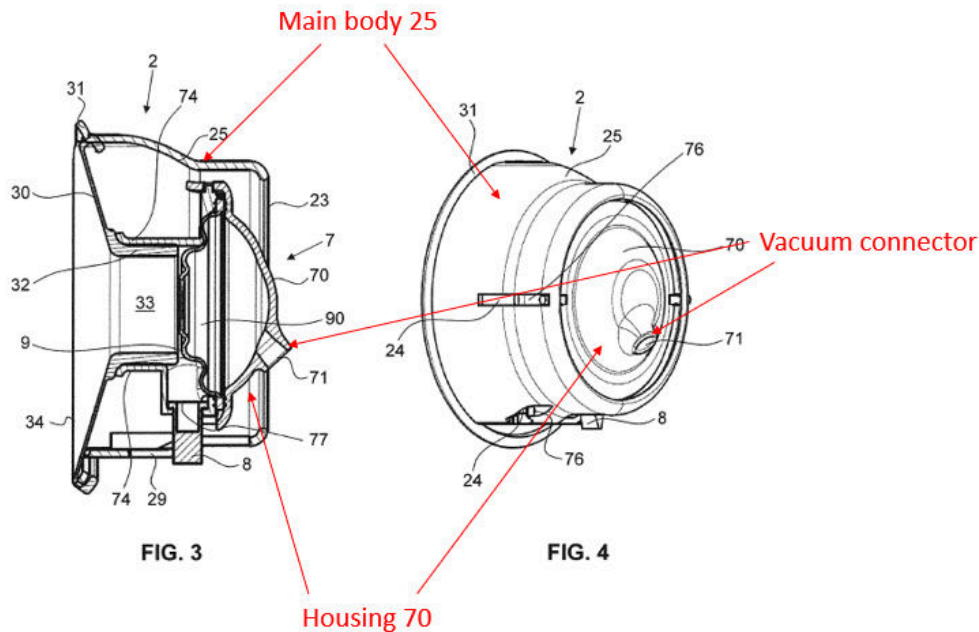
III. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. [GROUND 1A] – Claims 17-18, 21-22, 24-25, 27-28, 30-32 are rendered obvious by Furrer

1. Overview of Furrer

Furrer describes an improved breastshield for use with a breastpump.

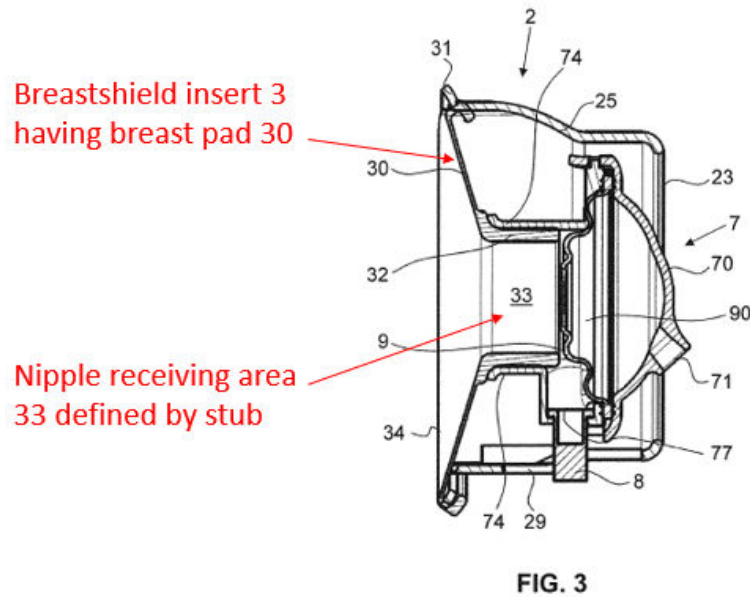
EX1004, Abstract. As shown in FIGs. 3-4, Furrer's device includes a breastshield 2 having a main body 25 and a housing 70:



EX1004, FIGs. 3-4 (annotated). Notably here, Furrer teaches that the housing 70 can be “arranged movably in the main body 25” or “connected rigidly and immovably thereto.” EX1004, 4:57-63. As shown above, the breastshield 2 further includes a vacuum connector 71 formed in the housing 70. *Id.*, 5:35-41.

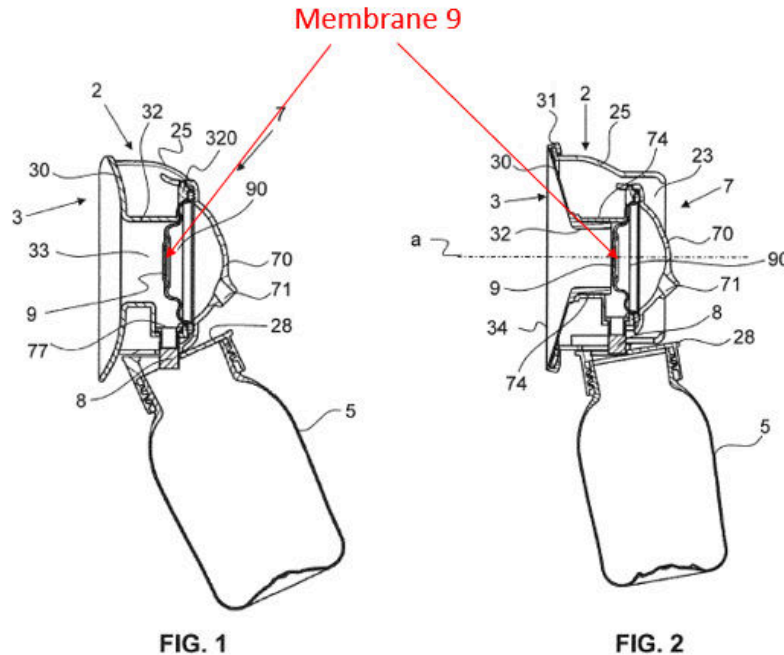
Furrer's device further includes a breast shield insert 3 having a breast pad 30 and a “stub 32” that defines a “receiving area 33 for receiving the nipple.”

EX1004, 5:11-34.



EX1004, FIG. 3 (annotated).

Media separation device 7, which includes the housing 70, further includes a membrane 9 that is, for example “clamped between the housing 70 and a flange 320,” that “forms a breast-side wall of a pump chamber 90.” EX1004, 5:50-67.



EX1004, FIGs. 1-2. Furrer describes that the membrane 9 acts a diaphragm that moves in response to suction being applied via vacuum connector 71 to “transfer[] the underpressure into a hollow space formed by the breastshield insert 3 and the mother’s breast” while “prevent[ing] expressed milk from passing into the pump chamber 90 and from there to the vacuum source.” *Id.*, 5:59-6:12.” The expressed milk “flows through the milk outlet opening 77, arranged before the membrane 9, into the milk collection container 5.” *Id.*

2. Application of Furrer to the '454 Claims

[17pre] A breast pump system comprising:

To the extent the preamble is limiting, Furrer describes “a breastshield unit for use with a breastpump for expressing human breastmilk.” EX1004, 1:16-18, 4:57-6:17; EX1003, ¶¶61-63, 88-89.

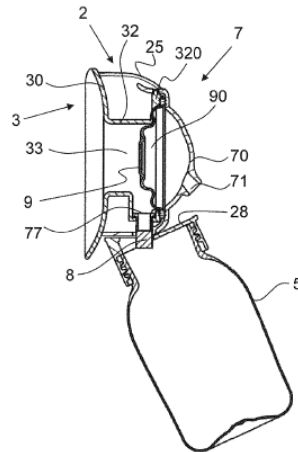


FIG. 1

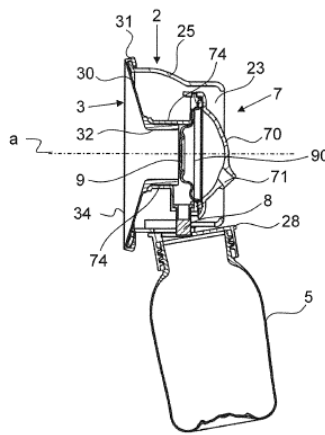


FIG. 2

EX1004, FIGs. 1-2.

[17a-1]-[17a-3] a control unit comprising: a battery, and a pump configured to be powered by the battery and to generate negative air pressure; and

Furrer's breast pump system includes "[a] vacuum connector 71 for connection to *a vacuum pump* (not shown)" via "a suction line." EX1004, 5:37-62.¹ Furrer's vacuum pump is motorized ("can be driven ... by motor") and applies "cyclically changing underpressure" via the vacuum connector 71. *Id.*, 5:40-41 and 59-62. Based on Furrer's express teachings here, a POSITA would have recognized that this motorized vacuum pump would have included, or at least plainly suggested, a conventional pump control unit so as to safely and repeatably achieve Furrer's "cyclically changing" negative pressure from the disclosed vacuum pump. EX1003, ¶¶90-93; EX1004, 5:40-41 and 59-62. Indeed, this suggestion in Furrer is fully consistent with Furrer's explanation that such "motor-

¹ All emphasis added unless otherwise noted.

driven breastpumps are commercially available.” EX1004, 1:22-33. Accordingly, Furrer discloses or renders obvious the claimed control unit. EX1003, ¶90.

Furthermore, it would have been obvious to POSITA to implement Furrer’s system to power the motorized vacuum pump using a conventional battery, which would have provided the known benefits of convenient portability and usage without a wall plug. EX1003, ¶¶92-93. Again, Furrer expressly described the well-known use of such “commercially available” motor-driven breastpumps (col. 1:22-33), and a POSITA would have readily recognized that the two most ubiquitous options for powering such a motorized vacuum pump would have been through use of a conventional power outlet (e.g., wall plug) or through use of a conventional battery. EX1003, ¶¶92-93 (citing to EX1005, [0082]; EX1011, [0005]; EX1013, 7:52-58, 8:14-17; EX1015, [0003], [0020]; EX1022, [0026]-[0027] to corroborate this ubiquitous option). A POSITA would have been prompted to implement Furrer’s conventional vacuum pump controller using battery power to provide an advantageously portable system that was usable during travel/in spaces without tethering to a wall plug—a traditional option that particularly aligns with Furrer’s suggestion for a “hands-free” and discrete solution. EX1004, 3:7-9; EX1003, ¶93. Additionally, a POSITA would have chosen to power the motor using battery power because “when [] there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options

within his or her technical grasp.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007); EX1003, ¶93.

[17b] a wearable milk collection hub configured to connect to the control unit via an air line, the wearable milk collection hub comprising:

Furrer discloses the claimed wearable milk collection hub in the form of the breastshield 2, shown in FIGs. 3-4, that provides a “‘hands-free’ solution[], in which the breastshield is worn in a bra under the clothes.” EX1004, 1:47-52, 3:5-10 (“...worn under a bra”), 7:25-31; EX1003, ¶¶94-96.

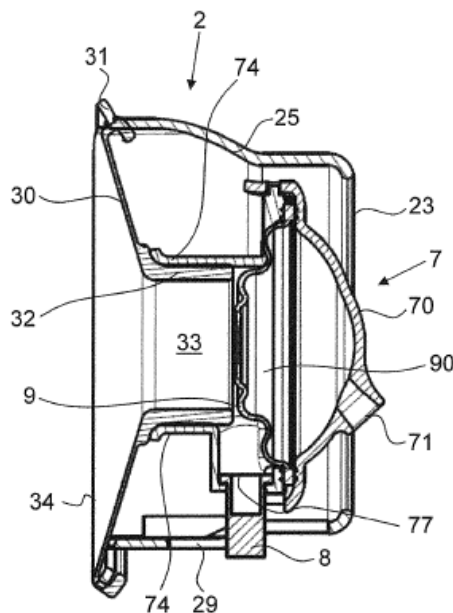


FIG. 3

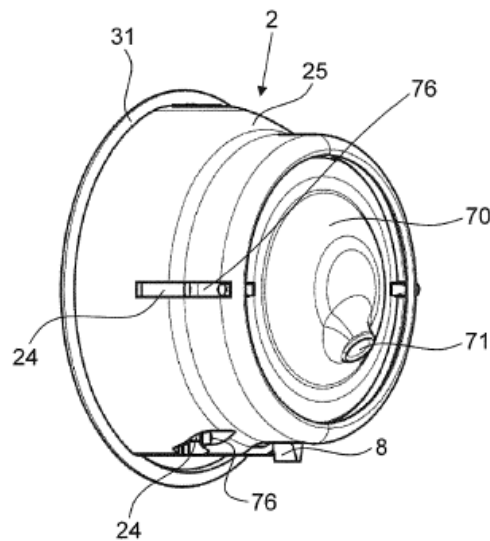


FIG. 4

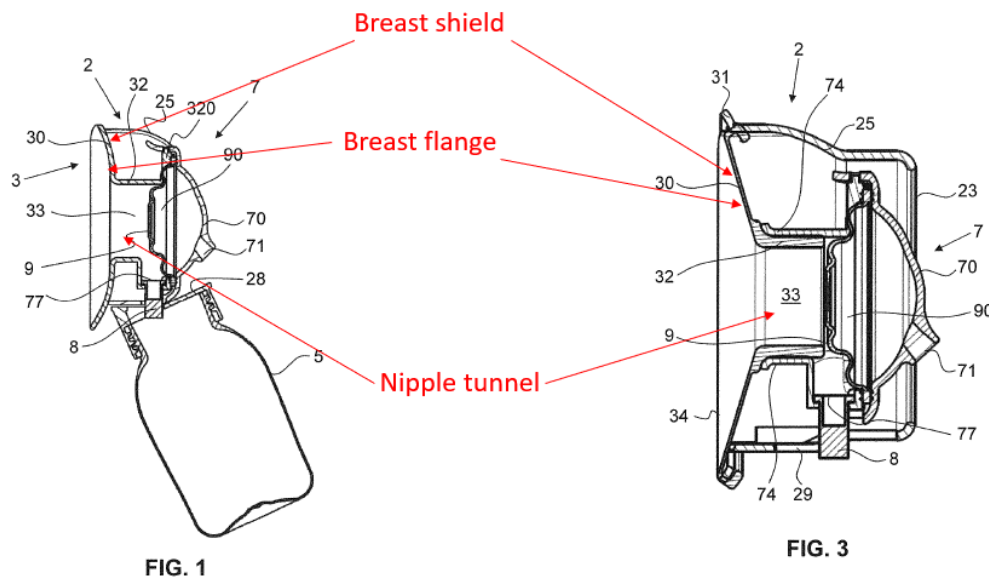
EX1004, FIGs. 3-4.

Furrer’s device forms “[a] milk flow path...through which expressed breast milk can pass from the receiving area 33 through the milk outlet opening 77...into

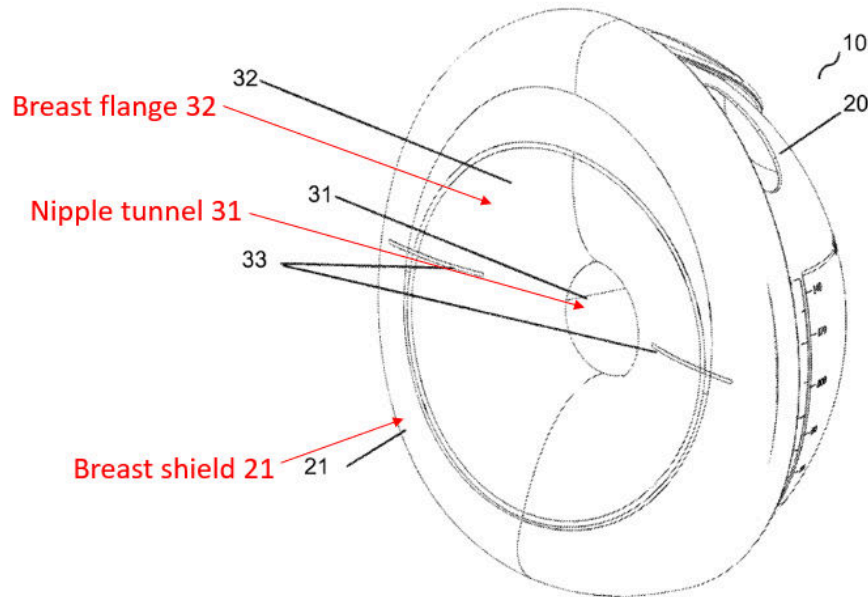
the milk collection container 5.” EX1004, 5:43-49. As described above, Furrer’s system includes “[a] vacuum connector 71 for connection to *a vacuum pump* (not shown)” via “*a suction line*.” EX1004, 5:37-40. Furrer describes that “[w]hen an underpressure is conveyed cyclically into the pump chamber 90 via the vacuum connector 71, the media separation membrane 9 moves synchronously with this and transfers the underpressure into a hollow space formed by the breastshield insert 3 and the mother’s breast B. Milk is express.” EX1004, 5:59-67.

[17c-1]-[17c-3] a breast shield comprising: a breast flange; and a nipple tunnel extending from the breast flange;

Furrer discloses the claimed breast shield in the form of breastshield insert 3 having breast pad 30 (the claimed breast flange) and stub 32 that extends from the breast pad 30 and defines a “receiving area 33 for receiving the nipple” (the claimed nipple tunnel). EX1004, 5:11-34; EX1003, ¶¶97-100.



EX1004, FIGs. 1, 3 (annotated). These structures of Furrer's device are highly similar to the breast shield, flange, and nipple tunnel of the preferred embodiment of the '454 patent:

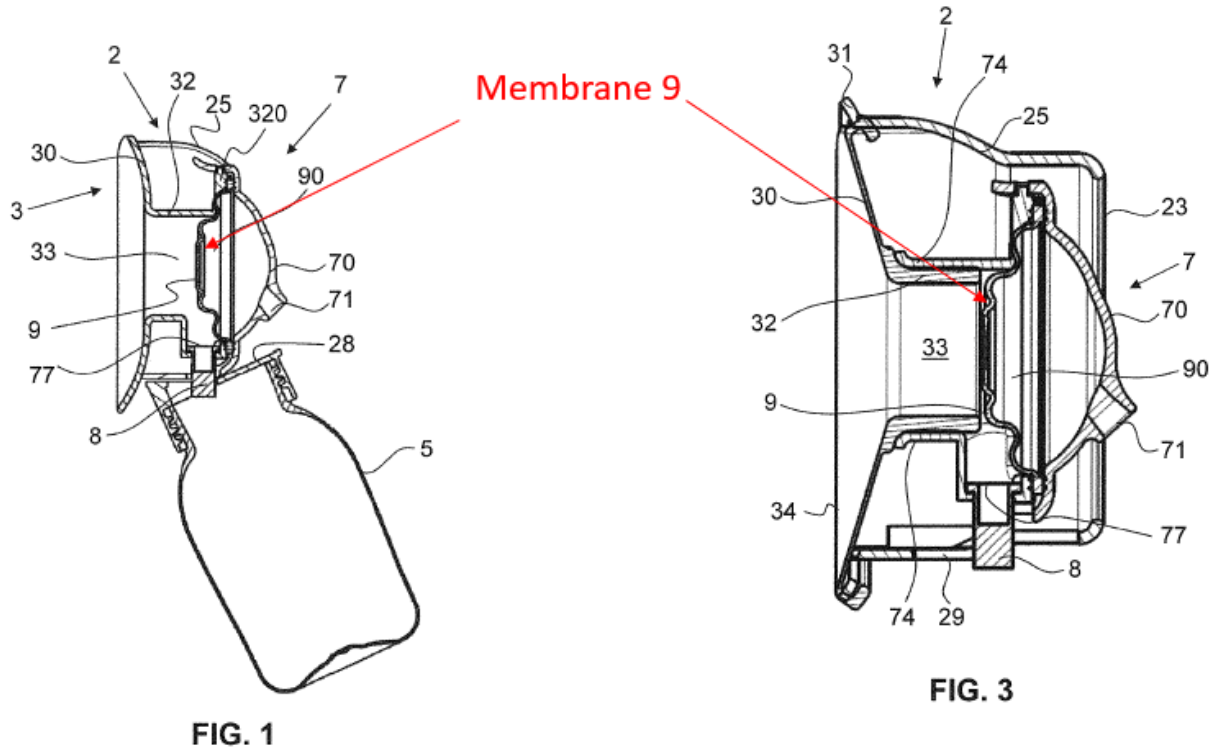


EX1001, FIG. 3, 6:23-29; EX1003, ¶¶98-100.

[17d] a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel;

Furrer's media separation membrane 9 provides the claimed diaphragm.

EX1004, 5:50-6:17; EX1003, ¶¶101-103. Furrer describes several alternative configurations for the membrane 9, including, for example “clamped between the housing 70 and a flange 320,” that “forms a breast-side wall of a pump chamber 90.” *Id.*



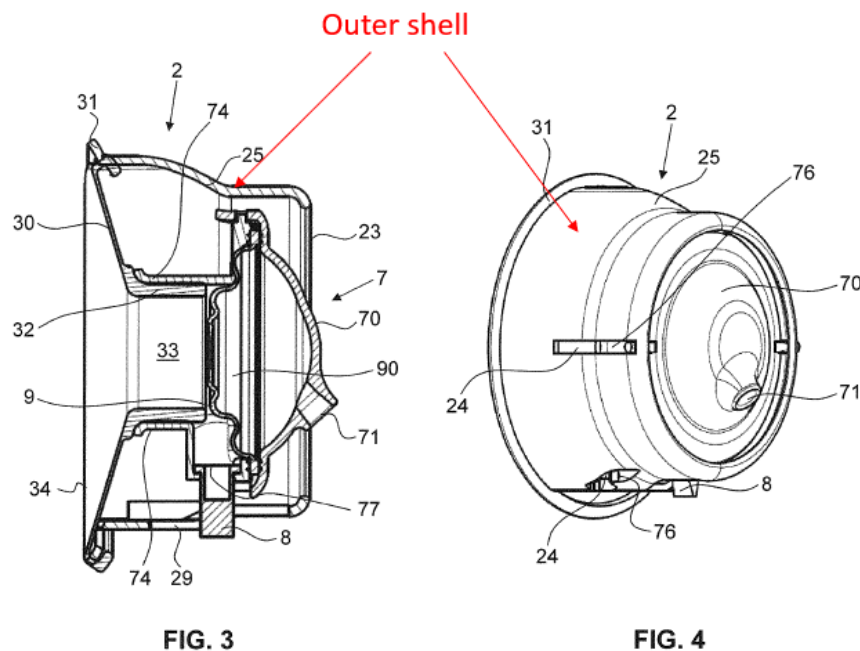
EX1004, FIGs. 1, 3 (annotated). Furrer describes that the membrane 9 acts as a diaphragm that moves in response to suction being applied via vacuum connector 71 to “transfer[] the underpressure into a hollow space formed by the breastshield insert 3 and the mother’s breast” while “prevent[ing] expressed milk from passing into the pump chamber 90 and from there to the vacuum source.” *Id.*, 5:59-6:12 (“the media separation membrane 9 moves synchronously” with the change in pressure “conveyed cyclically into the pump chamber 90 via the vacuum connector”). Specifically, the membrane 9 functions “to ensure that a cyclically changing underpressure applied via the vacuum connector 71 is transferred into the [nipple] receiving area 33.” *Id.*; EX1003, ¶¶102-103.

The media separation membrane 9 thus moves to and fro between two positions. The first position is not shown in the figures. It is directed away from the breast and is reached when an underpressure is applied. In this first position, the media separation membrane 9 is located in the rear area of the pump chamber 90, i.e. at the rear wall of the housing 70. The second position is shown in the figures. It is directed towards the breast.

EX1004, 6:5-12.

[17e] an outer shell comprising a rear end configured to removably attach to the breast shield and, an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk; and

Furrer's main body 25 in combination with housing 70 provides the claimed outer shell. EX1004, 5:11-24; EX1003, ¶¶104-109.



EX1004, FIGs. 3-4 (annotated). The main body 25 has a rear end configured to removably attach to the breast pad 30 of breastshield insert 3 (the claimed breast shield). EX1003, ¶106. As Furrer describes, the breast pad 30 of breastshield insert 3 “bears on the main body 25 or is secured releasably on the latter.” EX1004, 5:11-24. For example, in one configuration “[a] securing collar 31 formed integrally on a first insert end 34 of the insert 3 is turned back over a flange 22 of the main body 25 of the breastshield 2.” *Id.*, 6:43-46.

Rear end of outer shell
removably attached to
breast shield insert 3

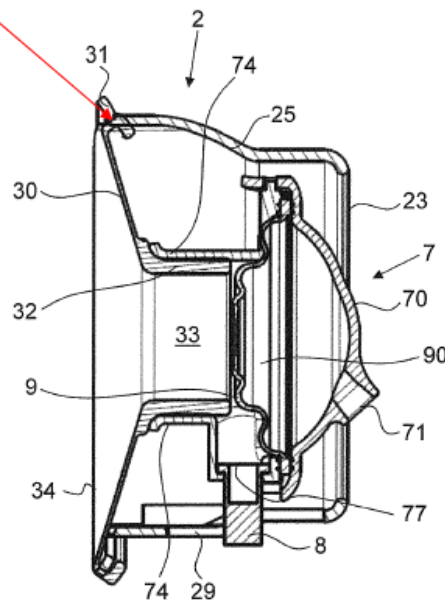


FIG. 3

EX1004, FIG. 3 (annotated).

Furthermore, Furrer discloses an interior volume between the main body 25 and the breastshield insert 3 defining a chamber to receive expressed milk.

EX1003, ¶¶108-109.

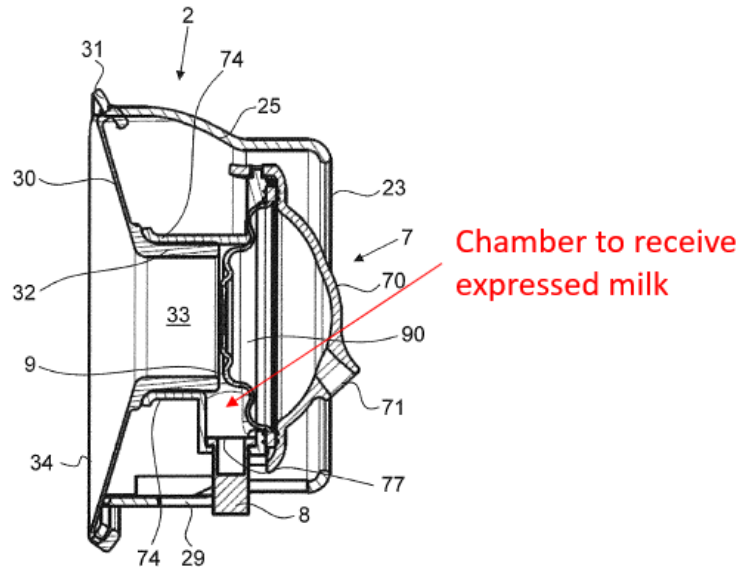


FIG. 3

EX1004, FIG. 3 (annotated). Furrer describes that the expressed milk “flows through the milk outlet opening 77, arranged before the membrane 9, into the milk collection container 5.” EX1004, 5:59-6:4. As demonstrated by, for example, FIG. 7, the indicated chamber is positioned between the nipple and the milk outlet opening 77 and therefore the milk would be received in the indicated chamber as it flows to the milk outlet opening 77 and then through the valve 8. EX1003, ¶109.

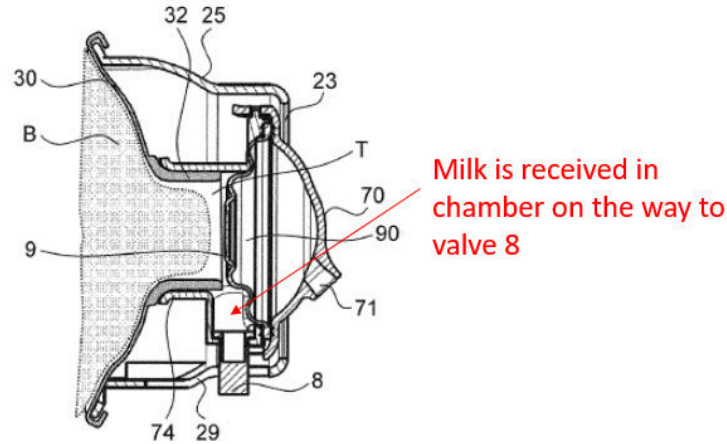


FIG. 7

EX1004, FIG. 7 (annotated).

[17f] a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end, the diaphragm cap forms a central region on a front surface of the outer shell.

Furrer's housing 70 provides the claimed diaphragm cap that forms a central region on a front surface of the outer shell. EX1004, 4:57-63, 5:35-58, 6:8-12, 6:24-30; EX1003, ¶¶110-116.

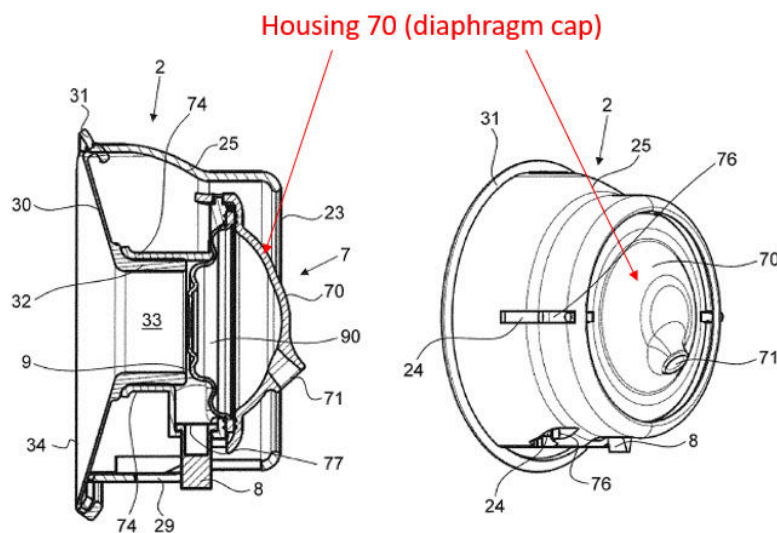


FIG. 3

FIG. 4

EX1004, FIGs. 3-4 (annotated). As shown in FIG. 4 (above) and FIG. 7 (below), the housing 70 can be positioned at a front end of the main body 25 (outer shell) to form a central region on a front surface of the outer shell. EX1003, ¶¶115-116.

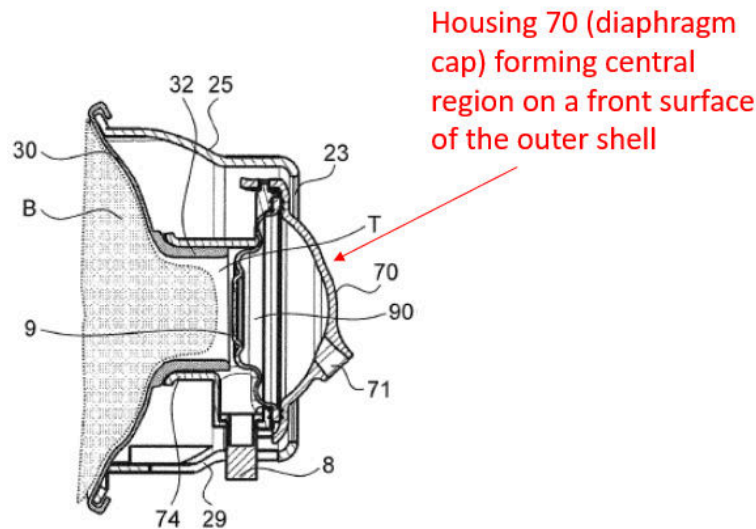
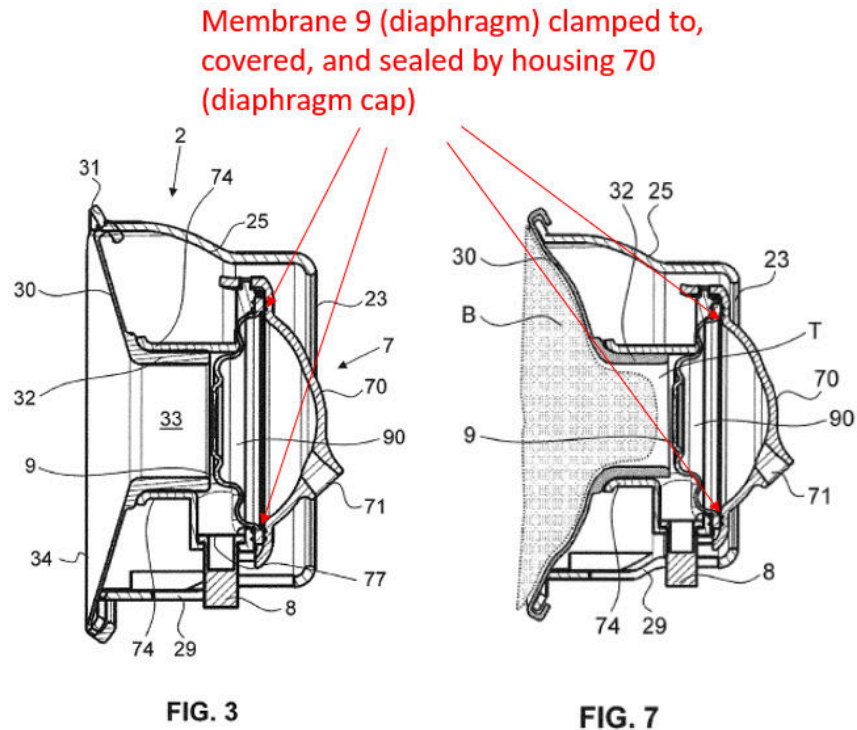


FIG. 7

EX1004, FIG. 7 (annotated). As shown in the figures above, the front end of the main body 25 is opposite the rear end that connects to the breastshield insert 3. EX1003, ¶116.

Furrer describes that “the housing can be arranged movably in the main body 25” or “it can also be connected rigidly and immovably thereto.” EX1004, 4:59-63. Furthermore, the media separation membrane 9 (diaphragm) “is held movably in the housing 70” such as, for example, being “clamped between the housing 70 and a flange 320 at the end of the stub 32 directed away from the breast.” *Id.*, 5:50-58, 6:8-8 (“the media separation membrane 9 is located in the

rear area of the pump chamber 90, i.e. at the rear wall of the housing 70.”). As shown, for example, in FIGs. 3 and 7, the membrane 9 is covered and sealed at the front end of the main body 25 by housing 70. EX1003, ¶113.



EX1004, FIGs 3, 7 (annotated).

[18] The breast pump system of claim 17, wherein the breast shield comprises an outer edge configured to be received by the rear end of the outer shell.

Furrer shows several arrangements in which the breastshield insert 3 (the claimed breast shield) has an outer edge received by the rear end of the main body 25 (the claimed outer shell). EX1003, ¶117.

Outer edge of breastshield insert 3
received by rear end of main body 25

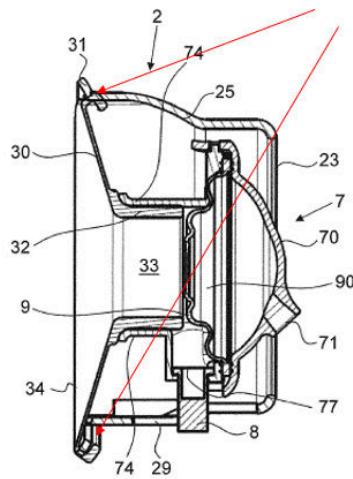


FIG. 3

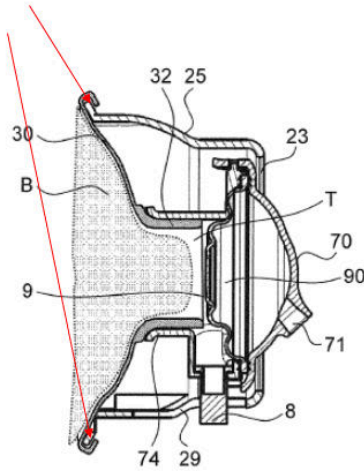


FIG. 7

EX1004, FIGs. 3, 7 (annotated).

Outer edge of breastshield insert 3
received by rear end of main body 25

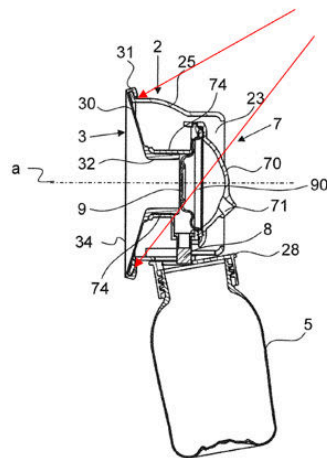


FIG. 2

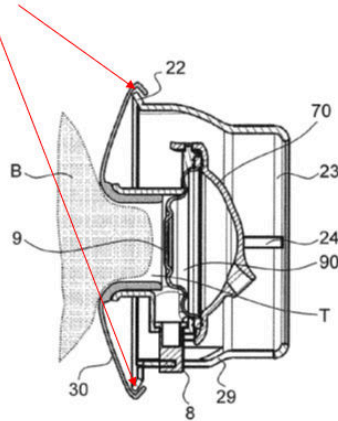
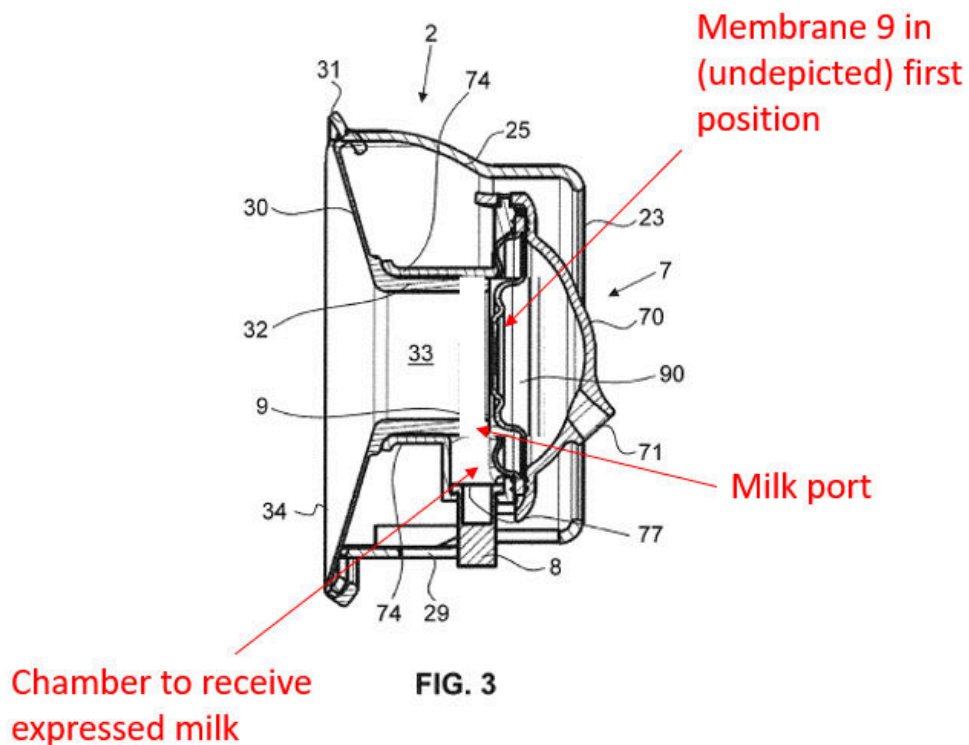


FIG. 5

EX1004, FIGs. 2, 5 (annotated).

[21] The breast pump system of claim 17, further comprising a milk port through which the expressed milk flows into the chamber.

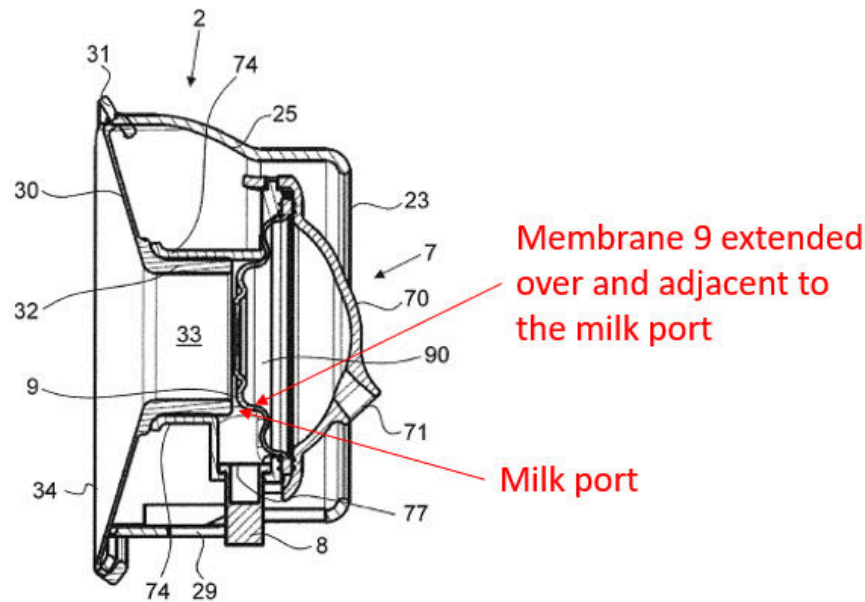
Furrer's device includes a milk port formed between the stub 32 and membrane 9 through which the expressed milk flows into the chamber. EX1003, ¶¶118-120. As Furrer states, the "first position" for the membrane 9 in which membrane 9 is located "at the rear wall of the housing 70" during underpressure "is not shown in the figures." EX1004, 6:5-12. FIG 3 shows the second position for the membrane 9 in which the membrane 9 "protrudes into th[e] receiving area 33" and abuts the stub 32. *Id.*, 6:11-17. A POSITA would have recognized that in the undepicted "first position," the membrane 9, together with the stub 32, defines a milk port through which the expressed milk flows into the chamber. EX1003, ¶120.



EX1004, FIG. 3 (modified and annotated).

[22] The breast pump system of claim 21, wherein the diaphragm is configured to extend over and adjacent to the milk port in a relaxed state.

Furrer shows that in the relaxed state or “second position,” the membrane “protrudes into th[e] receiving area 33” to extend over and adjacent to the milk port. EX1004, 6:11-17; EX1003, ¶121.



EX1004, FIG. 3 (annotated). Furrer explains that this extension of the membrane over the milk port “preferably interrupts and re-opens the milk flow path according to a cyclically applied underpressure” to “reduce[] the dead volume.” *Id.*, 2:53-56, 6:13-17, 9:3-5.

[24] The breast pump system of claim 17, wherein the diaphragm cap comprises an air port configured to receive an end of the air line.

Furrer's housing 70 (diaphragm cap) includes "vacuum connector 71 for connection to a vacuum pump...via a suction line." EX1004, 5:35-40; EX1003, ¶122.

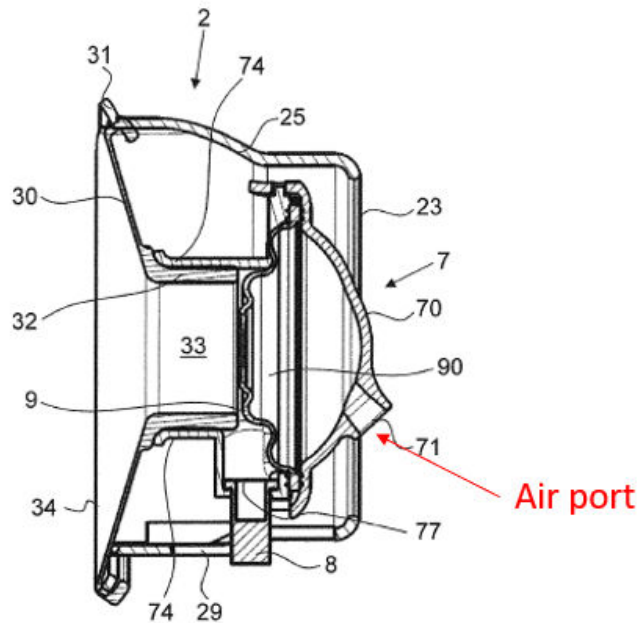


FIG. 3

EX1004, FIG. 3 (annotated).

[25] The breast pump system of claim 24, wherein the diaphragm cap is configured such that the air port can be located above the nipple tunnel.

Furrer teaches that both the housing 70 and membrane 9 have a circular shape and that guide slits 24 are positioned symmetrically across from each other in the main body 25. EX1004, FIGS. 4 and 6. As such, Furrer's housing 70 is ***configured*** such that the air port ***can be*** located above the nipple tunnel 33. (Note that this element uses the terms "configured" and "can be" in terms of a recited capability.) In particular, the evidence here confirms that a POSITA would have

readily understood from Furrer's depictions in FIGS. 3-6 that the housing 70 was capable of being inserted such that guide lugs of housing 70 are inserted into the opposite guide slits 24 (e.g., opposite from the orientation shown in FIGS. 4 and 6) such that the housing 70 is rotated 180 degrees from the depicted configuration and the vacuum connector 71 "can be" positioned above the nipple tunnel 33. EX1003, ¶¶123-124.

Alternatively, it would have been obvious to modify Furrer's device such that the vacuum connector 71 is positioned above (rather than below) the nipple tunnel 33. EX1003, ¶125. Furrer's device is designed to be "worn under a bra," and therefore such a modification would have been a more comfortable design that would have allowed the connecting suction line to protrude out of the top of the bra, rather than from the bottom of the bra, which would have been uncomfortable for users with respect to many bra designs (such as those having an underwire). EX1004, 1:47-52, 3:5-10, 7:25-31; EX1003, ¶125. Such a configuration also would have allowed the suction lines to exit the user's clothing through the top of a tank top or other top with a substantial collar line, rather than having to span the length of the user's shirt and protrude out of the bottom. EX1003, ¶125. A POSITA would have recognized that such a positioning of the vacuum connector and suction line would not have hindered the performance of the device. *Id.* Furthermore, positioning the vacuum connector above rather than below the nipple

tunnel would have been one of “a finite number of identified, predictable solutions” known to a POSITA (based on the two options dictated by Furrer’s lugs 76 being inserted into the slits 24) and “within his or her technical grasp” and therefore obvious. *KSR*, 550 U.S. at 421.

[27] The breast pump system of claim 17, wherein at least a part of the diaphragm is arranged concentric with the nipple tunnel.

As shown in FIG. 3, the membrane 9 (diaphragm) is arranged concentric with the nipple tunnel 33:

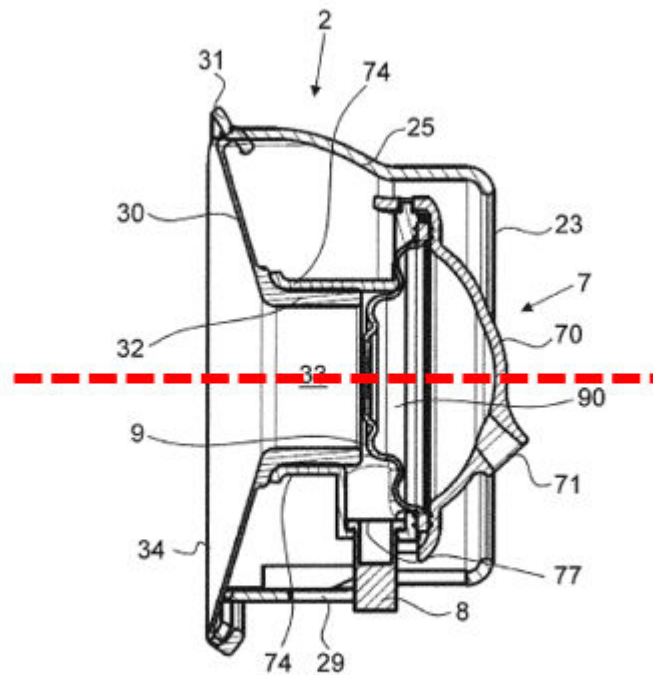


FIG. 3

EX1004, FIG. 3 (annotated), *see also* FIG. 7; EX1003, ¶126.

[28pre] A breast pump system comprising:

Supra, analysis of [17pre].

[28a-1]-[28a-3] a control unit comprising: a battery, and a pump configured to be powered by the battery and to generate negative air pressure; and

Supra, analysis of [17a-1]-[17a-3].

[28b] a wearable milk collection hub configured to connect to the control unit via an air line, the wearable milk collection hub comprising:

Supra, analysis of [17b].

[28c-1]-[28c-3] a breast shield comprising: a breast flange; and a nipple tunnel extending from the breast flange;

Supra, analysis of [17c-1]-[17c-3].

[28d] a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel, at least a part of the diaphragm is arranged concentric with the nipple tunnel;

Supra, analysis of [17d] and [27] (citing to annotated FIG. 3).

[28e] an outer shell comprising a rear end configured to removably attach to the breast shield, an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk; and

Supra, analysis of [17e].

[28f] a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end.

Supra, analysis of [17f].

[30] The breast pump system of claim 28, wherein the diaphragm cap forms a central region on a front surface of the outer shell.

Supra, analysis of [17f].

[31] The breast pump system of claim 28, further comprising a milk port through which the expressed milk flows into the chamber, wherein the diaphragm is configured to extend over and adjacent to the milk port in a relaxed state.

Supra, analysis of [21]-[22].

[32] The breast pump system of claim 28, wherein the diaphragm cap comprises an air port configured to receive an end of the air line.

Supra, analysis of [24].

B. [GROUND 1B] – Claims 17-18, 21-22, 24-25, 27-28, 30-32 are rendered obvious by Furrer and Alvarez

1. Overview of Alvarez

Alvarez describes “a system for expression of milk from a breast.” EX1005, [0008]-[0009]. Alvarez’s pumping device 100 “includes breast interfaces 105, a tube 110, and a controller 115...operatively coupled to breast interfaces 105 through tube 110.” *Id.*, [0069].

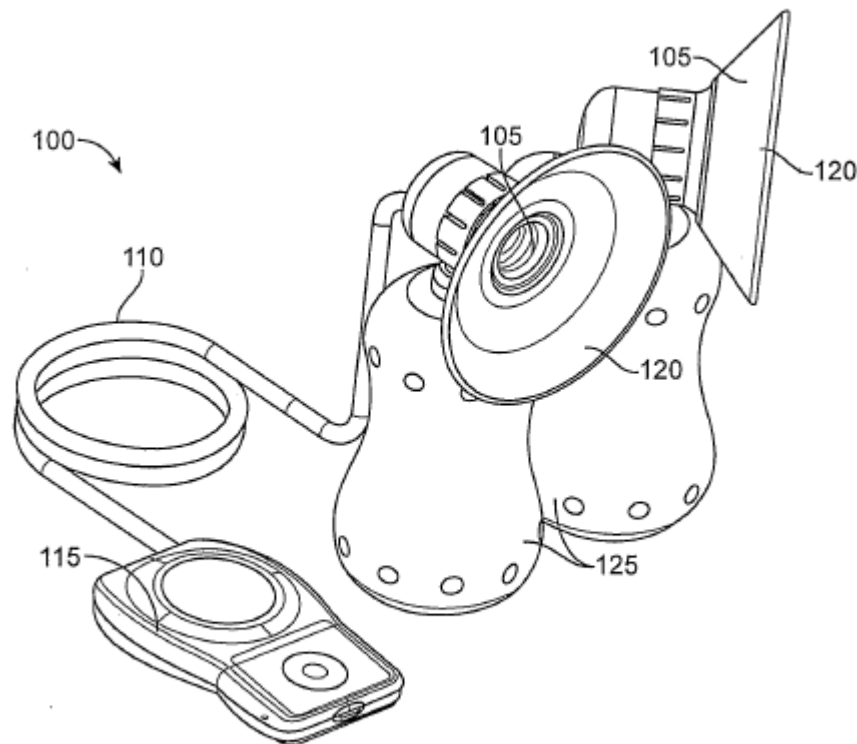


FIG. 1

EX1005, FIG. 1.

Alvarez describes that “[t]ube 110 transmits suitable energy inputs, such as mechanical energy inputs,” between the conventional controller 115 and the breast interfaces 105 to create “vacuum pressure against the breasts.” EX1005, [0069]. Alvarez plainly teaches that such a conventional controller 115 should contain “*the power source and drive mechanism* for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100.” *Id.* The driving mechanism can be powered by “a local battery.” *Id.*, [0082], [0112]. Alvarez describes several configurations for the pump that generates the negative pressure and that the driving mechanism for the pump is “housed within a controller.” *Id.*, [0070]-[0084], [0092], [0115] (“a pump unit 2100 preferably including a controller and processor 2104 as well as a motor 2102 for actuating the device.”)

2. The Furrer-Alvarez combination

A POSITA would have implemented Furrer’s vacuum pump in accordance with Alvarez’s suggestion for a conventional pump controller having a portable, battery-powered pump. Multiple reasons would have prompted a POSITA to apply Alvarez to Furrer in such a manner. EX1003, ¶¶138-142. First, Furrer expressly discloses that its vacuum connector 71 connects to a motor-driven “vacuum pump...via a suction line” and that such motor-driven breast pumps were “commercially available,” but Furrer does not include further details for control of

the vacuum pump. EX1004, 5:37-41, 1:22-25. A POSITA would have recognized Alvarez advantageously provides details for such a conventional vacuum pump suitable for safely and controllably delivering negative pressure using a “[c]ontroller 115 [that] houses the power source and drive mechanism.” EX1005, [0069], [0070]-[0084] (“a driving mechanism residing in controller 115”), [0092], [0115] (“a pump unit 2100 preferably including a controller and processor 2104 as well as a motor 2102 for actuating the device.”). Such a predictable combination would have beneficially aligned with Furrer’s teaching for a conventional vacuum pump that applies “cyclically changing underpressure” while further providing desirable portability of the resulting system. EX1004, 5:59-62; EX1005, [0069] (describing the option for a portable “pendant unit” configuration); EX1003, ¶¶138-139.

Second, implementing Furrer’s vacuum pump to use a battery-powered control unit (as suggested by Alvarez) would have advantageously provided a control unit that “contains hardware for various functions, such as controlling pumping device 100, milk production quantification, and communication with other devices.” EX1005, [0069], [0082] (“onboard electronics”); EX1003, ¶140. Alvarez expressly suggests a pump controller that compactly houses the battery and the motor-driven pump unit along with additional hardware that provides the user with added convenience (communication with other computers) and helpful

information (milk production quantification), all of which would have been recognized as known benefits for the resulting Furrer-Alvarez combination. EX1005, [0069], [0082], [0118].

Third, a POSITA would have been motivated to implement Furrer's vacuum pump in accordance with Alvarez's suggestion so that the pump controller unit beneficially monitors feedback on the use of the device to improve functionality of the pump. EX1005, [0098], [0114]-[0116]; EX1003, ¶141. Indeed, Alvarez expressly suggests the use of a pump controller that can determine changes to actuation parameters "in order to achieve and/or maintain optimal fluid expression." EX1005, [0114].

Finally, a POSITA would have had a reasonable expectation of success in modifying Furrer's system in accordance with Alvarez's suggestions, especially in view of the remarkable similarity of the breast pump systems in both teachings. EX1003, ¶142. Indeed, Furrer expressly suggestion the use of a conventional vacuum pump for connection to its vacuum connector 71, and Alvarez depicts a conventional example of such a vacuum pump unit that would likewise connect (via a suction line) to a vacuum connector. EX1004, 5:37-41, 1:22-25, FIGS. 3-4; EX1005, FIG. 1, [0069]. Here, this proposed modification would have been simply the application of a known technique to a known system to achieve

predictable results and a POSITA would have had a reasonable expectation of success in making such a modification. *KSR*, 550 U.S. at 417; EX1003, ¶142.

3. Application of Furrer-Alvarez to the '454 Claims

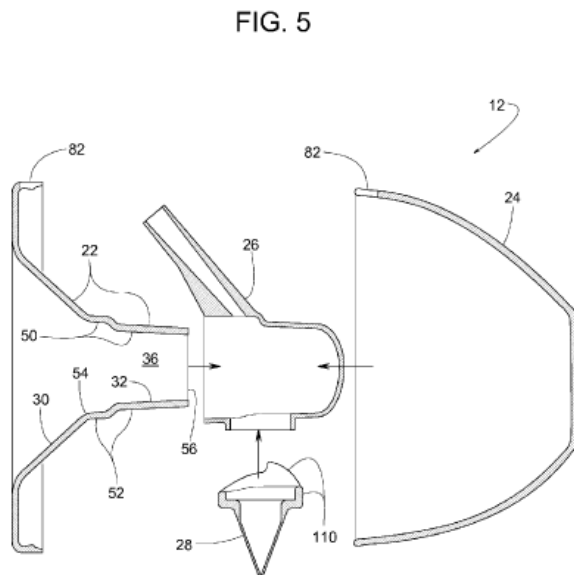
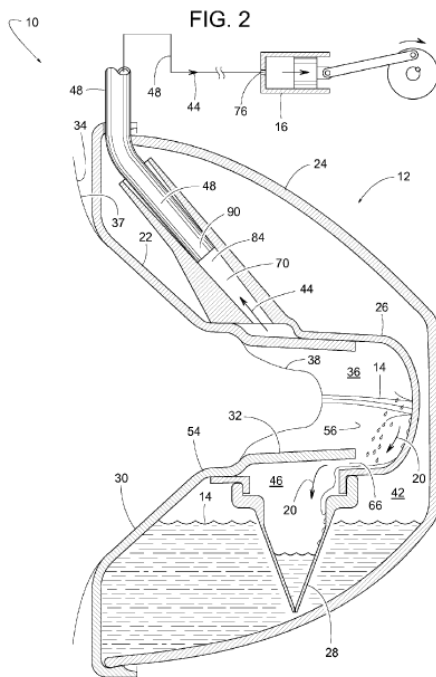
Regarding elements [17a-1]-[17a-3] and [28a-1]-[28a-3], the predictable Furrer-Alvarez combination provides a “[c]ontroller [that] houses the power source and drive mechanism for” the pumping device “and also contains hardware for various functions, such as controlling pumping device.” EX1005, [0069], *see also* [0092], [0115] (“a pump unit 2100 preferably including a controller and processor 2104 as well as a motor 2102 for actuating the device.”). The tube 110 of Alvarez would convey negative air pressure to the vacuum connector 71 of Furrer in the resulting combination. *Id.* [0069], [0074]-[0075] (“such as air”); EX1004, 5:37-41; EX1003, ¶¶64-66, 143. The pump’s “actuation assembly includes a driving element powered by a suitable driving mechanism, such as a driving mechanism residing in controller 115.” EX1005, [0080], *see also* [0070]-[0084] (describing various pump embodiments). Furthermore, in the predictable Furrer-Alvarez combination, the driving mechanism of the vacuum pump “can be powered by any suitable power source, such as a local battery.” *Id.*, [0082], [0112]. As such, the resulting combination provides the claimed control unit comprising the battery and pump to generate negative air pressure. EX1003, ¶¶138, 143, 145.

All other elements of the challenged claims are provided by the Furrer-Alvarez combination for the reasons discussed in Ground 1A, *supra*.

C. [GROUND 1C] – Claims 17-19, 21-25, 27-32 are rendered obvious by Furrer, Alvarez, and Pollen

1. Overview of Pollen

Pollen describes “an example breast pump system 10 that includes a milk collection device 12” configured to “prevent[] milk 14 from backflowing to a vacuum pump.” EX1006, [0060]. Pollen’s “milk collection device 12 comprises four main parts: a funnel-shaped breast receiver 22, a domed outer shell 24, a fluid exchanger 26, and a unidirectional valve 28 (e.g., a check valve, a duckbill check valve, a reed valve, a ball check valve, a diaphragm check valve, a swing check valve, etc.).” *Id.*, [0061].

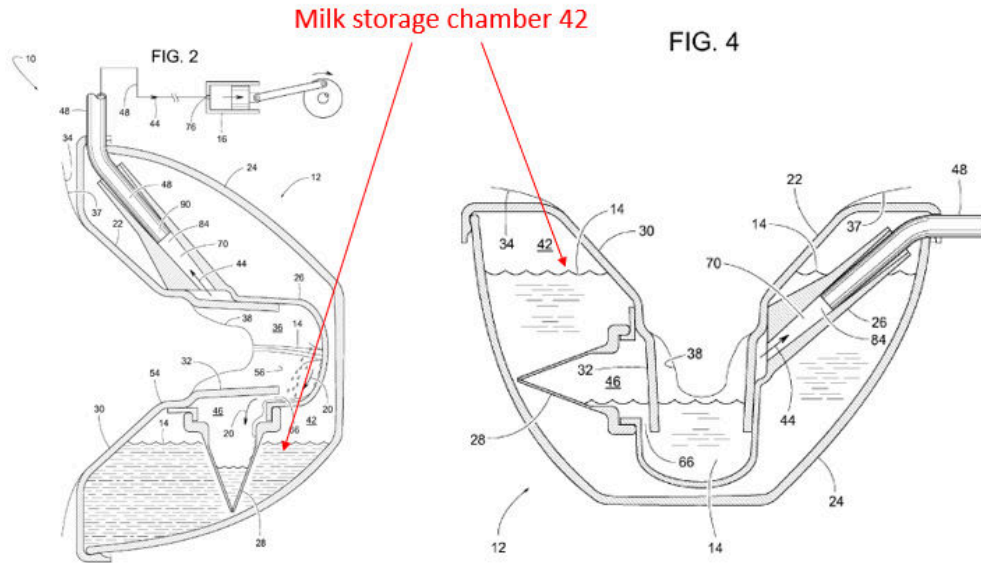


EX1006, FIGs. 2, 5.

Pollen describes that “outer shell 24 removably connects to a flange 40 of breast receiver 22 to *define a milk storage chamber 42 between outer shell 24 and breast receiver 22.*” *Id.*, [0062]. “During suction periods...vacuum pump 16 applies suction or air at sub-atmospheric pressure to a remote end 76 of suction tube 48...to draw milk expressed from nipple 38.” *Id.*, [0066]. Subsequently “expressed milk 14 flows from nipple chamber 36, flows through milk passage 66, and collects at the bottom of charging chamber 46.” *Id.* Then, during a pressurized air portion of the cycle, the positive air pressure “forces milk 14 (collected during the previous suction period) from charging chamber 46, down through valve 28, and into storage chamber 42.” *Id.*, [0067]-[0068].

2. The Furrer-Alvarez-Pollen combination

A POSITA would have been motivated to predictably apply the teachings of Pollen to the Furrer-Alvarez combination to implement the resulting breast pump system to advantageously store expressed milk in a storage chamber formed between the outer shell and breast shield of the resulting device (as suggested by Pollen’s milk storage chamber 42). EX1003, ¶¶149-155; EX1006, [0062], FIGs. 1-5, 20-28. Pollen depicts a number of suggested features for such an integrated milk storage chamber:



EX1006, FIG. 2, 4. A POSITA would have recognized that applying Pollen's suggestion to the Furrer-Alvarez combination (Ground 1B) would not have necessarily required bodily incorporation of Pollen's structure, but rather a POSITA would have beneficially applied Pollen's broader suggestion for using a milk storage chamber located between the outer shell and breast shield. EX1003, ¶¶149-150.

Multiple reasons would have prompted a POSITA to implement the Furrer-Alvarez combination (described above) in accordance with Pollen's suggestion to include a milk storage chamber between Furrer's main body 25 (outer shell) and breastshield insert 3. First, implementing such a milk storage chamber between the outer shell and breast shield would have given the user the beneficial option of foregoing detachable bottles extending from the user-worn portion of the system. EX1003, ¶151. For example, a POSITA would have been aware breast pump

configurations that require a separate bottle attached to the user-worn portion of the system require “a lactating woman [to] continuously hold a milk bottle, and thus, there is a limitation in that much inconvenience is involved in extracting milk.” EX1010, [6]; EX1003, ¶151. The resulting Furrer-Alvarez-Pollen system eliminates this disadvantage by “collect[ing] extracted breast milk even without using a separate milk bottle.” EX1010, [42]. As such, “there is a merit in that a lactating woman may use both hands because the lactating woman can extract breast milk even without holding a separate milk bottle.” *Id.*; EX1003, ¶151.

Second, Furrer discloses that its breast pump is intended to be “worn under a bra.” EX1004, 3:5-10, 7:25-31, 1:47-52. Elimination of separate bottles hanging from the bottom of Furrer’s outer shells (main body 25) would have allowed the resulting system to better fit under a user’s bra without requiring a specialized bra that provides openings for the bottles to protrude out of the bottom. EX1003, ¶152.

Third, application of Pollen’s “sealing interface 72” between the outer shell 24 and breast receiver 22 (breast shield) that together define the milk storage chamber would beneficially “increas[e] assembly reliability, reducing tooling costs, and simplify[] manufacturing.” EX1006, [0077]; EX1003, ¶153.

Fourth, a POSITA would have recognized that such a configuration in which milk is collected in a chamber within the user-worn portion of the device would have allowed the resulting system to “collect milk discreetly.” EX1014, 16:4-9,

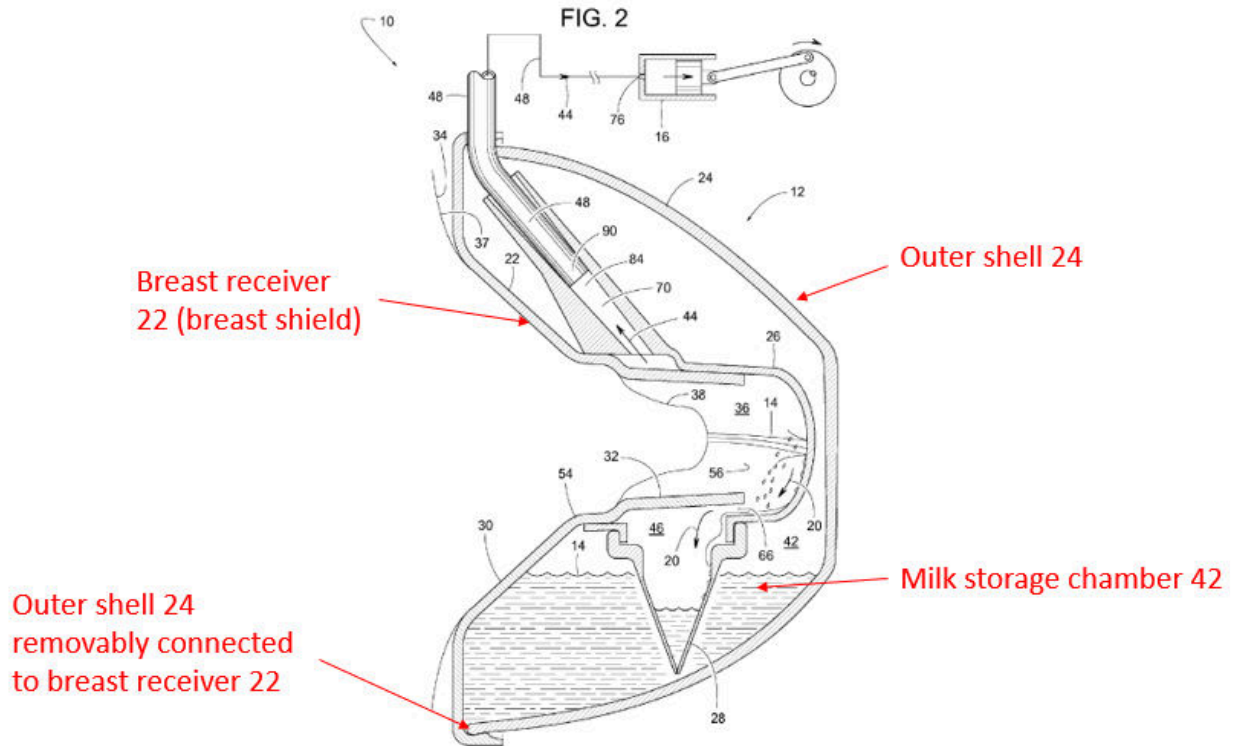
13:45-14:57, FIGs. 8A-8B, 10A-10C; EX1003, ¶154. Such a modification would have allowed a woman to go about her ordinary tasks while expressing and collecting milk in a discrete manner. EX1003, ¶154.

Finally, such a modification would have been simply the application of a known technique to a known system to achieve predictable results, and based on the functional similarities of a Furrer, Alvarez, and Pollen, a POSITA would have had a reasonable expectation of success in making such a modification. *KSR*, 550 U.S. at 417; EX1003, ¶155.

1. Application of Furrer-Alvarez-Pollen to the '454 Claims

Claim 17

With respect to element [17e], the predictable Furrer-Alvarez-Pollen combination provides an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk. EX1003, ¶¶156-158, 67-68. As discussed in Ground 1A, *supra*, Furrer discloses that the breast pad 30 of breastshield insert 3 “bears on the main body 25 or is secured releasably on the latter.” EX1004, 5:11-24, 6:43-46. Similarly, Pollen discloses that “outer shell 24 ***removably connects*** to a flange 40 of breast receiver 22 to ***define a milk storage chamber 42 between outer shell 24 and breast receiver 22.***” EX1006, [0062], [0068] (“...remove breast receiver 22 from outer shell 24”).



EX1006, FIG. 2 (annotated).

Pollen discloses that the milk storage chamber of the resulting Furrer-Alvarez-Pollen system receives expressed milk. EX1006, [0066]-[0068]; EX1003, ¶157.

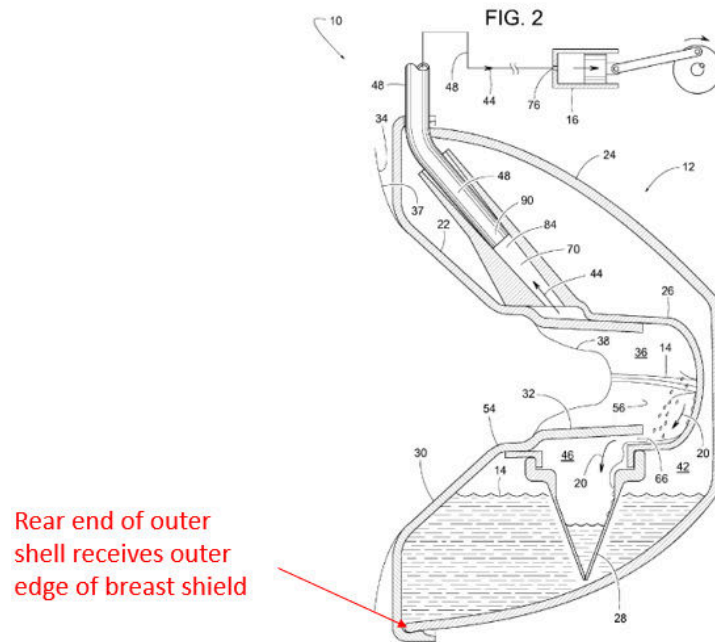
All other elements of Claim 17 are provided by the Furrer-Alvarez-Pollen system for the same reasons discussed in the predictable Furrer-Alvarez combination of Ground 1B, *supra*.

Claim [18]

As an initial matter, Furrer teaches this element as detailed above. *Supra*, Ground 1A. Furthermore, Pollen provides additional evidence that the Furrer-Alvarez-Pollen system provides that the breast shield comprises an outer edge

configured to be received by the rear end of the outer shell. EX1003, ¶159.

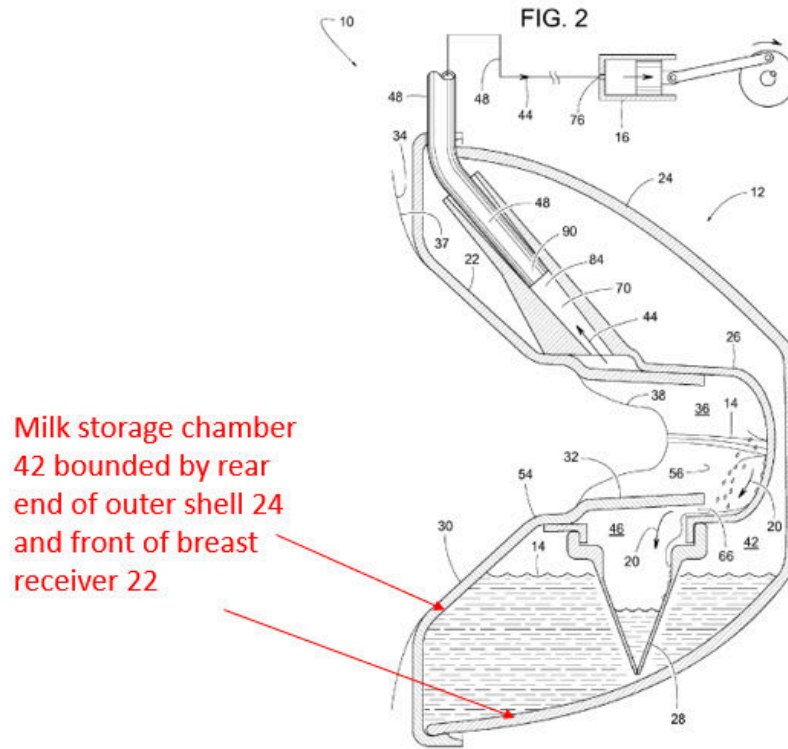
Specifically, Pollen discloses that “outer shell 24 **removably connects** to a flange 40 of breast receiver 22.” EX1006, [0062], [0068].



EX1006, FIG. 2 (annotated).

Claim [19] The breast pump system of claim 17, wherein the interior volume is bounded by the rear end of the outer shell and a front end of the breast shield.

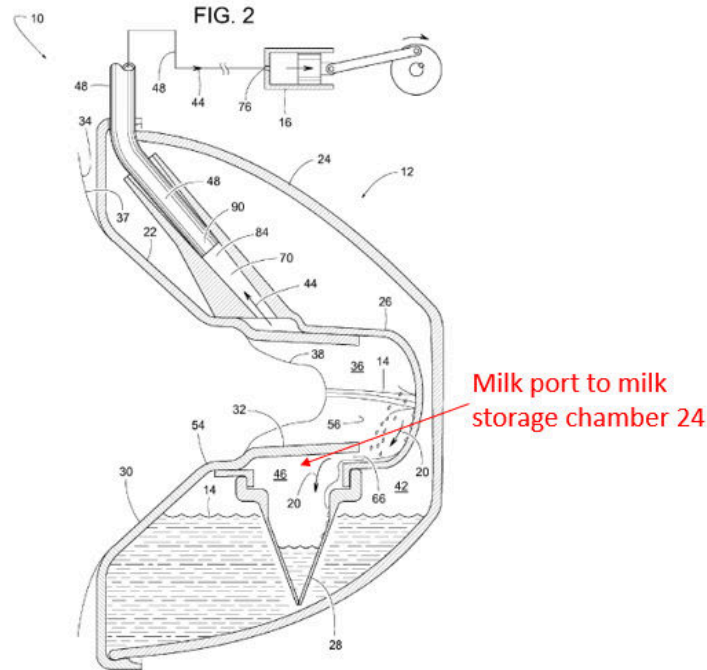
As shown in FIG. 2 of Pollen, in the Furrer-Alvarez-Pollen combination, the rear end of the outer shell and front end of the breast shield bound the interior volume. EX1003, ¶160.



EX1006, FIG. 2 (annotated).

Claim [21]

Furrer teaches this element as detailed above. *Supra*, Ground 1A. In addition to the milk port disclosed by Furrer, Pollen provides additional evidence that the Furrer-Alvarez-Pollen system provides a milk port through which the expressed milk flows into the chamber. EX1003, ¶161.



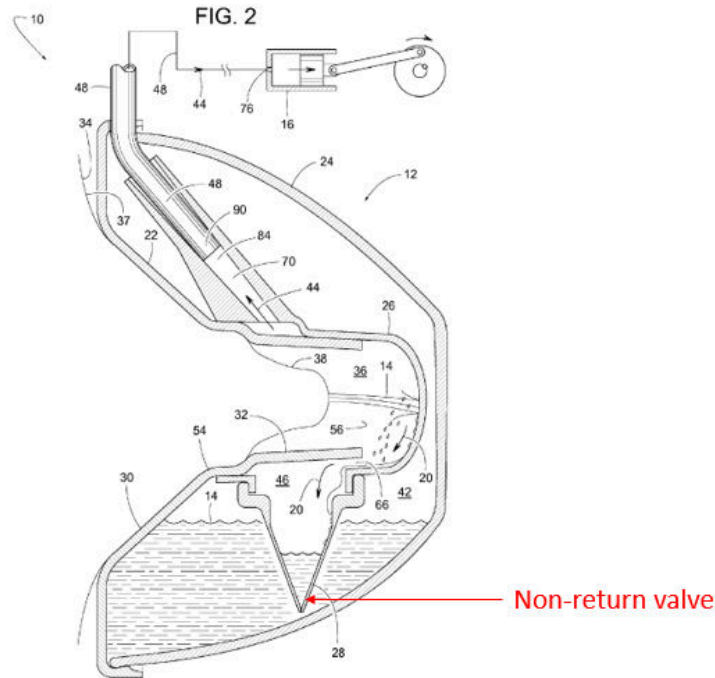
EX1006, FIG. 2 (annotated), [0066]-[0068] (describing expressed milk flowing through milk port to milk storage chamber 42).

Claim [22]

Furrer teaches this element as detailed above. *Supra*, Ground 1A.

Claim [23] The breast pump system of claim 21, further comprising a non-return valve configured to be mounted to the milk port.

Pollen discloses a non-return valve mounted to the milk port. EX1003, ¶163. Specifically, Pollen discloses “a unidirectional valve 28” that “establishes a milk charging chamber 46 between nipple receptacle 36 and storage chamber 42.” EX1006, [0061]-[0062], [0065]. A POSITA would have recognized that the description of a “unidirectional” valve indicates that the valve is a non-return valve. EX1003, ¶163.



EX1006, FIG. 2 (annotated).

Furrer similarly discloses the importance of a non-return valve positioned along the flow path between the nipple tunnel and the ultimate milk collection receptacle. EX1004, 4:36-5:4 (“valve 8, preferably a check valve” to “prevent expressed milk from flowing back.”), 5:41-49, 6:31-33, FIGs. 1-3, 7; EX1003, ¶164.

Claim [24]

Furrer teaches this element as detailed above. *Supra*, Ground 1A.

Claim [25]

Furrer teaches this element as detailed above. *Supra*, Ground 1A.

Claim [27]

Furrer teaches this element as detailed above. *Supra*, Ground 1A.

Claim [28]

Supra, Analysis of Ground 1A, Ground 1B, and Claim 17 (Ground 1C, Element [17e] applies similarly to Element [28e], and citing to Ground 1B for the Furrer-Alvarez teachings). EX1003, ¶168.

Claim [29]

Supra, Analysis of Claim 19 (Ground 1C).

Claim [30]

Furrer teaches this element as detailed above. *Supra*, Ground 1A.

Claim [31]

Furrer teaches this element as detailed above. *Supra*, Ground 1A, Claim 21 (Ground 1C).

Claim [32]

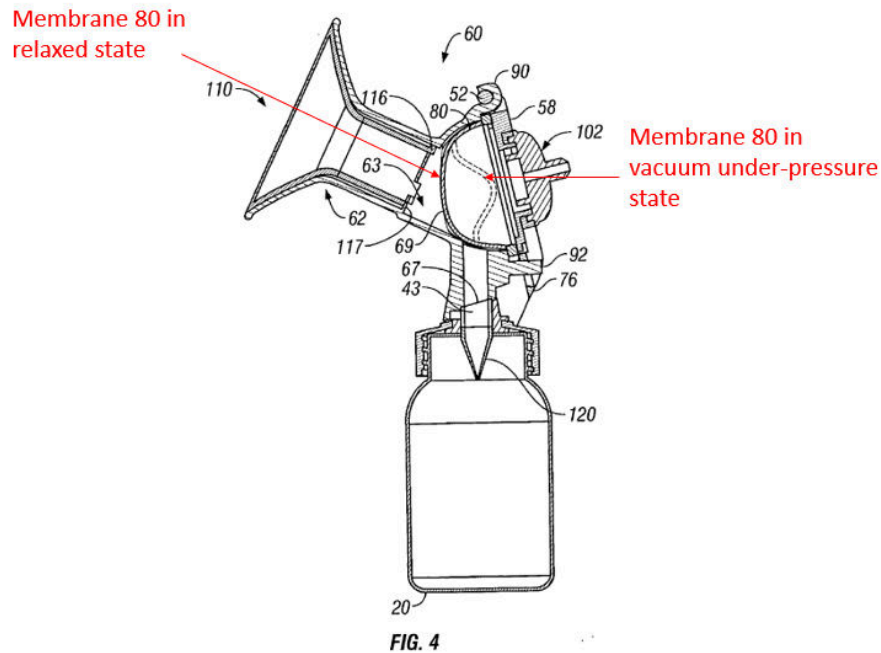
Furrer teaches this element as detailed above. *Supra*, Ground 1A.

D. [GROUND 1D] – Claims 22, 31 are rendered obvious by Furrer, Alvarez, Pollen, and Weniger

1. Overview of Weniger

Weniger describes “a breast pump assembly for expressing milk” that “includes an interface connected to a breast shield, a container and a vacuum source.” EX1007, [0021]. Similar to Furrer’s device, Weniger discloses a “membrane 80” that “collapses in response to a negative pressure generated by the vacuum source so that a vacuum is generated in the vacuum chamber 64 in order to

express milk from the mammary glands” such that “the vacuum source is physically isolated from the expressed milk.” *Id.*, [0033], [0038], [0040].

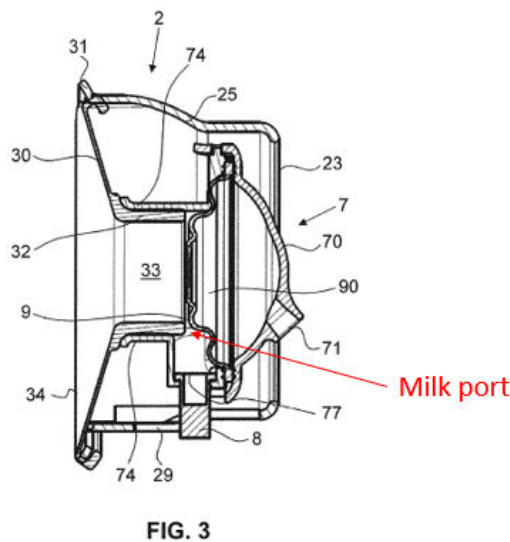


EX1007, FIG. 4 (annotated).

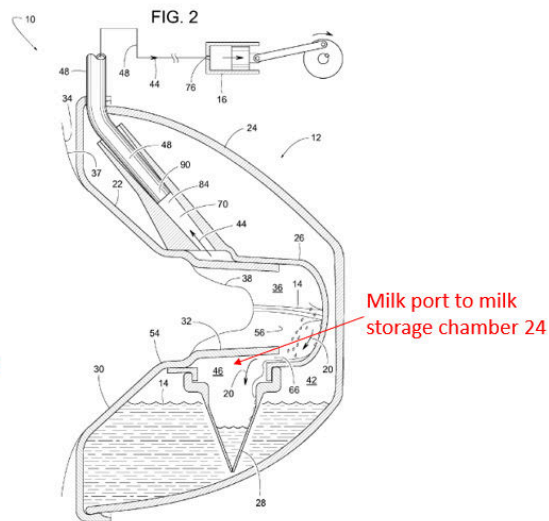
Weniger’s vacuum chamber 64 and funnel portion 62 “define a passageway 63 for expressed milk” such that “[t]he *passageway is discontinuous* (as shown in FIG. 4) when the hemispherical membrane 80 is disposed in an unaltered configuration.” EX1007, [0041]. Subsequently “[w]hen the hemispherical membrane generates a vacuum in the funnel portion 62 by collapsing in response to a negative pressure to applied to the membrane 80 by the vacuum source (as shown in phantom), not only is milk expressed, but *the passageway is made continuous such that the expressed milk may flow through the outlet 67* which is in communication with the conduit 43 of the base portion 42.” *Id.*

2. The Furrer-Alvarez-Pollen-Weniger combination

A POSITA would have been motivated to predictably apply the teachings of Weniger to the Furrer-Alvarez-Pollen combination to implement the resulting breast pump system such that the membrane (Furrer's membrane 9) extends over and adjacent the milk port in a relaxed state to achieve known benefits. EX1003, ¶¶174-180; EX1007, [0022], [0041], FIG. 4. As discussed in Grounds 1A and 1C, *supra*, both Furrer and Pollen disclose the milk port recited in claims 21, 22, and 31.



EX1004, FIG. 3



EX1006, FIG. 2

Regardless of whether the milk port of Furrer or the milk port of Pollen is utilized in the resulting combination, a POSITA would have been motivated to

apply Weniger's teachings to the resulting Furrer-Alvarez-Pollen-Weniger system such that the membrane (diaphragm) extends over and adjacent the milk port in a relaxed state for multiple reasons. EX1003, ¶177. First, such an implementation would have prevented milk that has passed through the milk port from returning to the nipple tunnel, which could cause discomfort for the user or potentially cause the nipple tunnel to overflow with expressed milk. *Id.* Preventing milk from returning to the nipple tunnel when the diaphragm is in a relaxed state helps to prevent leaks/loss of breast milk when the system is removed from the breast. *Id.*

Second, such a modification would have caused the membrane/diaphragm to create "positive pressure in the area below the milk port when the membrane/diaphragm moves from the underpressure state to the relaxed state which would have helped to advance the expressed milk through the one-way valve (e.g., Pollen's unidirectional valve 28) in the resulting system to ensure the bolus is completely pushed into the collection container and thus further preventing backup of milk in the nipple tunnel which can lead to spills or unnecessary mess." EX1003, ¶178. A POSITA would have recognized that providing additional pressure to the area between the milk port and the one-way valve would have "advanced expressed milk through the valve and into the milk storage chamber more efficiently than relying on gravity alone and prevented backed up milk from impeding the movement of the diaphragm." *Id.*

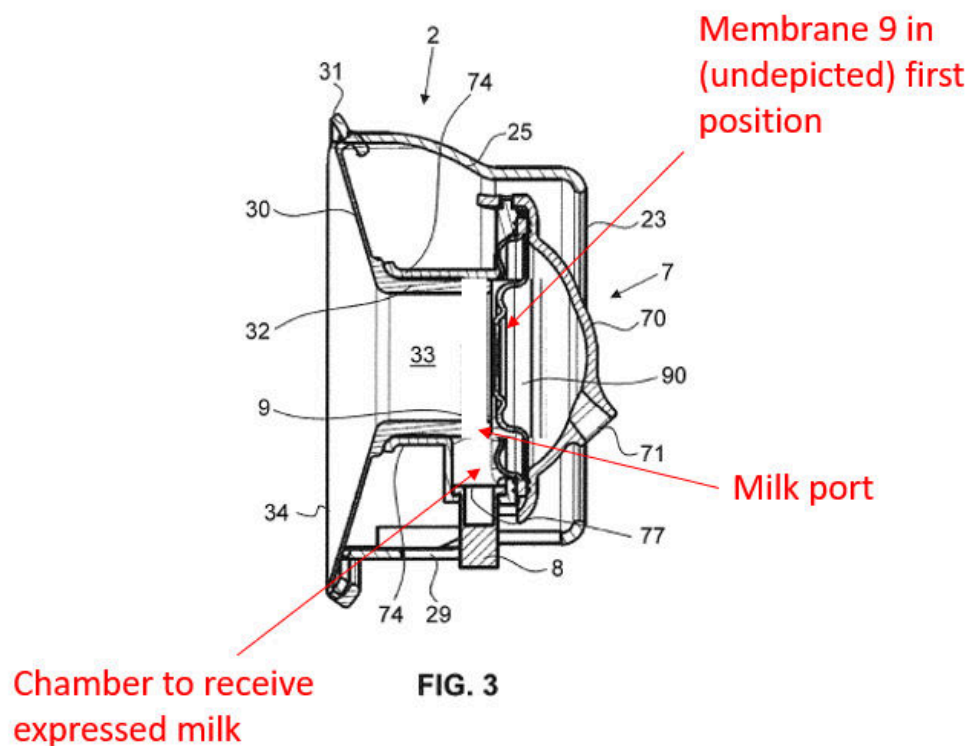
Third, as Furrer expressly teaches, a POSITA would have known that continually interrupting and re-opening the milk flow path “according to a cyclically applied underpressure” in the manner described by Weniger would have “reduce[d] the dead volume” in the resulting device. EX1004, 2:49-56, 6:13-17; EX1003, ¶179. Reduction of the dead volume would have predictably and beneficially reduced the strain on the vacuum pump thereby reducing energy requirements and cost and minimizing pump noise. EX1011, [0013]-[0014]; EX1003, ¶179.

Finally, such a modification would have been simply the application of a known technique to a known system to achieve predictable results and a POSITA would have had a reasonable expectation of success in making such a modification. *KSR*, 550 U.S. at 417; EX1003, ¶180.

3. Application of Furrer-Alvarez-Pollen-Weniger to the '454 Claims

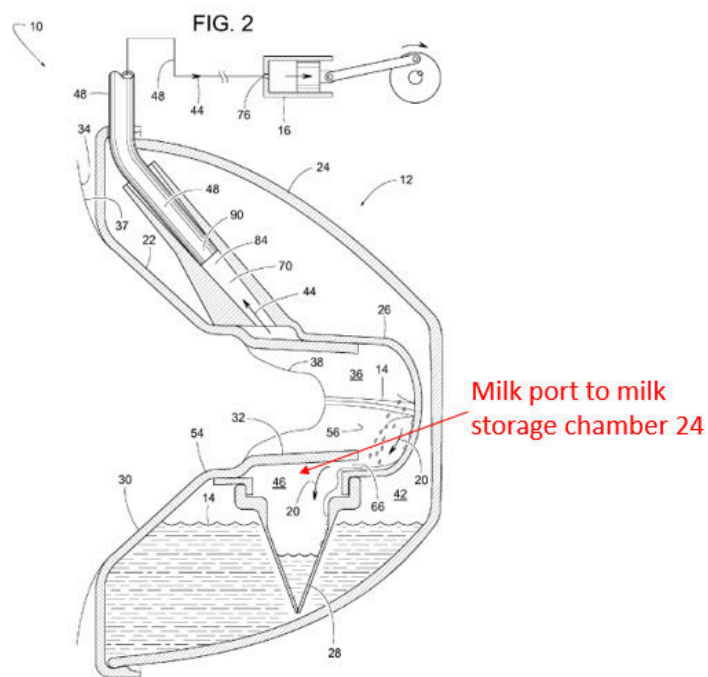
Claims [22] and [31]

As discussed with respect to Grounds 1A and 1C, *supra*, both Furrer and Pollen demonstrate that the resulting breast pump system includes a milk port. EX1003, ¶¶181-183, 174. For example, Furrer describes an undepicted “first position” in which membrane 9 is located “at the rear wall of the housing 70” such that membrane 9, together with the stub 32, defines a milk port through which the expressed milk flows into the chamber. EX1003, ¶182; EX1004, 6:5-12.



EX1004, FIG. 3 (modified and annotated).

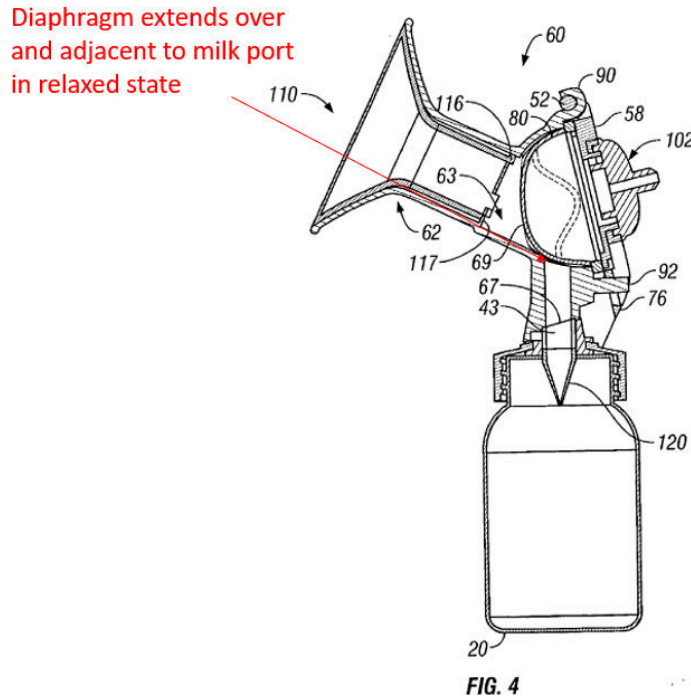
Pollen discloses a milk port. EX1003, ¶183.



EX1006, FIG. 2 (annotated), [0066]-[0068].

As discussed in Section III.D.2, *supra*, regardless of whether the milk port of Furrer or the milk port of Pollen is utilized in the resulting combination, a POSITA would have predictably applied Weniger's teachings to Furrer-Alvarez-Pollen such that the membrane (diaphragm) of the resulting breast pump system extends over and adjacent the milk port in a relaxed state. EX1003, ¶¶174-177.

Specifically, Weniger describes that in the predictable combination, vacuum chamber 64 and funnel portion 62 “define a passageway 63 for expressed milk” such that “[t]he *passageway is discontinuous* (as shown in FIG. 4) when the hemispherical membrane 80 is disposed in an unaltered configuration.” EX1007, [0041]. Subsequently “[w]hen the hemispherical membrane generates a vacuum in the funnel portion 62 by collapsing in response to a negative pressure to applied to the membrane 80 by the vacuum source (as shown in phantom), not only is milk expressed, but *the passageway is made continuous such that the expressed milk may flow through the outlet 67* which is in communication with the conduit 43 of the base portion 42.” *Id.*



EX1003, ¶¶184-185, 174-177, 69-70.

E. [GROUND 1E] – Claim 25 is rendered obvious by Furrer, Alvarez, Pollen, and Rigert

1. Overview of Rigert

Rigert describes “a breast pump for pumping human breast milk” having “a flexible media separation diaphragm, which is accommodated in the chamber and separates the chamber into a pump-side and a breast-shield-side area.” EX1008, Abstract. Rigert describes a “breast shield 1” having a nipple tunnel in the form of “tubular connection part 10” extending from “funnel 11.” *Id.*, [0052]-[0053]. Rigert’s device further includes “a cover 24 so that the media separating diaphragm 4 is able to be inserted into the housing or into the basic body 28 of the

adapter 2.” *Id.*, [0056]. The breast pump further includes a “suction connection 23 [that] is integrally moulded [*sic*] in the top region of the cover 24.” *Id.*, [0058].

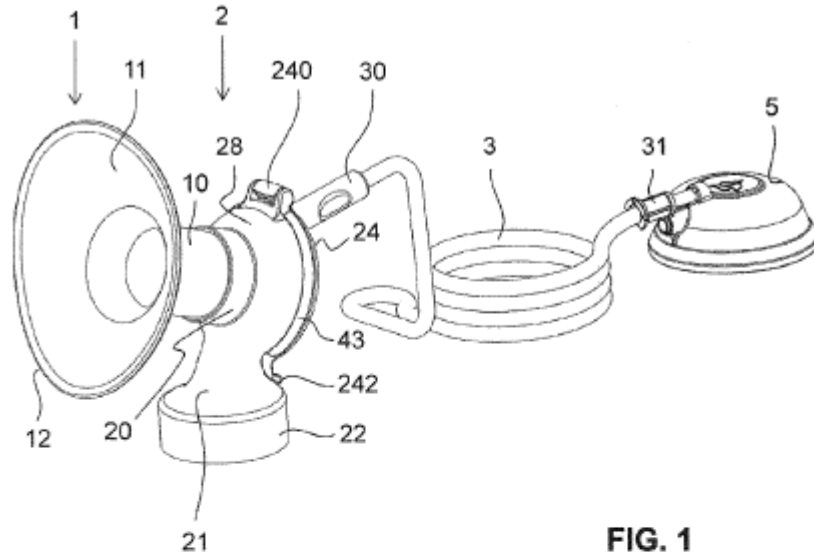


FIG. 1

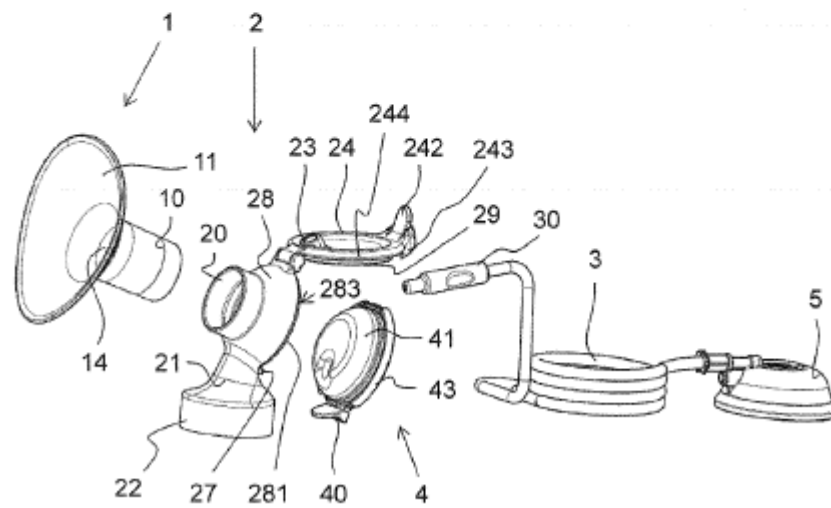


FIG. 2

EX1008, FIGs. 1-2.

2. The Furrer-Alvarez-Pollen-Rigert combination

As discussed in Ground 1A, *supra*, Furrer's housing 70 (diaphragm cap) includes "vacuum connector 71 for connection to a vacuum pump...via a suction line." EX1004, 5:35-40, FIG. 3. A POSITA would have been prompted to position this vacuum connector port above the nipple tunnel 33 in the Furrer-Alvarez-Pollen-Rigert combination (based on Rigert's teachings) for multiple reasons. EX1003, ¶¶187-192; EX1008, [0052]-[0058], FIGs. 1-4, 7, 13.

First, Furrer's device is designed to be "worn under a bra," and therefore such a modification would have provided a comfortable design allowing the connecting suction line to protrude out of the top of the bra, rather than from the bottom of the bra, which would have been uncomfortable for users with respect to many bra designs (such as those having an underwire). EX1004, 1:47-52, 3:5-10, 7:25-31; EX1003, ¶189.

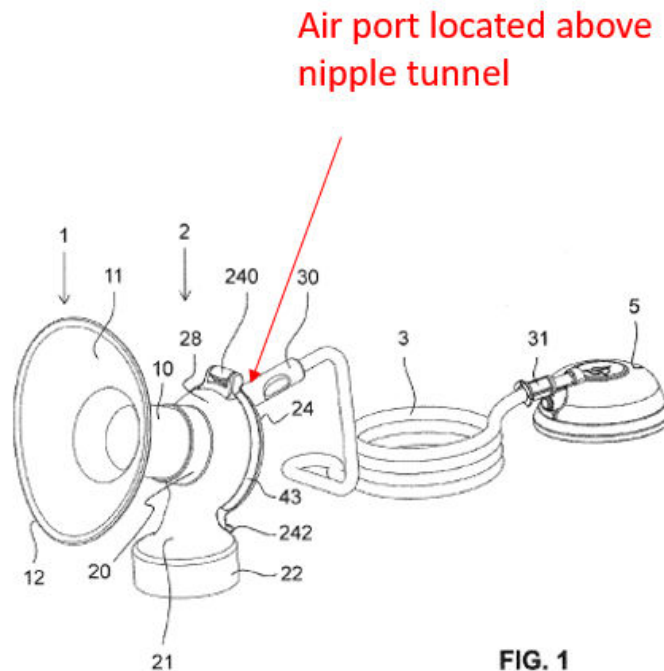
Second, such a configuration also would have allowed the suction lines to exit the user's clothing through the top of a tank top or other top with a substantial collar line, rather than being directed throughout the length of the user's shirt through the bottom. EX1003, ¶190. Third, such a modification would have allowed the user to more easily visually observe the vacuum lines to readily identify kinks or other obstructions that could prevent or diminish suction. EX1003, ¶191. A POSITA would have recognized that such a positioning of the vacuum connector and suction line would not have hindered the performance of the device. *Id.*

Finally, such a modification would have been simply the application of a known technique to a known system to achieve predictable results and a POSITA would have had a reasonable expectation of success in making such a modification. *KSR*, 550 U.S. at 417; EX1003, ¶192.

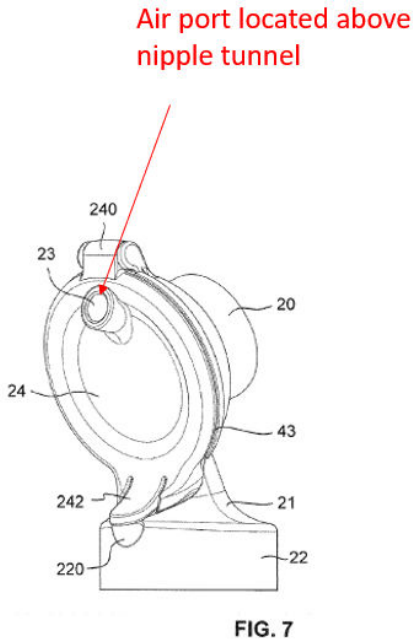
3. Application of Furrer-Alvarez-Pollen-Rigert to the '454 Claims

Claim [25]

FIGs. 1 and 7 of Rigert demonstrate that, in the predictable Furrer-Alvarez-Pollen-Rigert combination, the air port can be located above the nipple tunnel. EX1003, ¶¶193, 71-72; EX1008, [0056]-[0058].



EX1008, FIG. 1.

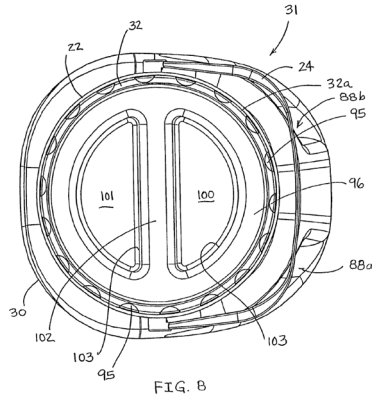


EX1008, FIG. 7, *see also*, FIGs. 2-4, 13.

F. [GROUND 1F] – Claims 26 and 33 are rendered obvious by Furrer, Alvarez, Pollen, and Kasting

1. Overview of Kasting

Kasting describe “[a] container for the storage and dispensing of a liquid” having a “closing lid” for sealing the storage container. EX1012, 3:6-16. This lid/cap includes “two recessed pockets 100 and 101” that “enable the cap 32 to be grasped in an ergonomically-convenient manner so as to more easily remove the cap...and also to more easily reapply cap 32.” EX1012, 11:33-43.



EX1012, FIG. 8.

2. The Furrer-Alvarez-Pollen-Kasting combination

Multiple reasons would have prompted a POSITA to predictably and beneficially apply the teachings of Kasting to the Furrer-Alvarez-Pollen to implement Furrer's housing 70 to include recessed finger grip features. EX1003, ¶¶194-198. First, such a modification would have allowed users to more easily "grasp" and manipulate the housing 70 "in an ergonomically-convenient manner." EX1012, 11:33-43. For example, Furrer describes that "the housing 70 can be arranged moveably in the main body 25." EX1004, 4:60-63. A POSITA would have recognized that including recessed finger grips (as suggested by Kasting) would "facilitate gripping" of the housing 70 "by the hand of user" such as by the user's fingers. EX1012, 11:24-32; EX1003, ¶195. Such gripping features would have allowed the user to more easily slide housing 70 along slits 24. EX1004, 7:25-31; EX1003, ¶195. Second, such recessed gripping features would have allowed the user to

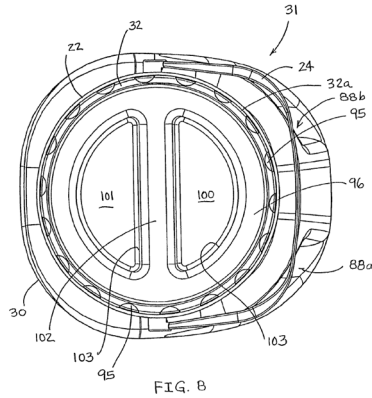
more easily manipulate the device as a whole when applying or removing the device to/from the breast. EX1003, ¶196. Providing a better gripping surface through the use of recessed finger grip features would have helped prevent dropping and potential breaking of the device. *Id.* Third, including recessed finger grips, as suggested by Kasting, would have allowed the user to “more easily reapply” the diaphragm cap after, for example, disassembling to clean the inside of the device. EX1012, 11:38-43; EX1003, ¶197.

Finally, such a modification would have been simply the application of a known technique to a known system to achieve predictable results and a POSITA would have had a reasonable expectation of success in making such a modification. *KSR*, 550 U.S. at 417; EX1003, ¶198.

3. Application of Furrer-Alvarez-Pollen-Kasting to the '454 Claims

Claim [26] and Claim [33]

The resulting Furrer-Alvarez-Pollen-Kasting combination includes “two recessed pockets 100 and 101” to enable Furrer’s housing 70 (the claimed diaphragm cap) “to be grasped in an ergonomically-convenient manner.” EX1012, 11:33-43.

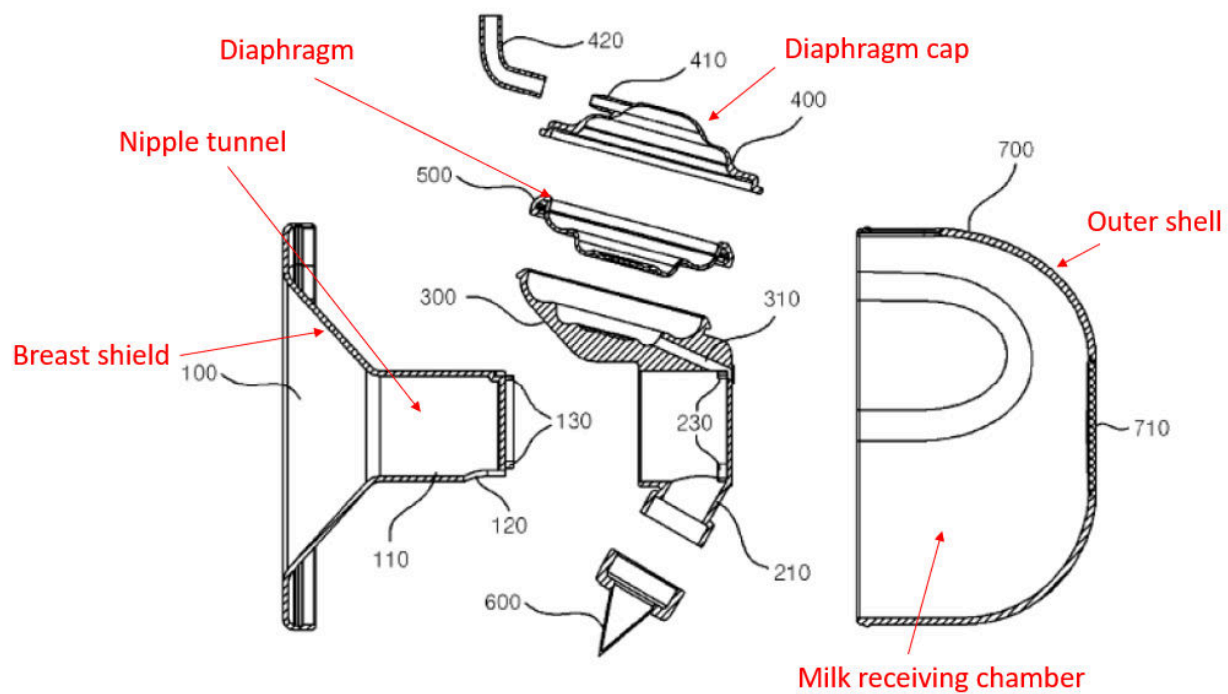


EX1012, FIG. 8. A POSITA would have recognized that a user would have grasp the recessed pockets using their fingers. EX1003, ¶¶199, 84; *see e.g.* EX1012, 7:63-8:3 (describing “finger recesses”), 8:18-22 (“...uses finger recesses 70 to manipulate the cap.”), 11:24-27.

G. [GROUND 2A] – Claims 17-19, 21, 23-24, 27-30, and 32 are Obvious in view of Park and Silver

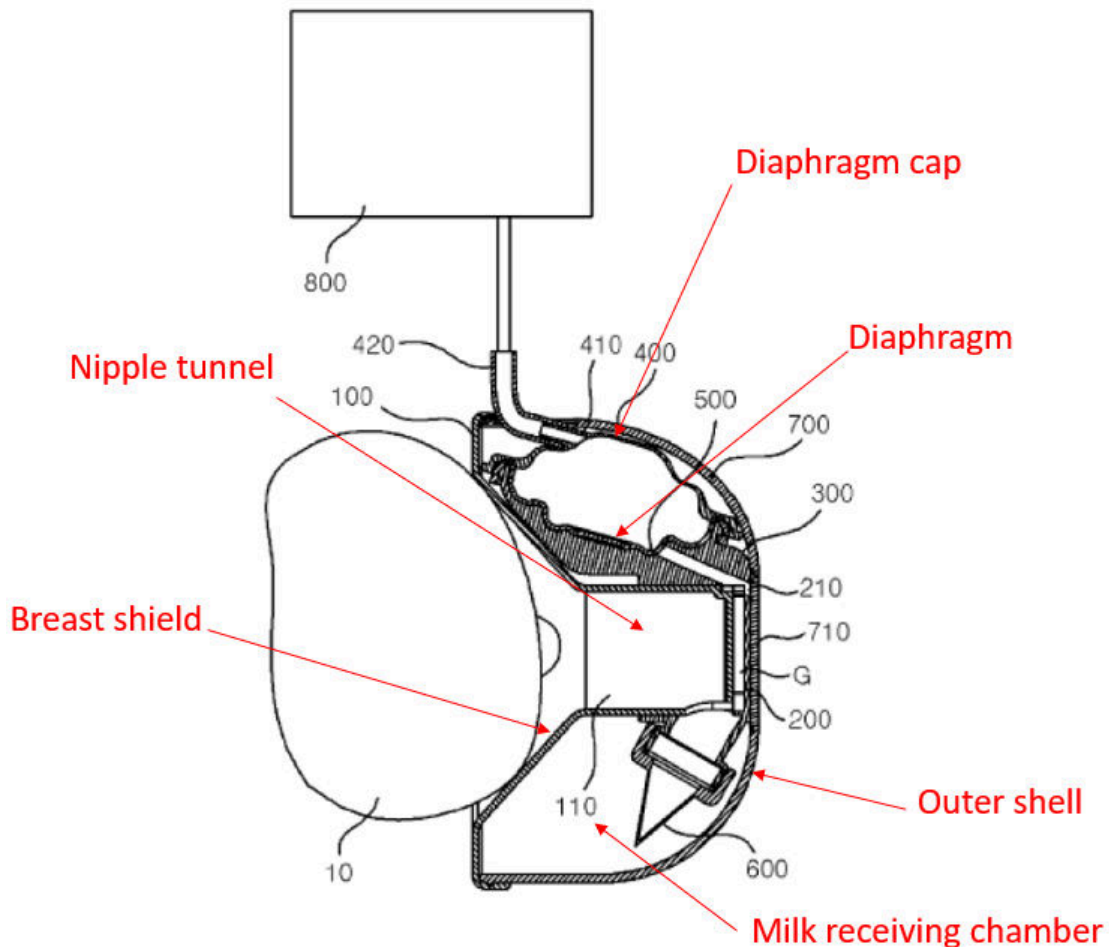
1. Overview of Park

Park’s wearable breast pump includes a breast shield (housing 100) with a nipple tunnel extending therefrom (protruding part 110) configured such that expressed milk passes through the nipple tunnel and into a chamber defined by an outer shell (storing housing 700). EX1010, [10],[37]-[39], [44]-[46]. Park’s device includes a diaphragm (flow separation membrane 400) covered by a diaphragm cap (cover 400) having an air nozzle 410. *Id.*



EX1010, FIG. 5 (annotated).

Fig. 7



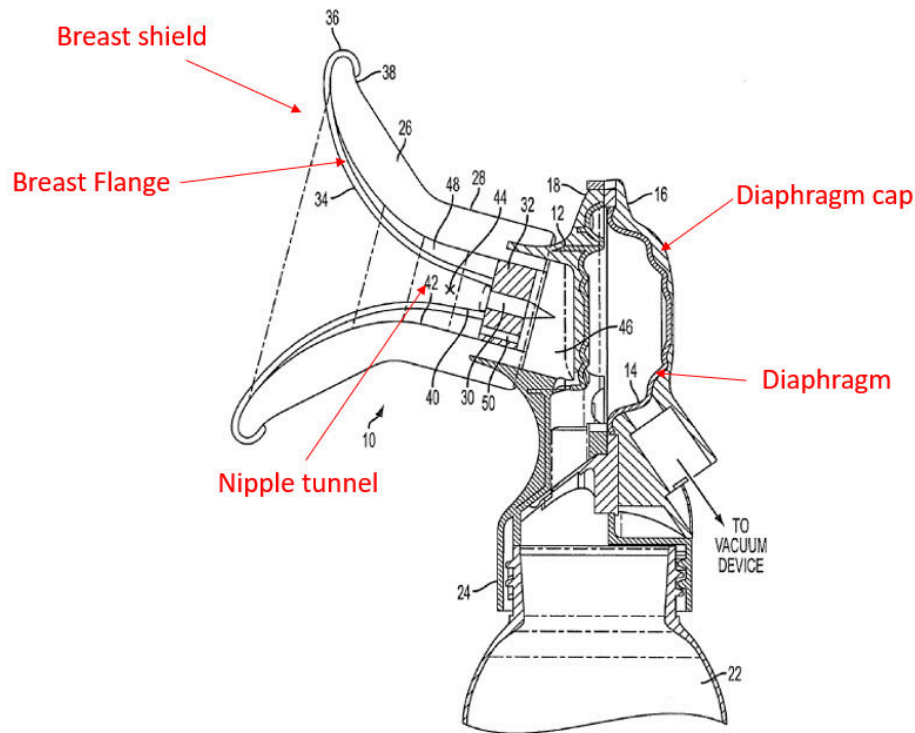
EX1010, FIG. 7 (annotated).

Park further discloses “an electric pump 800 for suctioning air through the air tube 420.” EX1010, [37], [49].

2. Overview of Silver

Silver describes “an improved breastpump assembly” that “eliminates any ‘dead volume’ in pumping.” EX1011, [0003]. Silver’s improved design “virtually eliminates any air at least in the area of the breast and nipple.” *Id.*, [0013]. As such “the mechanism used for generating the pressure difference in the breastshield

(e.g., vacuum or negative pressure), such as a diaphragm pump, does not need to do as much work.” *Id.* Similar to both Park and the ’454 patent, Silver’s device uses “a barrier component” or “diaphragm 14” enclosed in a housing such that “[t]he barrier is reciprocated within the space of the housings 16, 18 by an intermittent vacuum from a vacuum source (not shown) which is connected via a tube 20.” *Id.*, [0059], [0067].

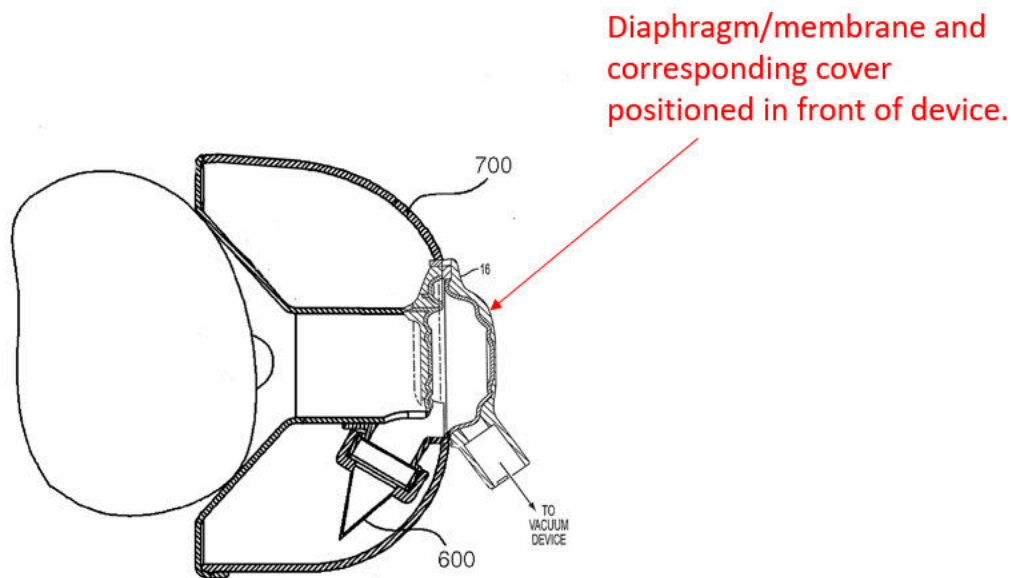


EX1011, FIG. 5 (annotated).

3. Combination of Park and Silver

A POSITA would have predictably and beneficially applied the teachings of Silver to Park’s breast pump in at least two ways; As a first modification, to reposition Park’s diaphragm 500 and corresponding cover 400 to the front of

Park's storing housing 700 (at the location of Park's sealing packing 710 in Park's unmodified device) as taught by Silver to beneficially "substantially limit[] the amount of air between the breast/nipple and the breastshield" thus "resulting in improved comfort." EX1011, [0013]-[0014], [0016], [0019]; EX1003, ¶¶201-217. For example, a POSITA would have arranged the resulting combination in the following exemplary manner:



EX1003, ¶205 (mockup of proposed combination based on EX1010, FIG. 7 and EX1011, FIG. 5).²

² The mockup of the proposed combination of Park with Silver is provided as an example and the various components are not necessarily drawn to scale. A POSITA would have possessed the skill to arrange and configure the components

As a second modification, a POSITA would have beneficially implemented Park's electric pump 800 to be powered with a battery as taught by Silver. EX1011, [0005]; EX1003, ¶¶218-220.

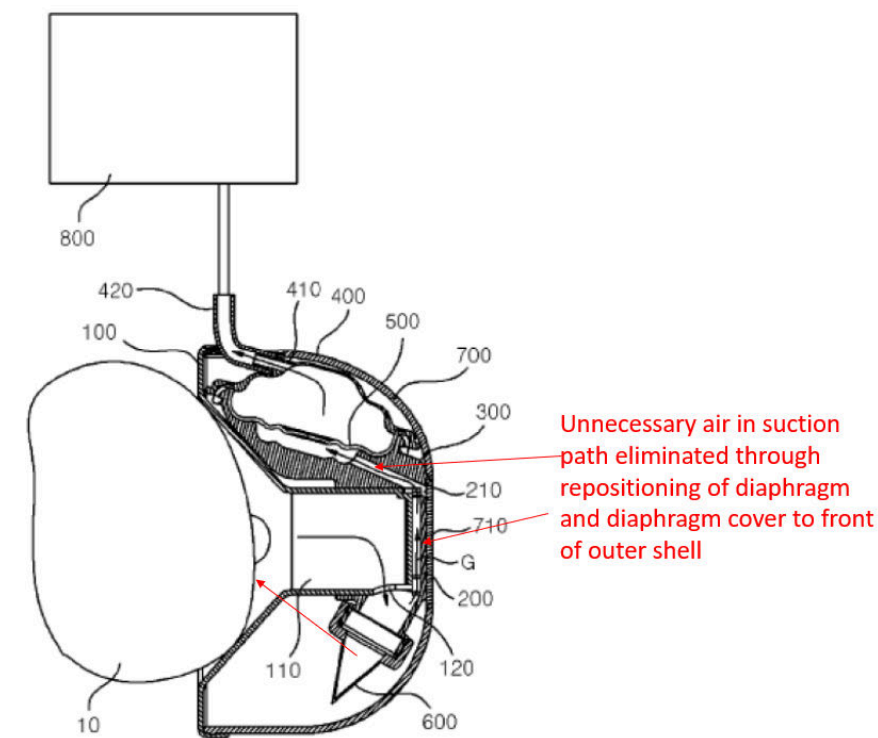
Motivation for first modification

Multiple reasons would have prompted a POSITA to apply Silver's teachings to Park's breast pump to reposition the diaphragm to the front of the storing housing 700. EX1003, ¶¶201-217. First, such a configuration would "substantially limit[]" or "virtually eliminate[]" any air at least in the area of the breast and nipple." EX1011, [0013], [0016] ("...the amount of air in the system reduced or virtually eliminated"); EX1003, ¶¶205-207. A POSITA would have been well-aware that when "the media separation membrane is arranged in the area of nipple...the dead volume, i.e. the volume to be evacuated in the breastshield during the expression of milk, is further minimized." EX1004, 2:4-9; EX1003, ¶206. Consequently, "[w]ith the amount of air limited, the mechanism used for generating the pressure difference in the breastshield (e.g., vacuum or negative pressure), such as a diaphragm pump, does not need to do as much work." EX1011, [0013]. As such, "[l]ess energy is required for the expression of milk,

in the proposed manner to achieve the benefits described herein when implementing the Park-Silver combination. EX1003, ¶205

and thus the size of pump used can be decreased, thereby ***reducing the overall cost of the device.***” *Id.*; EX1003, ¶206. This reduction of the amount of air in the resulting device would include eliminating much of the air in Park’s suction flow path by repositioning the diaphragm and diaphragm cap to the front of the nipple tunnel (as taught by Silver). EX1003, ¶206.

Fig. 8



EX1010, FIG. 8 (annotated). As Silver describes “reduction of air...in the entire system” helps to achieve the recited “inventive objectives.” EX1011, [0018], [0028]. A POSITA would have recognized that positioning the diaphragm/membrane at the front of the outer shell in front of the nipple would have significantly contributed to this reduction in dead volume. EX1004, 2:4-20;

EX1003, ¶¶206-207, 50-51, 63, 82.

Second, the reduced air in the breast and nipple area allows the resulting system “to be smaller and lighter, which means that it is in turn less conspicuous to onlookers” allowing the wearer to “use the vacuum pump more discreetly.”

EX1011, [0014]; EX1004, 8:28-30; EX1003, ¶¶208, 50-51.

Third, “because of the lower energy, the vacuum pump is quieter during use, which in turn increases the comfort and discretion.” EX1011, [0014]; EX1003, ¶¶209, 51, 82.

Fourth, such a modification allows the vacuum to “act on a smaller portion of the mother's breast, indeed on the nipple alone” which can “more closely duplicat[e] conditions in normal breastfeeding.” EX1011, [0017]; EX1003, ¶210.

Fifth, reducing the amount of air in the vacuum area and limiting suction to the nipple “will limit the expansion of the nipple from applied negative pressure, resulting in improved comfort.” EX1011, [0019]; EX1003, ¶¶211.

Sixth, such a modification would allow for a sensation for the mother that is “much more like what an infant’s suckling actually does,” thus additionally improving comfort. EX1011, [0020]-[0021], [0029], [0032]; EX1003, ¶212.

Seventh, positioning the diaphragm cap at the front/center of the device, as suggested by Silver, would have both provided for easy removal of the diaphragm cap for allow for cleaning/replacement of the diaphragm and other components,

but also would have contributed toward reducing dead volume. EX1003, ¶213.

Eighth, “due to the substantial elimination of air from the system of the present invention, the mother is not required to be in a substantially vertical position while expressing milk; further the container into which the expressed breastmilk flows does not need to be located downwardly with respect to the mother” and is thus “not reliant on gravity.” EX1011, [0030]; EX1003, ¶241.

Therefore, such a modification “provides flexibility for the mother in the type of activities in which she can participate while expressing milk.” EX1011, [0030].

Therefore, such a modification allows “the container into which the expressed milk is collected, to be located other than downwardly with respect to the mother's breast,” which would have allowed for a larger portion of the chamber defined by Park's storing housing 700 to be used for storing expressed milk (areas both above and below the nipple). *Id.*; EX1003, ¶214. Furthermore, “[t]he mother may, for example, even express milk while lying down.” *Id.*, [0030].

Finally, such a modification would have been simply the application of a known technique to a known system to achieve predictable results and a POSITA would have had a reasonable expectation of success in making such a modification. *KSR*, 550 U.S. at 417; EX1003, ¶¶215-216.

Furthermore, a POSITA would have recognized that by making the above described modification to Park's device based on the teachings of Silver, while

retaining the remaining components of Park's system (including storing housing 700) the resulting device would retain the benefits described by Park. Specifically, retention of the storing housing 700 for storing the expressed milk in the resulting device would have allowed for "collect[ing] extracted breast milk even without using a separate milk bottle," eliminating the need for "a lactating woman [to] continuously hold a milk bottle." EX1010, [6], [42]; EX1003, ¶216. As such, by retaining such features of Park's device "a lactating woman may use both hands because the lactating woman can extract breast milk even without holding a separate milk bottle." *Id.*

Furthermore, the resulting system would have retained Park's functionality of preventing "the breast milk filled in the storing housing 700 [from] flow[ing] backward through the breast milk discharge tube 210" by retaining the valve 600 described by Park. EX1010, [44]; EX1003, ¶217. The resulting device would have similarly still prevented suction of milk into the air tube 420 because the flow separation membrane 500 of Park would be retained and simply repositioned/reconfigured as taught with respect to Silver's membrane 14. EX1010, [53]-[55]; EX1003, ¶217.

Motivation for second modification

Multiple reasons would have prompted a POSITA to implement Park's electric pump 800 to be battery operated, as taught by Silver. First, Park expressly

describes that “electric breast pumps include an air pressure generating pump having a motor and an air cylinder” such as Park’s electric pump 800. EX1010, [5], [37], [49]. Park does not include details on how the electric pump is powered and therefore a POSITA would have turned to other references, such as Silver, to identify suitable methods of powering such a pump motor, such as using a “battery” which beneficially does not depend on being near a wall outlet and can still function during power outages. EX1011, [0005]; EX1003, ¶218.

Second, a POSITA would have implemented Park’s electric pump to run on batter power, as taught by Silver, to provide mobility because Park’s breast pump is intended to be worn by the user. EX1010, [5]; EX1003, ¶219.

Third, the two most common methods of powering such a pump would have been through wall outlet power or battery power. EX1003, ¶218; *see also e.g.*, EX1005, [0082]; EX1011, [0005]; EX1013, 7:52-58, 8:14-17. A POSITA would have used a battery powered pump (as taught by Silver) because “when [] there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” *KSR*, 550 U.S. at 421. Battery operated pumps were “commonplace,” making the use of battery power a natural choice. EX1011, [0005]; EX1003, ¶218.

Finally, such a modification would have been simply the application of a known technique to a known system to achieve predictable results and a POSITA

would have had a reasonable expectation of success in making such a modification.

KSR, 550 U.S. at 417; EX1003, ¶220.

4. Application of Park and Silver to the '454 Claims

Preamble [17pre]

Park describes “a breast pump which enables a lactating woman to freely use both hands.” EX1010, [8]; *see also* EX1011, [0003]; EX1003, ¶¶221, 73-80.

Elements [17a-1]-[17a-3]

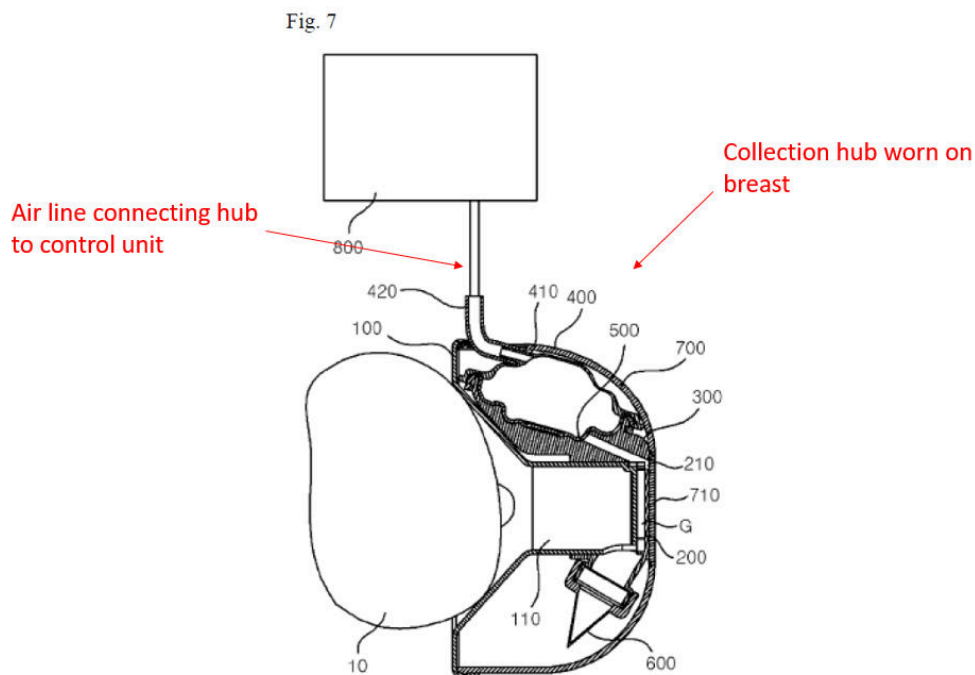
As discussed above, the resulting Park-Silver combination uses a battery powered electric pump 800. EX1010, [5] (“electric breast pumps include an air pressure generating pump having a motor and an air cylinder”), [21], [37], [49]; EX1011, [0005] (“vacuum pumps...driven by a motor (house current, **battery**, pneumatic, etc.)”); EX1003, ¶¶222-223. Park discloses that such breast pumps create suction or “negative [air] pressure.” EX1010, [4]-[6], [21], [37].

Park’s pump has states in which is “operated” and “not operated” and therefore a POSITA would have recognized that it is a control unit. EX1010, [53]-[54]; EX1003, ¶223. Alternatively, it would have been obvious to implement Park’s system to include a control unit to switch the electric pump between the operational and non-operational states (e.g., an on/off switch) so that the device did not need to have the batteries removed to turn it off. EX1003, ¶224. In yet another alternative configuration, a POSITA would have found it obvious and beneficial to include Silver’s microprocessor (a control unit) to “drive[] the pump” to process

“vacuum level reading[s]” and “ensure the appropriate vacuum profile is produced” which would beneficially “allow the [resulting device] to perform consistently from mom to mom and will also allow for an improved reproduction of vacuum profiles of an infant.” EX1011, [0015]; EX1003, ¶224.

Element [17b]

Both Park and Silver demonstrate that the resulting breast pump system includes a wearable milk collection hub. EX1003, ¶¶225-228. As discussed in Park, the resulting system includes “a funnel-shaped suctioner connected to the air pressure generating pump and worn on a breast of a lactating woman.” EX1010, [5]. For example, as shown for example in FIG. 7, air tube 420 connects the wearable milk collection hub to electric pump 800 (the claimed control unit). EX1010, [37], [49], [54].

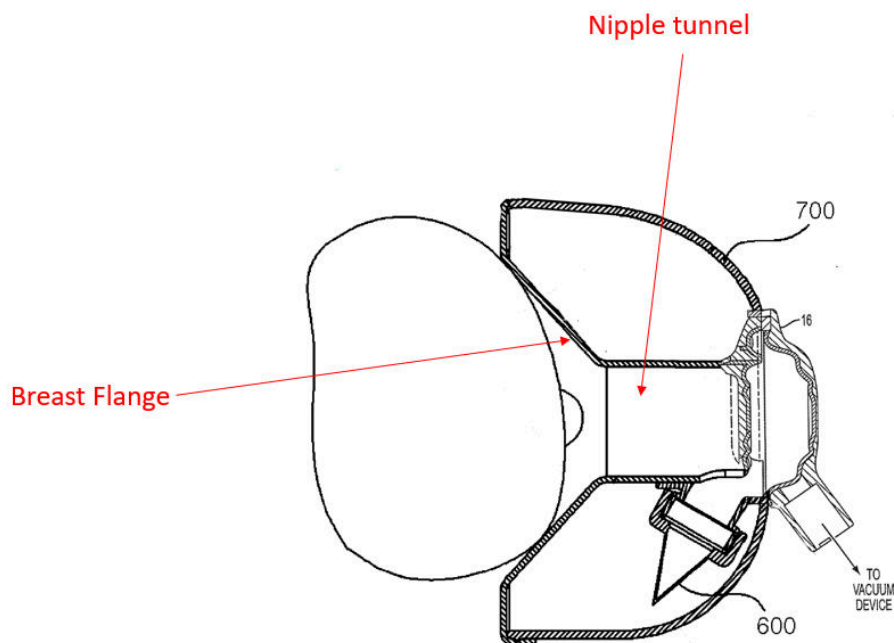


EX1010, FIG. 7 (annotated). Silver similarly discloses a “breastshield surrounding the breast/nipple” that is “connected via a tube 20” to a vacuum source (pump).

EX1011, [0013], [0059], [0067], [0081], [0091]. As discussed with respect to Elements [17a-1]-[17a-3], *supra*, it would have been obvious to implement the pump in the resulting system as part of a battery powered control unit, such as Silver’s “microprocessor [that] drives the pump.” EX1011, [0015]; EX1003, ¶228.

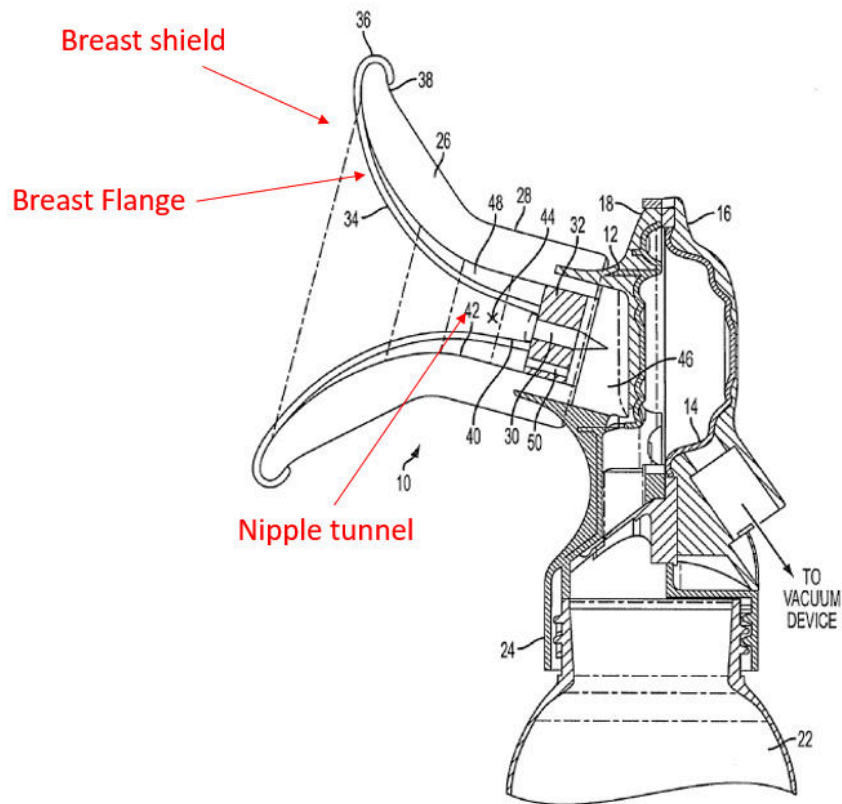
Elements [17c-1]-[17c-3]

As shown in the below figure showing the predictable combination of Park (FIG. 7) and Silver (FIG. 5), the resulting system includes a breast shield comprising: a breast flange; and a nipple tunnel extending from the breast flange. EX1003, ¶¶229-232.



Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

For example, Park discloses “a close-contact housing 100 having a protruding part 110, which extends forward and is formed in the portion corresponding to a nipple of a lactating woman.” EX1010, [37]; EX1003, ¶230. Silver similarly discloses a “breastshield” having “a sheath-like member 34” (the claimed breast flange) and a “nipple tunnel.” EX1011, [0063]-[0064].



EX1011, FIG. 5 (annotated).

Element [17d]

The Park-Silver combination provides the claimed diaphragm. EX1003, ¶¶233-236. For example, Park discloses the claimed diaphragm in the form of separation membrane 500. EX1010, [39]-[42], [54-56], FIGs. 5, 7. Park describes

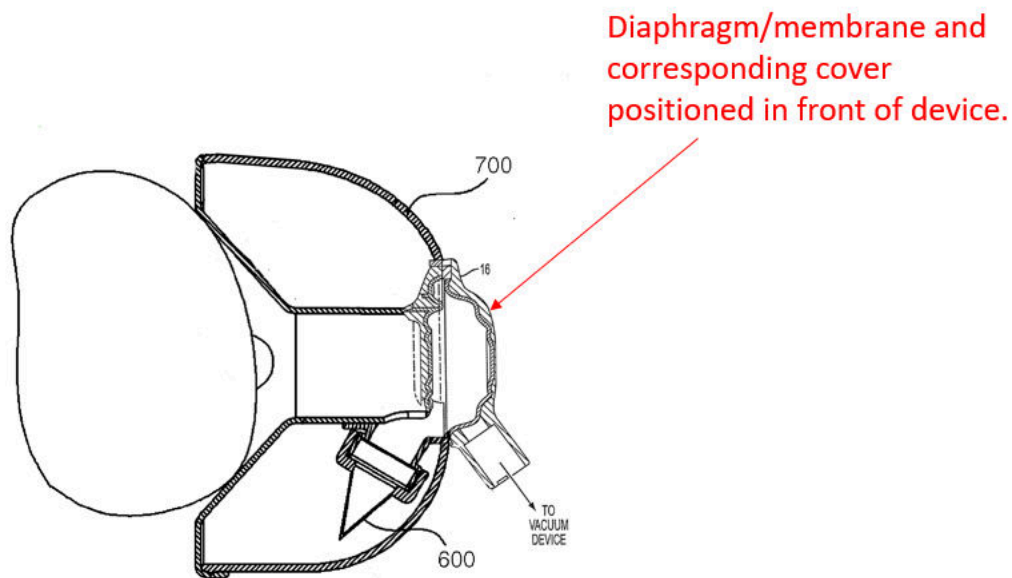
“when *air* between the cover 400 and the flow separation membrane 500 *is suctioned to the outside through an air nozzle 410*, the flow separation *membrane 500 is moved*” such that “the space between the flow separation membrane 500 and the funnel connector 300 is expanded to form a vacuum pressure.” *Id.*, [39]. This vacuum pressure is then “transferred to a breast 10 of a lactating woman.” *Id.*; *see also* [54] (“the *flow separation membrane 500 is pulled toward the cover 400* as illustrated in FIG. 8, and then, a space is formed between the flow separation membrane 500 and the funnel connector 300, and thus, a *vacuum pressure is generated* in the communication flow passage 310. The *vacuum pressure* generated in the communication flow passage 310 *is applied into the protruding part 110*.”).

Silver similarly discloses “a barrier component” or “diaphragm 14” enclosed in a housing such that “[t]he *barrier is reciprocated* within the space of the housings 16, 18 by an intermittent *vacuum from a vacuum source* (not shown) which is connected via a tube 20.” *Id.*, [0059]. In further detail, Silver describes:

Vacuum is applied from the vacuum source (pump) via the tube 20, with the *vacuum conveyed to the breastshield by action of the barrier 14* within the clamshell-like chamber. The vacuum evacuates an antechamber 46 within the base 12, and is further *conveyed into the space 48*...the vacuum is thus applied on the distal end of the nipple.

EX1011, [0067].

As discussed in Section III.G.3, *supra*, in the predictable Park-Silver combination, the diaphragm would have been positioned at the front of the resulting device based on Silver's suggestion as shown below. EX1003, ¶¶236, 201-215.



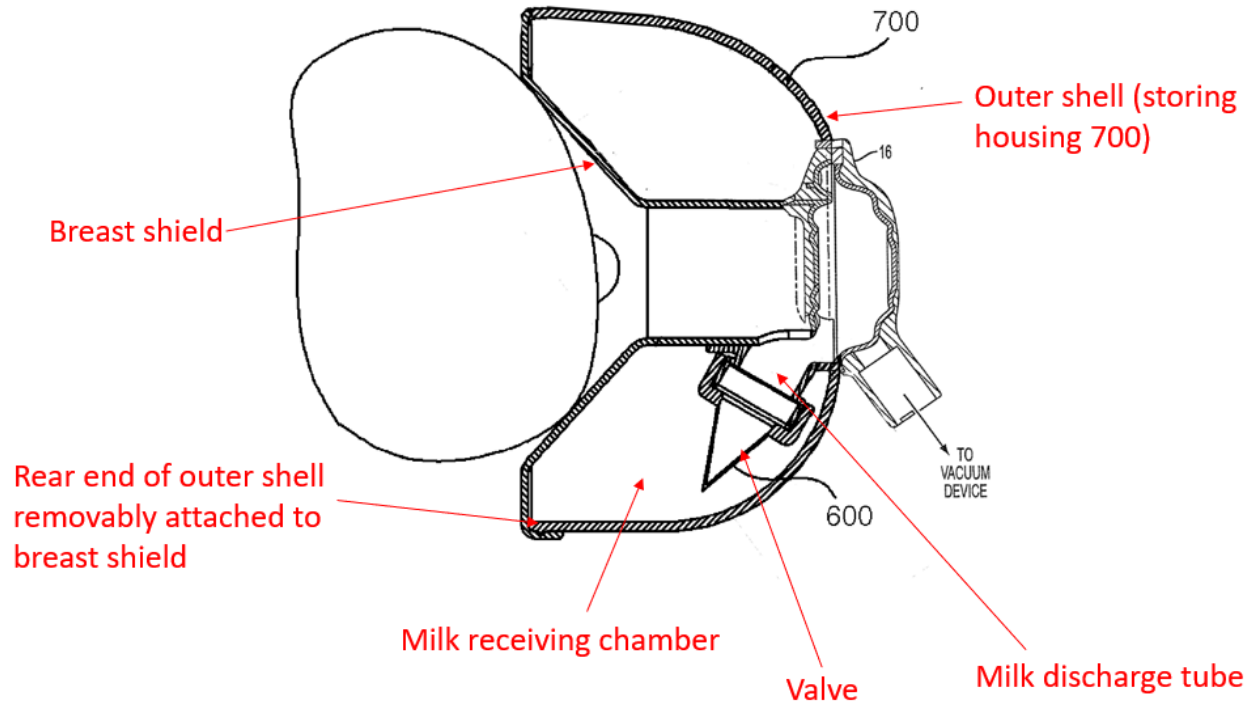
Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

Element [17e]

As discussed in Section III.G.3, *supra*, the predictable Park-Silver combination, includes the claimed outer shell in the form of Park's storing housing 700. EX1003, ¶¶239-240, 202, 214, 216. As shown below, in the predictable combination, Park's storing housing 700 includes a rear end configured to removably attach to the breast shield (close-contact housing 100) and, together

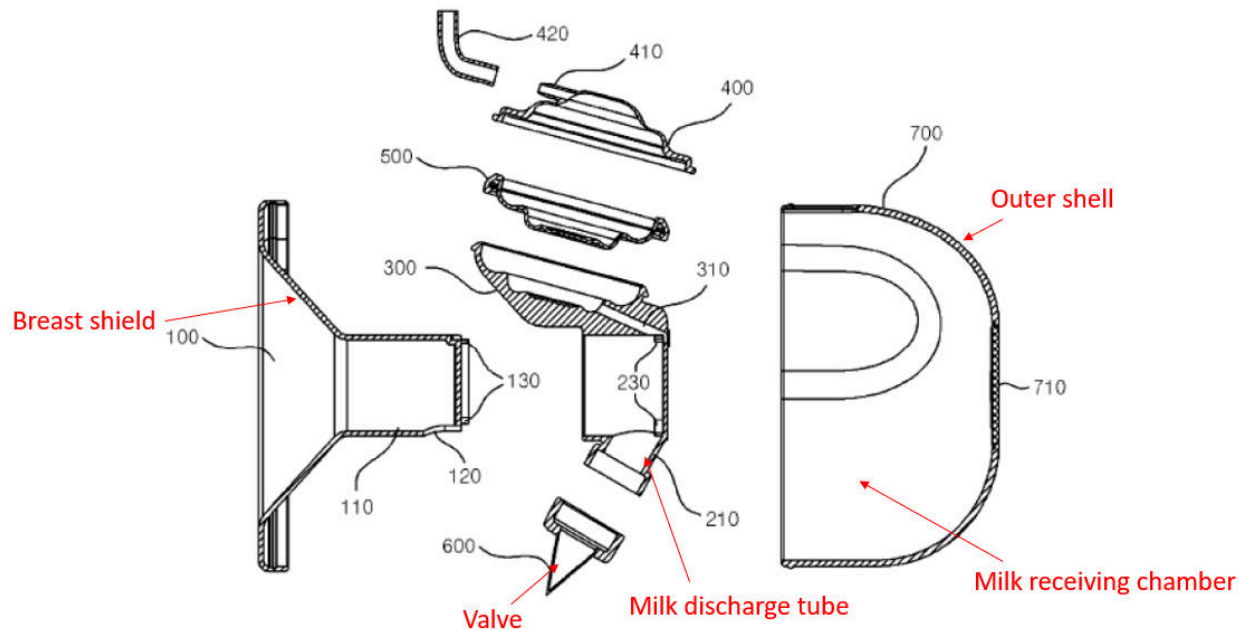
with the breast shield, defines a chamber to receive expressed milk. EX1003,

¶¶239-240.



Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

As Park describes, “the *storing housing 700 is coupled to the close-contact housing 100 in a detachable structure*, and thus, a user can collect breast milk by separating the storing housing 700 from the close-contact housing 100 after a certain amount of *breast milk is stored in the storing housing 700*.” EX1010, [42]. Park goes on to describe that “breast milk discharged through the breast mil[k] discharge tube 210 is introduced in the silicon valve 600, and is then filled in the storing housing 700.” *Id.*, [44].

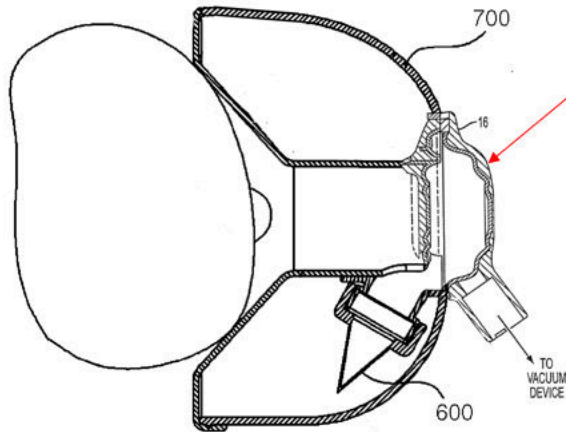


EX1010, FIG. 5 (annotated).

Element [17f]

As discussed in Section III.G.3, *supra*, the predictable Park-Silver combination, includes the claimed diaphragm cap in the form of Park's diaphragm cover 400 repositioned to the front of the front surface of Park's storing housing 700 based on the positioning of Silver's rear housing 16 (which covers diaphragm 14 and forms a front surface of Silver's housing). EX1003, ¶¶241-244, 201-215; EX1010, [37], [39], [42], [54]-[56], FIGs 5, 7; EX1011, [0059], FIG. 5.

Diaphragm/membrane and
corresponding cover
positioned in front of device.



Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

As can be seen in the above predictable configuration, the diaphragm cap of the resulting system forms a central region on a front surface of the outer shell (storing housing 700). EX1003, ¶243.

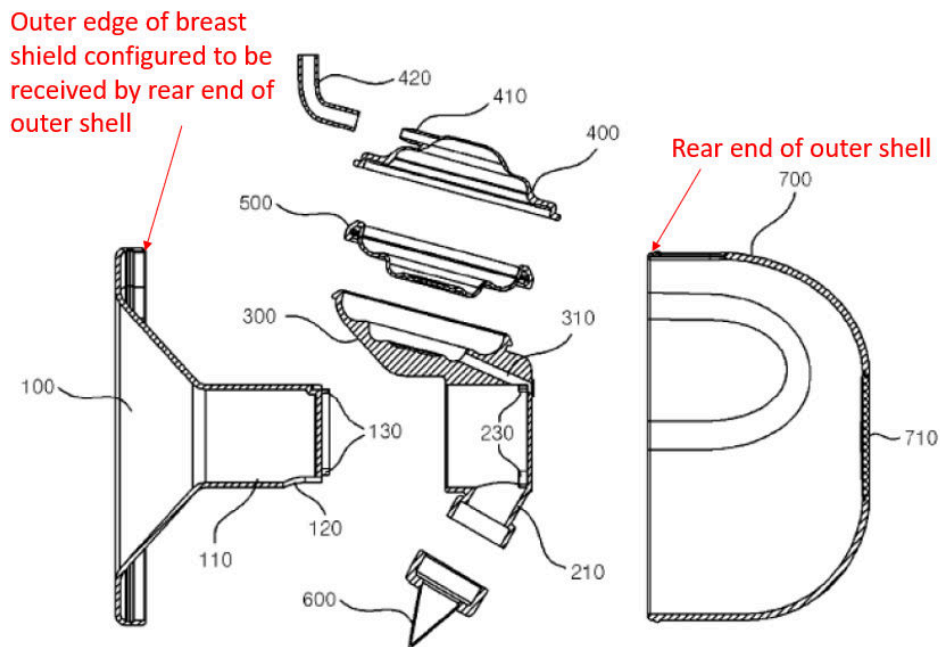
As Park describes “cover 400 [is] coupled so as to cover the inner space of the funnel connector 300” in which the membrane 500 resides. EX1010, [37], FIGs. 5, 7. Park describes that “when the electric pump 800 is operated and then air between a cover 400 and the flow separation membrane 500 is discharged through an air tube 420 and an air nozzle 410, the flow separation membrane 500 is pulled toward the cover 400 as illustrated in FIG. 8.” *Id.*, [54]-[56]. A POSITA would have recognized from this disclosure, and the figures of Park, that the cover 400 covers and seals the flow separation membrane 500 (diaphragm). EX1003,

¶243.

Silver similarly discloses that the “barrier component” or “diaphragm 14” is covered and sealed by rear housing 16 such that “[t]he *barrier is reciprocated* within the space of the housings 16, 18 by an intermittent *vacuum from a vacuum source* (not shown) which is connected via a tube 20.” *Id.*, [0059], *see also* [0067]; EX1003, ¶245.

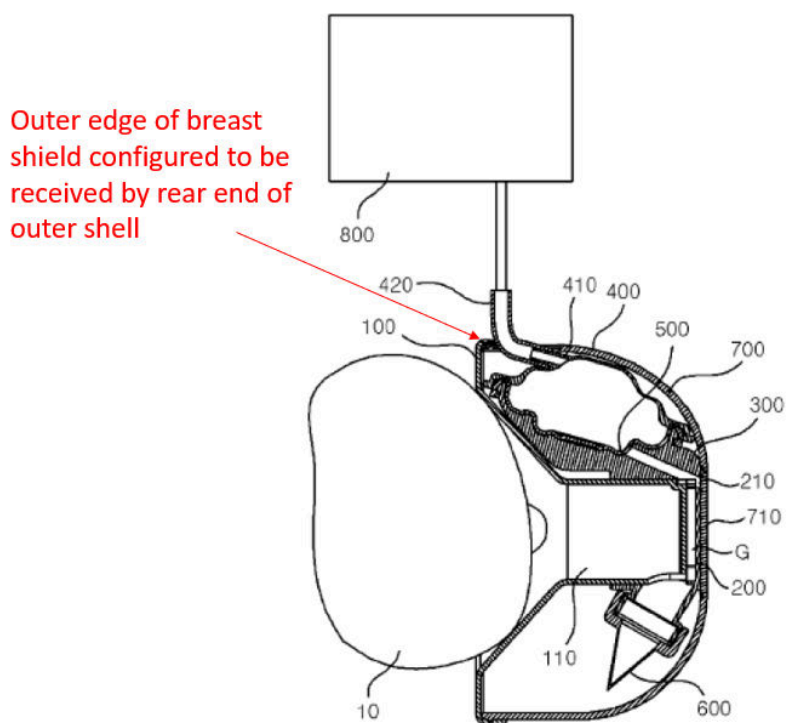
Claim [18]

Park demonstrates that the breast shield in the Park-Silver combination includes an outer edge configured to be received by the rear end of the outer shell. EX1003, ¶246.

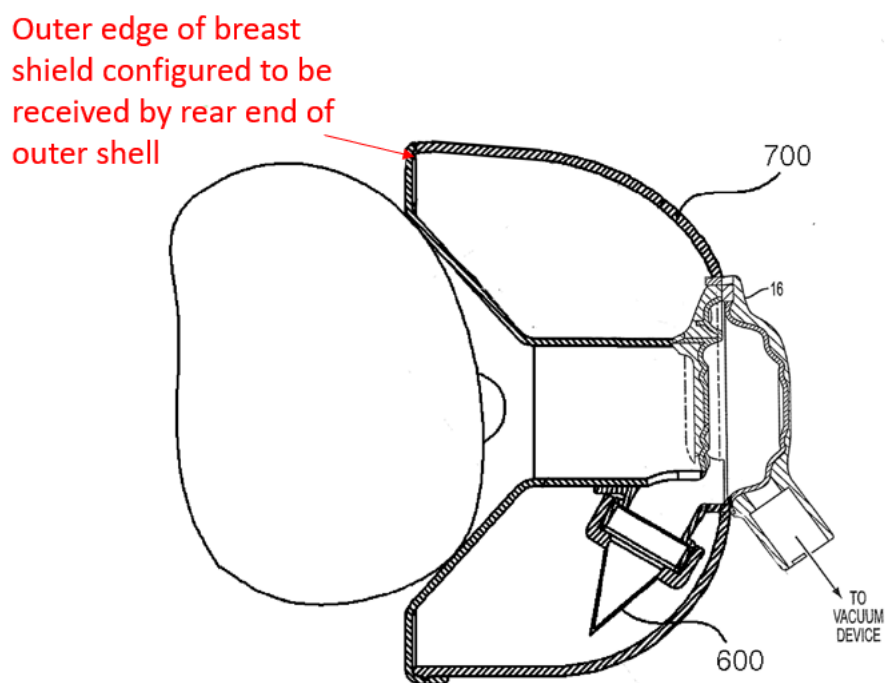


EX1010, FIG. 5 (annotated).

Fig. 7



EX1010, FIG. 7 (annotated).



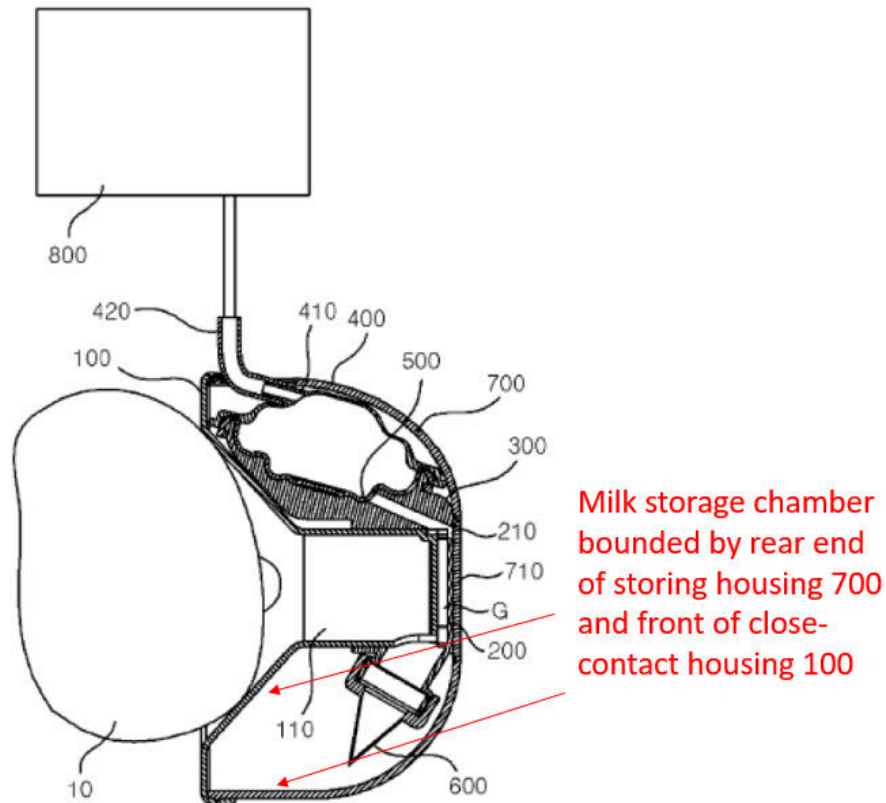
Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

Claim [19]

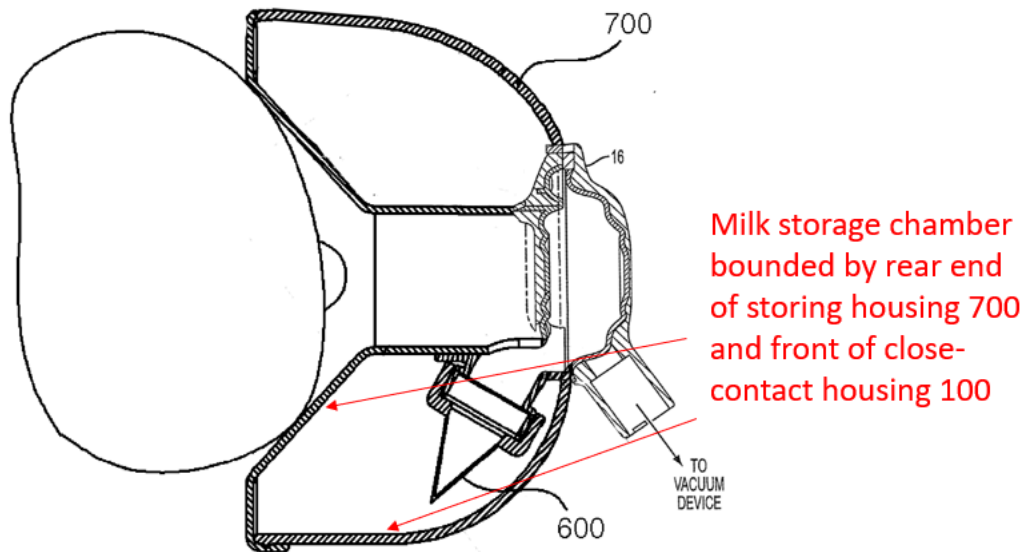
As shown in FIG. 7 of Park, in the Park-Silver combination, the rear end of the outer shell and front end of the breast shield bound the interior volume.

EX1003, ¶247.

Fig. 7



EX1010, FIG. 7 (annotated).

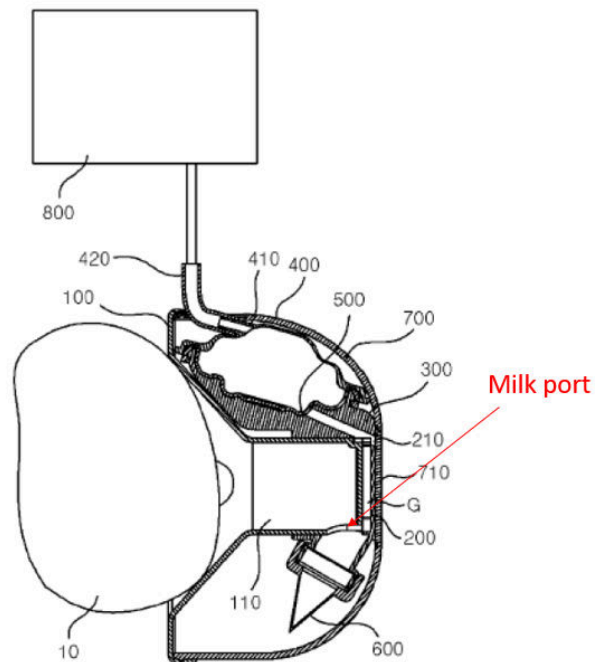


Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

Claim [21]

Figure 7 of Park shows that the Park-Silver combination includes a milk port in the nipple tunnel. EX1003, ¶¶248-249.

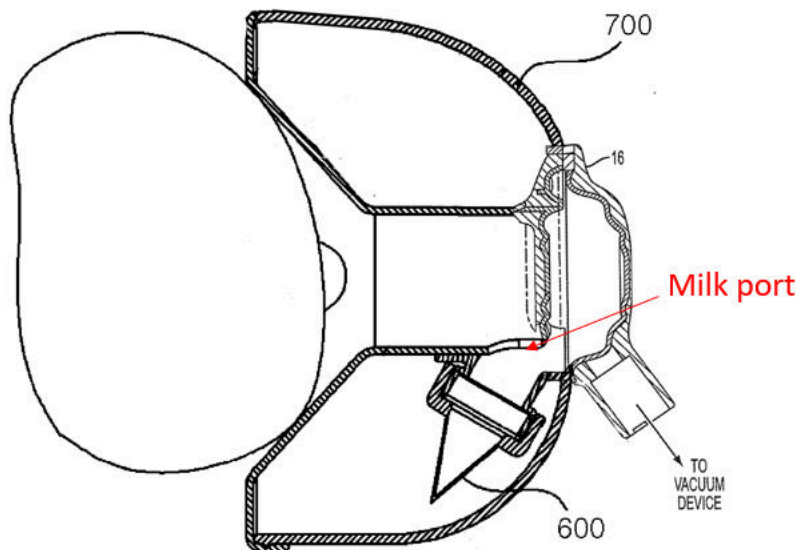
Fig. 7



EX1010, FIG. 7 (annotated).

Park describes this milk port as “a breast milk discharging hole 120” and describes that milk flows from the user’s breast, through “breast milk discharging hole 120,” a discharging tube, and the valve 600 to the storage chamber (storing housing 700). EX1010, [37], [44].

The breast pump resulting from the combination of Park and Silver retains this milk port:



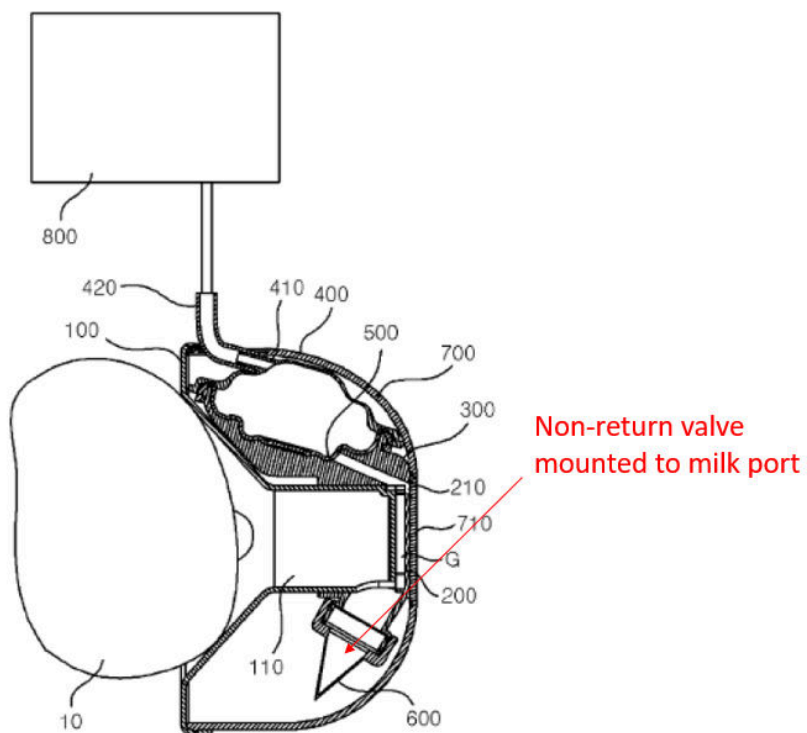
Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

Claim [23]

Park discloses that the resulting Park-Silver system includes “silicon valve 600” which prevents “breast milk filled in the storing housing 700 [from] flow[ing] backward through the breast milk discharge tube” and thus constitutes a non-return valve. EX1010, [44]; EX1003, ¶¶250-251. As shown in FIG. 7 of Park, the valve

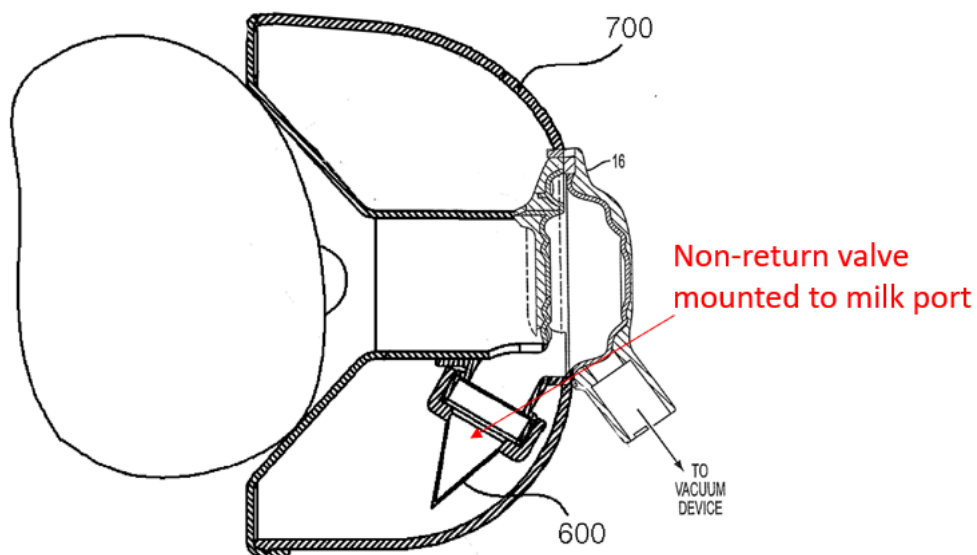
600 is mounted to the milk port:

Fig. 7



EX1010, FIG. 7 (annotated).

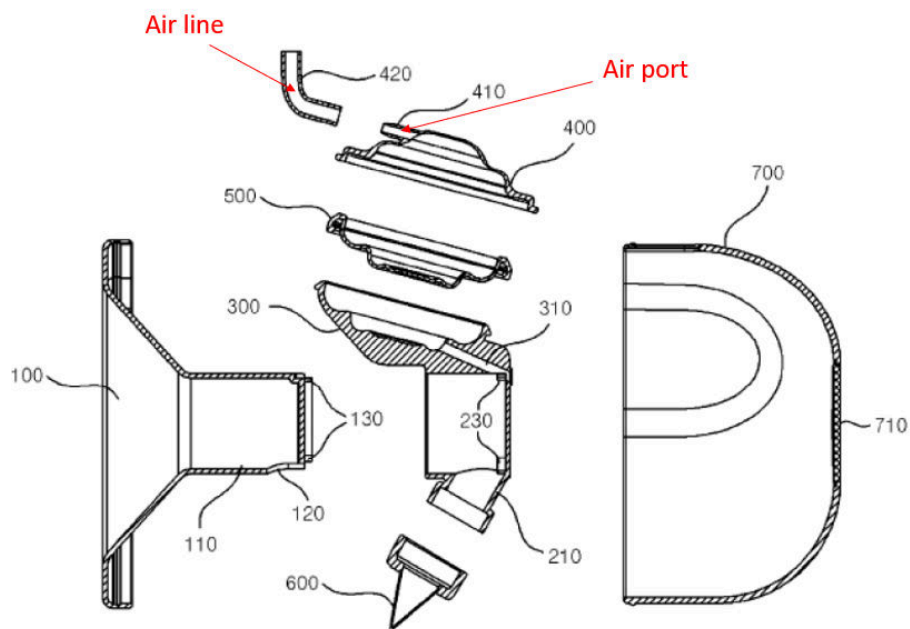
The breast pump resulting from the combination of Park and Silver retains this non-return valve:



Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

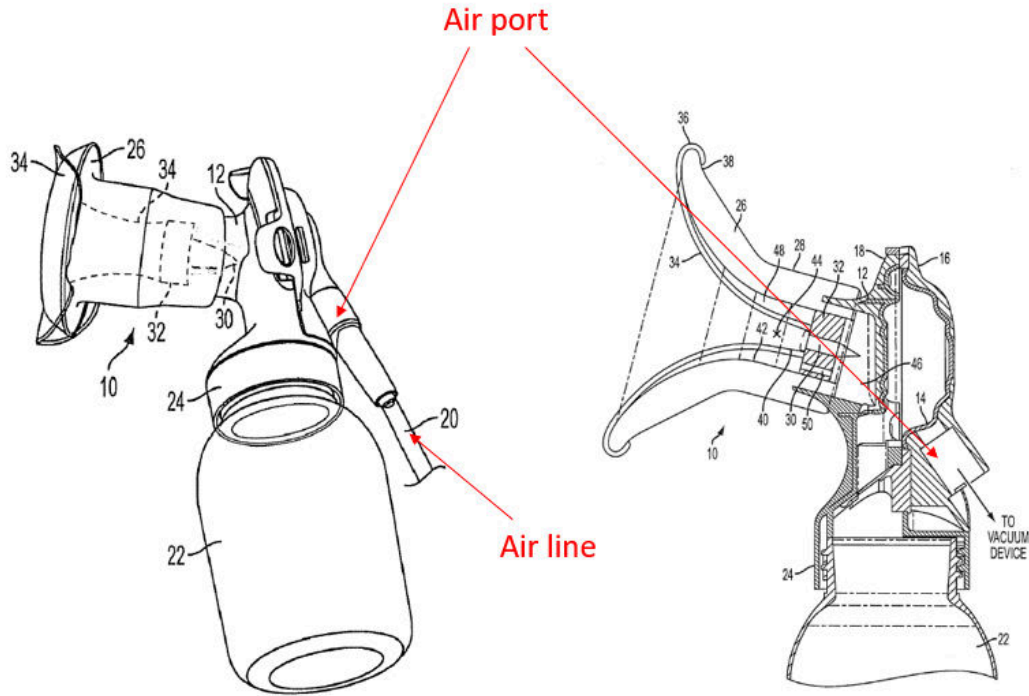
Claim [24]

Park's cover 400 an air nozzle 410 for connecting to air tube 420. EX1010, [54]-[55]; EX1003, ¶¶252-253.



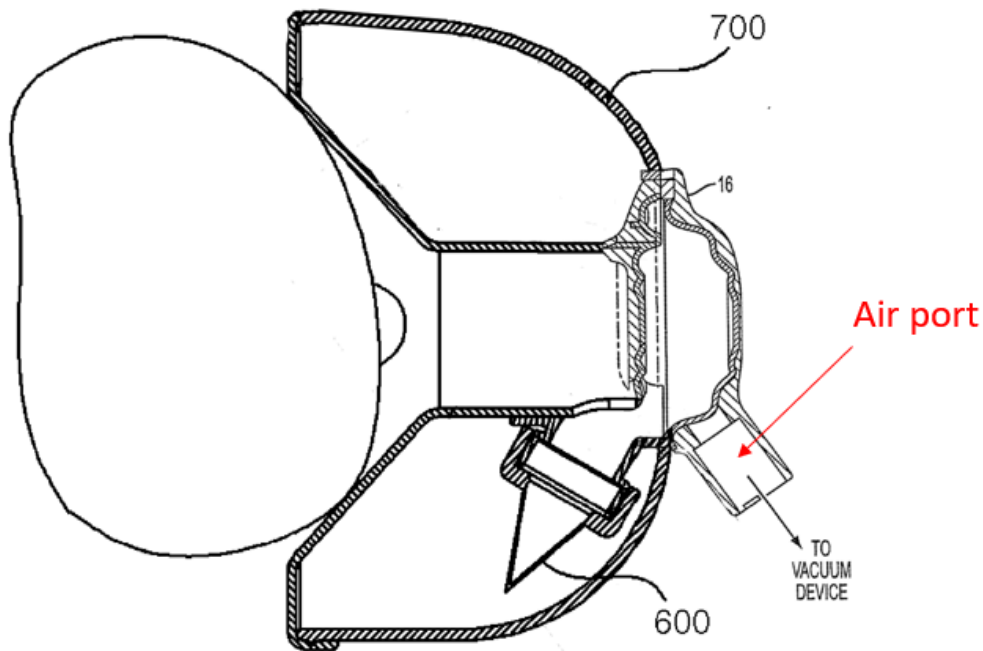
EX1010, FIG5 (annotated).

Silver similarly demonstrates that the predictable Park-Silver combination includes an air port configured to receive an air line. EX1011, [0059], [0067].



EX1011, FIGs. 1, 5 (annotated).

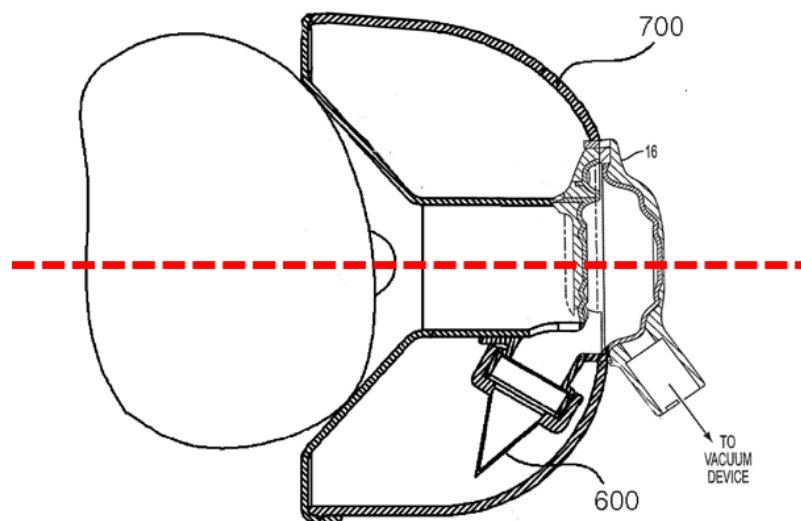
The system resulting from the combination of Park and Silver thus includes an air port. EX1003, ¶¶252-253.



Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

Claim [27]

As discussed in Section III.G.3, *supra*, a POSITA would have predictably and beneficially applied the teachings of Silver to Park's device to position the diaphragm and diaphragm cap at the front of Park's storing housing 700 at the location of the sealing packing 710 in the unmodified version of Park. EX1003, ¶¶254. As such, as shown in the below illustration of the Park-Silver combination, the diaphragm is arranged concentric with the nipple tunnel. *Id.*



Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

Element [28pre]

Supra, [17pre]

Elements [28a-1]-[28a-3]

Supra, [17a-1]-[17a-3]

Elements [28b]

Supra, [17b]

Elements [28c-1]-[28c-3]

Supra, [17c-1]-[17c-3]

Element [28d]

Supra, [17d] and [27]

Element [28e]

Supra, [17e]

Element [28f]

Supra, [17f]

Claim [29]

Supra, [19]

Claim [30]

Supra, [17f]

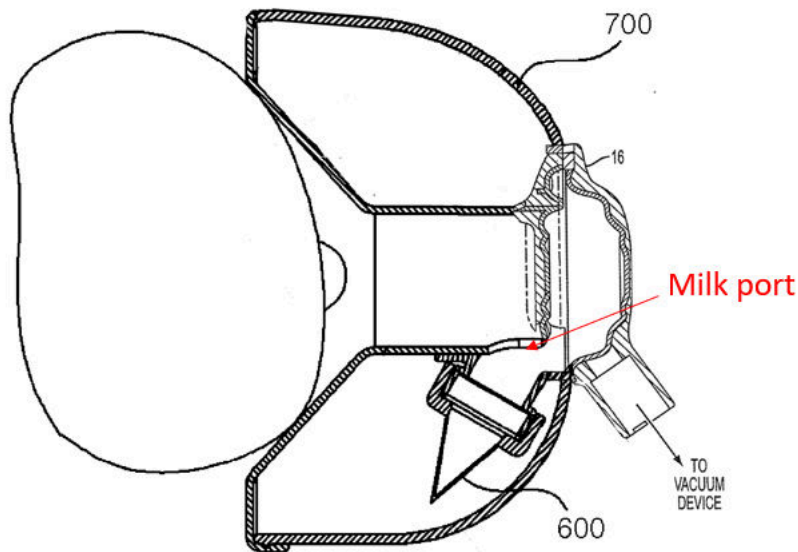
Claim [32]

Supra, [24]

**H. [GROUND 2B] – Claims 22, 31 are rendered obvious by
Park, Silver, and Weniger**

1. The Park-Silver-Weniger combination

A POSITA would have been motivated to predictably and beneficially apply the teachings of Weniger to the Park-Silver combination to implement the resulting breast pump system such that the diaphragm (Park's flow separation membrane 500, repositioned to the front of the storing housing 700 based on Silver's teachings) extends over and adjacent the milk port in a relaxed state. EX1003, ¶¶265-271; EX1007, [0022], [0041], FIG. 4. As discussed in Ground 2A, *supra*, the Park-Silver combination includes a milk port.



Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

A POSITA would have been prompted to apply Weniger's teachings to the Park-Silver system such that the membrane (diaphragm) extends over and adjacent the milk port in a relaxed state for the same reasons discussed in Ground 1D, *supra*. EX1003, ¶¶265-271. That is, a POSITA would have recognized that such a modification would have prevented milk that has passed through the milk port from returning to the nipple tunnel thus preventing spillage and discomfort, would create positive pressure in the area below the milk port when the membrane/diaphragm moves from the underpressure state to the relaxed state to help advance expressed milk through the one-way valve which prevents milk backup, reduces the dead volume in the resulting configuration, and would have been simply the application of a known technique to a known system to achieve predictable results and a POSITA would have had a reasonable expectation of

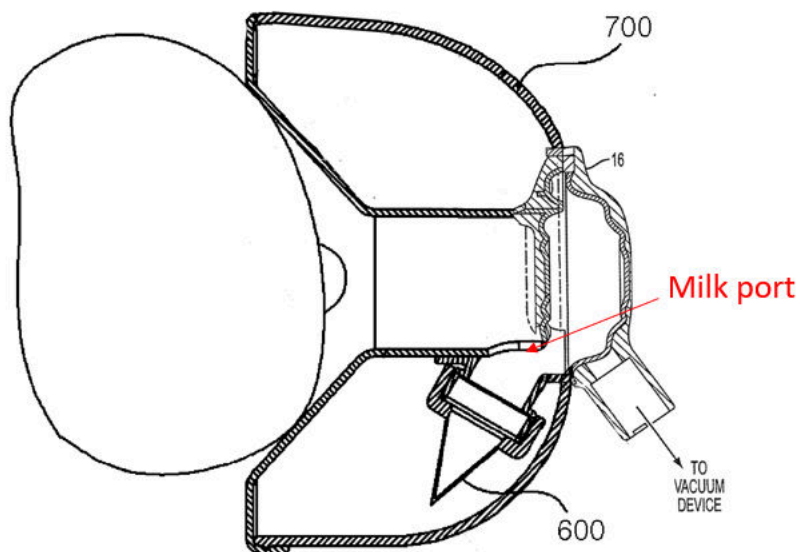
success in making such a modification. EX1004, 2:49-56, 6:13-17; *KSR*, 550 U.S.

at 417; EX1003, ¶¶265-271.

2. Application of Park-Silver-Weniger to the '454 Claims

Claims [22] and [31]

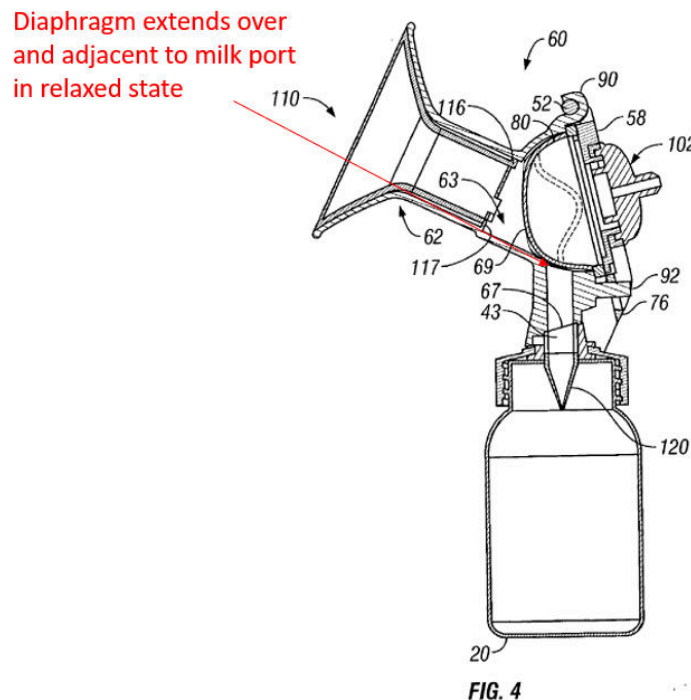
As discussed in Ground 2A, *supra*, the resulting Park-Silver breast pump system includes a milk port. EX1010, [37], [44].



Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

As discussed in Section III.H.1, *supra*, a POSITA would have predictably applied Weniger's teachings to the Park-Silver combination such that the flow separation membrane (diaphragm) of the resulting breast pump system extends over and adjacent the milk port in a relaxed state. EX1003, ¶¶265-274.

Specifically, Weniger describes that in the predictable combination, vacuum chamber 64 and funnel portion 62 “define a passageway 63 for expressed milk” such that “[t]he *passageway is discontinuous* (as shown in FIG. 4) when the hemispherical membrane 80 is disposed in an unaltered configuration.” EX1007, [0041]. Subsequently “[w]hen the hemispherical membrane generates a vacuum in the funnel portion 62 by collapsing in response to a negative pressure to applied to the membrane 80 by the vacuum source (as shown in phantom), not only is milk expressed, but *the passageway is made continuous such that the expressed milk may flow through the outlet 67* which is in communication with the conduit 43 of the base portion 42.” *Id.*



- I. [GROUND 2C] – Claims 25, 27-30, and 32 are rendered obvious by Park, Silver, and Rigert

1. The Park-Silver-Rigert combination

A POSITA would have been motivated to predictably and beneficially apply the teachings of Rigert to the Park-Silver combination in at least two ways: (1) to implement the resulting breast pump system such that the air port can be located above the nipple tunnel; and (2) to position the diaphragm of the resulting system to be concentric with the nipple tunnel. EX1003, ¶¶276-285; EX1008, [0052]-[0058], FIGs. 1-4, 7, 13. As discussed in Ground 2A, *supra*, both Park and Silver disclose an air port (e.g., Park's air nozzle 410) configured to connect to a suction tube. EX1010, [54]-[55], FIGs. 5, 7; EX1011, [0059], [0067], FIGs. 1, 5; EX1003, ¶¶277, 252-253.

Regarding the first modification, POSITA would have been promoted to position the vacuum connector port above the nipple tunnel in the resulting system (based on Rigert's teachings) for the same reasons discussed in Ground 1e, *supra*: (1) to allow the connecting suction line to protrude out of the top of the bra, rather than from the bottom of the bra; (2) to allow the suction lines to exit the user's clothing through the collar of a shirt/top, rather than being directed throughout the length of the user's shirt; (3) to allow the user to more easily visually observe the vacuum lines to identify kinks or other obstructions; and (4) because such a modification would have been simply the application of a known technique to a known

system to achieve predictable results with a reasonable expectation of success.

EX1003, ¶¶276-282.

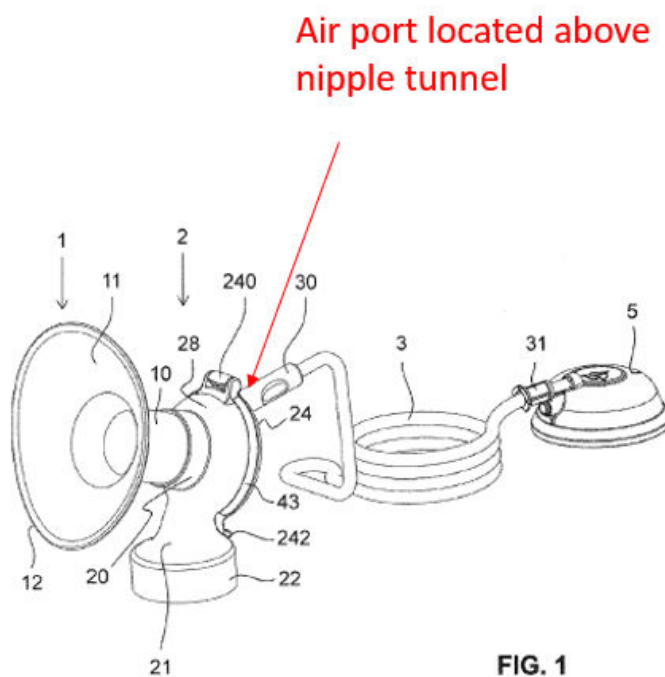
Regarding the second modification, to the extent that it is believed that the Park-Silver combination does not render obvious that the diaphragm is arranged concentric with the nipple tunnel, a POSITA would have applied Rigert to Park-Silver to position the diaphragm of the resulting system to be concentric with the nipple tunnel for multiple reasons. EX1003, ¶¶283-285. First, such a modification would have provided for more even distribution of suction to the nipple, therefore increasing comfort and efficacy of the resulting device. EX1003, ¶283. Second, such a modification would have contributed toward reducing the dead volume in the device by arranging the diaphragm more closely with “[t]he area of the nipple” to further reduce the amount of power needed from the pump, thereby increasing the benefits discussed in Section III.G.3, *supra*. EX1004, 2:49-56, 6:13-17; EX1011, [0013]-[0014]; EX1003, ¶¶284, 50-51, 63, 82.

Finally, such a modification would have been simply the application of a known technique to a known system to achieve predictable results and a POSITA would have had a reasonable expectation of success in making such a modification. *KSR*, 550 U.S. at 417; EX1003, ¶285.

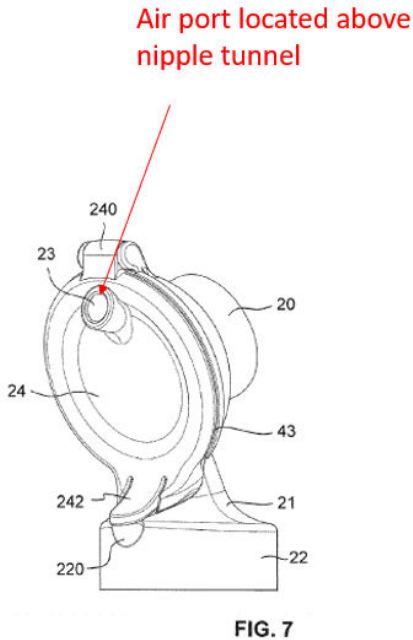
2. Application of Furrer-Alvarez-Pollen-Rigert to the '454 Claims

Claim [25]

FIGs. 1 and 7 of Rigert demonstrate that, in the predictable Park-Silver-Rigert combination, the air port can be located above the nipple tunnel. EX1003, ¶286; EX1008, [0056]-[0058].



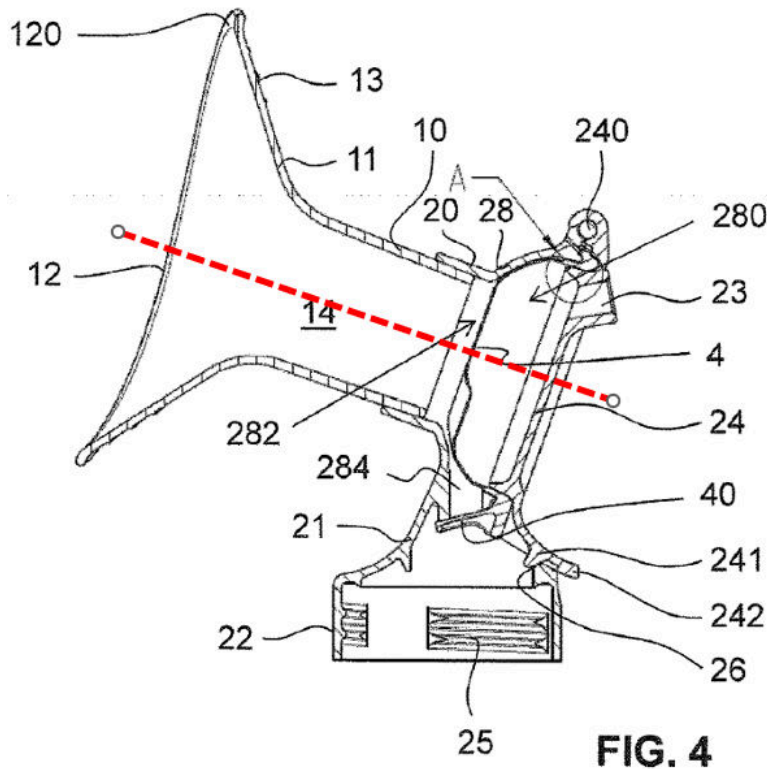
EX1008, FIG. 1.



EX1008, FIG. 7, *see also*, FIGs. 2-4, 13.

Claims [27]-[30], [32]

To the extent that it is believed that the Park-Silver combination does not fully disclose or render obvious Claim [27] or Element [28d], a POSITA would have found it beneficial and obvious to apply the teachings of Rigert to the Park-Silver combination such that at least a part of the diaphragm is arranged concentric with the nipple tunnel, for the reasons discussed in Section III.I.1, *supra*. EX1003, ¶287. As FIG. 4 of Rigert shows, in the predictable Park-Silver-Rigert combination the diaphragm (e.g., Park's membrane 500 positioned in the manner of Rigert's flexible media separating diaphragm 4) is concentric with the nipple tunnel (e.g., Rigert's milk channel 14). EX1003, ¶287.



EX1008, FIG. 4, [0055]-[0056].

All other elements of claims 27-30 and 32 are provided by the Park-Silver-Rigert combination for the reasons discussed in Ground 2A, *supra*. EX1003, ¶288.

J. [GROUND 2D] – Claim 31 is rendered obvious by Park, Silver, Rigert, and Weniger

A POSITA would have applied Weniger to the Park-Silver-Rigert combination in the same manner and for the same reasons discussed in Ground 2B, *supra*, and therefore the Park-Silver-Rigert-Weniger combination renders obvious Claim [31]. EX1003, ¶¶289, 265-271.

K. [GROUND 2E] – Claims 26 and 33 are rendered obvious by Park, Silver, and Kasting

1. The Park-Silver-Kasting combination

A POSITA would have predictably applied the teachings of Kasting to the Park-Silver combination to implement the resulting breast pump system such that diaphragm cap (e.g., Park's cover 400 or Silver's rear housing 16) includes recessed finger grip features, such as the recessed pockets 100/101 disclosed by Kasting, for the same reasons and in the same manner described in Ground 1F, *supra*. EX1003, ¶¶290-295. For example, such a modification would have allowed users to more easily grip and manipulate the diaphragm cap (cover 400/rear housing 16). EX1012, 11:33-43. For example, such gripping features would have allowed user's to more easily grip the diaphragm cap when opening the device to clean the inside components. EX1003, ¶¶291-292 (citing EX1008, [0027], [0056]); EX1012, 11:33-43. As shown in FIG. 1 of Silver, the rear cover 16 of the device clips onto the device and a POSITA would have recognized that gripping features on the rear cover 16 would have allowed for easily manipulation of the cover when attaching or detaching it. EX1003, ¶292.

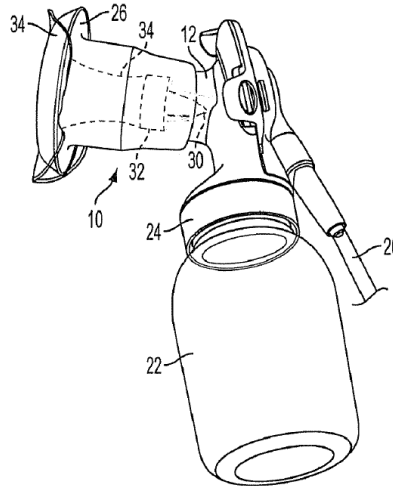


FIG. 1

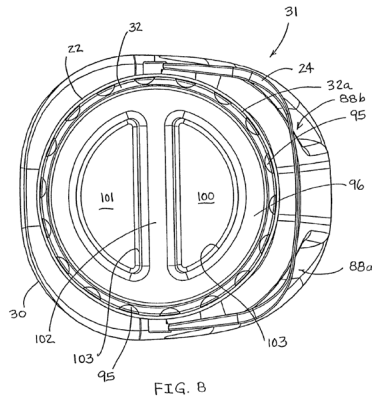
EX1011, FIG. 1.

Additionally, such recessed gripping features would have allowed the user to more easily manipulate the device as a whole when applying or removing the device to/from the breast. EX1003, ¶293. Providing a better gripping surface through the use of recessed finger grip features would have helped prevent dropping and potential breaking of the device. EX1003, ¶294.

Finally, such a modification would have been simply the application of a known technique to a known system to achieve predictable results and a POSITA would have had a reasonable expectation of success in making such a modification. *KSR*, 550 U.S. at 417; EX1003, ¶295.

2. Application of Park-Silver-Kasting to the '454 Claims *Claims [26] and [33]*

The resulting Park-Silver-Kasting combination includes “two recessed pockets 100 and 101” to enable the diaphragm cap (e.g., Park’s cover 400 or Silver’s rear housing 16) “to be grasped in an ergonomically-convenient manner.” EX1012, 11:33-43.



EX1012, FIG. 8, 11:24-43, 7:63-8:3, 8:18-22; EX1003, ¶296; *see e.g.* EX1012,.

L. [GROUND 2F] – Claim 33 is rendered obvious by Park, Silver, Rigert, and Kasting

A POSITA would have applied Kasting to the Park-Silver-Rigert combination in the same manner and for the same reasons discussed in Ground 2E, *supra*, and therefore the Park-Silver-Rigert-Kasting combination renders obvious Claim [33]. EX1003, ¶¶297, 291-295.

IV. DISCRETION DENIAL IS UNWARRANTED HERE

A. 35 U.S.C. §325(d) – *Advanced Bionics*

Patent Publications having the same inventors and containing similar Figures as Furrer and Pollen were submitted in IDS’s but never applied in a rejection during prosecution of the ’454 Patent. EX1002, 107, 156. Similarly, Alvarez and Weniger

were submitted in IDS's but were never applied in a rejection during prosecution of the '454 Patent. EX1002, 104, 107.

Rigert was applied to certain claims during prosecution but is relied on with respect to only limited dependent claim features in the present petition (*See* Grounds 1E, 2C, 2D, 2F, *supra*). EX1002, 171-181.

As such, Grounds 1A-1F do not involve the same or substantially the same art or arguments previously presented. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-9 (PTAB February 13, 2020) (precedential).

Regarding Grounds 2A-2F, a U.S. Patent Publication claiming priority to the same foreign application as Park was applied by the Examiner during prosecution. EX1002, 168-183. However, the present Petition presents Park in combination with Silver such that Silver demonstrates that the features believed to be missing from Park were known in similar prior art systems. Silver was not before the Examiner during prosecution of the '454 Patent.

Specifically, issued claim 17 was allowed after the Examiner entered an examiner's amendment to add the recitation of "the diaphragm cap forms a central region on a front surface of the outer shell." EX1002, 283. The Examiner went on to expressly state that "Park fails to teach among all the limitations or render obvious the diaphragm cap forms a central region on a front surface of the outer shell." *Id.*,

285. The Examiner also indicated in the reasons for allowance that issued claim 28 was allowed because it was believed that Park-2018/0104396 and the other prior art of record failed to disclose “at least a part of the diaphragm is arranged concentric with the nipple tunnel.” *Id.*, 284. However, as demonstrated in Ground 2A, *supra*, the Silver reference, which was not before the Examiner during prosecution, discloses such features and, when predictably applied to Park, provides all elements of independent claims 17 and 28.

Therefore, under part 2 of the *Advanced Bionics* framework, original examination involved material errors in that the Examiner failed to identify Silver and predictably apply its teachings to Park to achieve the known benefits described in Section III.G.3, *supra*. As such, the record here demonstrates the examiner overlooked or otherwise erred in the reasons for allowance.

B. 35 U.S.C. §314(a) - *Fintiv*

The *Fintiv* factors weigh against discretionary denial. The related litigation in the Western District of Washington (2:23-cv-00631) remains in its infancy. Petitioner filed the complaint in the Lawsuit on 4/28/2023, seeking declaratory judgment of noninfringement and invalidity of one of PO’s patents. EX1016, Dkt.1. Patent Owner subsequently counterclaimed to allege infringement of two patents. *Id.*, Dkt.69. On May 1, 2024—more than a year after the lawsuit commenced—Patent Owner then added counterclaims to assert two more patents, including the

'454 patent. *Id.*, Dkt.114; EX1017, 3. The District Court subsequently struck the trial schedule in its entirety and adopted a reset (partial) schedule that set some initial dates through claim construction briefing in February 2025 while leaving subsequent dates, including a trial date, undefined. EX1017, 3-5; EX1018, 11-12. Petitioner did not receive infringement contentions until June 2024, and has been diligent in preparing this Petition.

Factor 1—No motion to stay has been filed. This factor is neutral or favors institution.

Factor 2—Factor 2 heavily favors institution. In May 2024, PO added multiple patents to the litigation, including the '454 patent, doubling the number of patents more than a year after the lawsuit commenced. The District Court then essentially reset the schedule in June 2024—striking the existing schedule in its entirety. EX1017, 3-5; EX1018, 11-12. All dates subsequent to the claim construction briefing, including a trial date, remain undefined and will not be scheduled until after the *Markman* hearing (which itself has an undefined date sometime in 2025). *Id.* The Board's final decision will thus surely precede the not-yet-scheduled trial in district court.

Factor 3—Neither party has invested in *Markman* briefing, and discovery remains in its infancy. As such, the investment “in the []lawsuit, particularly as related to any validity issues, has not been substantial.” *Illumina, Inc. v. Ravgen*,

Inc., IPR2021-01271, Paper 12, 27 (January 26, 2022). The average time to trial from initial complaint (30.8 months) has limited bearing where, as here, the trial date and case schedule was essentially reset more than a year after the initial complaint in order to accommodate newly-added patents. If anything, this average time should be applied from the starting point of the counterclaims introduced in 2024. EX1017, 3.

Factors 4 and 5—Factors 4 and 5 are neutral or favor institution. Resolution by the Board is expected in advance of a decision in the District Court, which mitigates against duplication of effort and serves efficiency and integrity goals.

Factor 6—The merits of this Petition are compelling as demonstrated by the above Grounds. Factor 6 weighs heavily in favor of institution.

V. CONCLUSION AND FEES

The Challenged Claims are unpatentable. Petitioner authorizes charge of fees to Deposit Account 06-1050.

VI. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Petitioner identifies itself and the entities listed below as real parties in interest:

Shenzhen Root Technology Co., Ltd., which was also known as Shenzhen Lutejiacheng Network Technology Co., Ltd., which changed its name to Shenzhen Lute Innovation Technology Co., Ltd., in September 2023

Hong Kong Lute Technology Co., Ltd.

Shenzhen Conglin E-Commerce Co., Ltd.

Shenzhen Jinruihang Technology Co, Ltd.

Shenzhen Xitao Network Technology Co., Ltd.

ROOT Technology Ltd.

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

The '454 patent is involved in the litigation in the Western District of Washington, as identified above (case no. 2:23-cv-00631).

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

Petitioner provides the following designation of counsel.

Lead Counsel	Backup counsel
Michael Hawkins (Reg. No. 57,867) hawkins@fr.com Fish & Richardson P.C. 60 South Sixth Street, Suite 3200 Minneapolis, MN 55402 Tel: 612-337-2569 Fax: 877-769-7945	Patrick J. Bisenius, (Reg. No. 63,893) Craig A. Deutsch (Reg. No. 69,264) Terry Stalford (Reg. No. 39,522) Yong Peng (Reg. No. 76,048) Ryan Chowdhury (Reg. No. 74,466) 60 South Sixth Street, Suite 3200 Minneapolis, MN 55402 Tel: 202-783-5070 Fax: 877-769-7945 PTABInbound@fr.com

D. Service Information

Please address all correspondence and service to the address listed above.

Petitioner consents to electronic service by email at IPR58498-0005IP1@fr.com

(referencing No. 58498-0005IP1 and cc'ing PTABInbound@fr.com,

hawkins@fr.com, and bisenius@fr.com).

Respectfully submitted,

Dated March 6, 2025

/Patrick J. Bisenius/

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Attorneys for Petitioner

CERTIFICATION UNDER 37 CFR § 42.24

Pursuant to 37 C.F.R. §42.24(a), Petitioners hereby certify that portions of the above-captioned Petition for Inter Partes Review of U.S. Patent 11,806,454, in accordance with and reliance on the word count provided by the word-processing system used to prepare this Petition, that the number of words in this paper is 13,912. Pursuant to 37 C.F.R. §42.24(a), this word count is in compliance and excludes the table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, appendix of exhibits, and any claim listing. This word count was prepared using Microsoft Word.

Dated March 6, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on March 6, 2025, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided by Federal Express, to the Patent Owner, by serving the correspondence address of record as follows:

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