

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

DECLARATION OF RYAN BAUER

I currently hold the opinions set expressed in this declaration. But my analysis may continue, and I may acquire additional information and/or attain supplemental insights that may result in added observations.

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Date: January 24, 2025

By: /Ryan Bauer/
Ryan Bauer

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I, Ryan Bauer, hereby declare:

I. BACKGROUND AND QUALIFICATIONS

1. I have been retained by Petitioner Shenzhen Root Technology Co., Ltd. (“Shenzhen” or “Petitioner”) to provide my opinions regarding claims 17-19, 21-33 (“Challenged Claims”) of U.S. Patent 11,806,454 (“the ’454 Patent,” EX1001).

2. A copy of my current curriculum vitae is submitted herewith as Appendix A to this declaration, which provides details about my academic and professional background and qualifications.

3. I am being compensated for my services and reimbursed for reasonable expenses that I may incur while working on this matter. I have no financial interest in the outcome of this matter or any other matter that may exist between Petitioners and Chiaro Technology (“Chiaro” or “Patent Owner”). This compensation does not depend in any way on the conclusions I reach.

A. Educational Background

4. I earned a Bachelor’s degree in Mechanical Engineering from Purdue University in 2000 and a Master’s degree in Product Development from Northwestern University in 2004.

B. Professional Experience

5. I have extensive experience and training in the specific technical field of the ’454 patent. Based on my education and experience, I was at the time the

earliest priority application leading to the '454 patent was filed, and continue to be, a person of ordinary skill in the relevant art.

6. For 12 years, from 2006 through 2018, I designed breast pumps and breast pump-related equipment at Medela, a leading company in the human breast milk equipment industry. I started my career at Medela as a product development engineer designing human breast milk products. My responsibilities expanded over the next seven years until 2013, when I became the Director of Product Development. As Director, I led a team of two dozen engineers and other professionals to design and obtain FDA and global market approvals for equipment for expressing and handling human breast milk.

7. I am an inventor or co-inventor of many patents and patent applications in the human breast milk field. Some of my issued patents are directed to systems and methods for managing breast milk supply, a one-time use breast pump assembly, a container with a sealed cap and venting system, and a breast milk handling apparatus for use with warming breast milk containers.

II. RELEVANT LEGAL STANDARDS

8. I am not an attorney and offer no legal opinions, but in the course of my work, I have had experience studying and analyzing patents and patent claims from the perspective of a person skilled in the art.

9. In expressing my opinions and considering the subject matter of the claims of the '454 Patent, I am relying upon certain basic legal principles that have been explained to me.

10. I understand that “the time the claimed invention was made” is often referred to as the priority or critical date.

11. I understand that, before considering the prior art, the claims are first construed to determine their scope. I understand that the claims are read from the perspective of POSITA at the time of the alleged invention. I understand that the words of a claim are generally given their ordinary and customary meaning as understood by a POSITA in light of the entire patent specification in which they appear, as well as the prosecution history of the patent.

12. I understand, however, that the words of a claim may be given a meaning other than their plain and ordinary meaning if: (1) a patentee expressly and unambiguously defined a term in a way that is different from its plain meaning; or (2) a patentee “disclaims” the full scope of a claim term’s plain meaning, for instance, by making clear and unambiguous statements during prosecution that a claim term does or does not encompass certain features.

13. I understand that, after construing the claims, the teachings of the prior art are considered. I also understand that a POSITA is assumed to be aware of all

relevant prior art in the field of endeavor covered by the patent-at-issue and all analogous prior art.

14. I understand that although the ultimate question of the obviousness of a claimed invention is a legal determination, obviousness is based on several factual inquiries, including: the scope and content of the prior art, the differences between the claimed subject matter and the prior art, the level of ordinary skill in the art at the time of the invention, and any “objective indicia” or “secondary considerations” of non-obviousness, which must all be considered.

15. I understand that, in determining the scope and content of the prior art, a reference is considered relevant prior art if it falls within the field of the inventor’s endeavor, or if it is reasonably pertinent to the particular problem that the inventor was trying to solve. A reference is reasonably pertinent if it logically would have commended itself to an inventor’s attention in considering his problem.

16. I understand that, to assess the differences between prior art and the claimed subject matter, the claimed invention must be considered as a whole.

17. I understand that there are several rationales for combining prior-art references. For instance, I understand that it is considered obvious to: combine prior-art elements according to known methods to yield predictable results; substitute one known element for another to obtain predictable results; use the prior-art elements in a predictable way according to their established functions; apply a known

technique to a known device (method or product) ready for improvement to yield predictable results; choose from a finite number of identified, predictable solutions, with a reasonable expectation of success; or if there is some teaching, suggestion, or motivation in the prior art that would have led a POSITA to modify a prior-art reference or combine prior-art teachings to arrive at the claimed invention. I understand, however, that a POSITA does not need to have the same motivations or reasons to combine the prior art as the inventors, and can arrive at the claimed invention for completely different reasons than the inventors.

18. I also understand that the prior art cannot be modified or combined using “hindsight.” I understand that hindsight refers to situations in which the patent-at-issue is used as a framework to pick and choose pieces from the prior art to arrive at the claims, or adopting rationales identified by the patent-at-issue that those in the art would not have recognized. Instead, I understand that the obviousness inquiry is evaluated from the perspective of a POSITA as of the critical date of the patent-at-issue, with all the prior art before them, to determine whether the POSITA would have independently arrived at the claimed invention without the benefit of the patent-at-issue for guidance.

19. I understand that “objective indicia” or “secondary considerations” of non-obviousness include whether: (1) there was a long-felt need for the claimed invention; (2) the claimed invention has achieved commercial success; (3) there was

copying of the claimed invention by others; (4) there were failed attempts by others to make the alleged invention; (5) there was praise of the invention in the field; and (6) there was skepticism the claimed invention could be achieved, among a few others.

20. As of the time that I prepared this declaration, the Patent Owner had not identified any secondary considerations of non-obviousness. Therefore, I might address any secondary considerations if the Patent Owner later identifies any.

21. Finally, I understand that, in an *inter partes* review proceeding, the Petitioner bears the burden of proving obviousness of a challenged patent claim by “a preponderance of the evidence.” I understand that the preponderance of the evidence standard requires that a reasonable factfinder could find a material fact is more probable than the nonexistence of that fact.

22. I have applied the “preponderance of the evidence” standard throughout my declaration.

III. MATERIALS CONSIDERED

23. The opinions contained in this declaration are based on the documents I reviewed, my professional judgment, as well as my education, experience, and knowledge regarding electro-mechanical engineering.

24. In forming my opinions expressed in this declaration, I reviewed all the materials cited within this declaration, including:

- U.S. Patent No. 11,806,454 to De Becdelievre et al. (“the ’454 Patent”; EX1001)
- Excerpts from the Prosecution History of the ’454 Patent (“the ’454 Prosecution History”; EX1002)
- U.S. Patent No. 10,149,929 to Furrer et al. (“Furrer”; EX1004)
- U.S. Patent Application Pub. No. 2015/0283311 to Alvarez et al. (“Alvarez”; EX1005)
- U.S. Patent Application Pub. No. 2015/0217035 to Pollen et al. (“Pollen”; EX1006)
- U.S. Patent Application Pub. No. 2004/0087898 to Weniger (“Weniger”; EX1007)
- U.S. Patent Application Pub. No. 2018/0021491 to Rigert et al. (“Rigert”; EX1008)
- Certified English translation of PCT Application Pub. No. WO2016/186452 to Park (“Park”; EX1010)
- U.S. Patent Application Pub. No. 2011/0071466 to Silver et al. (“Silver”; EX1011)
- U.S. Patent No. 7,677,423 to Kasting et al. (“Kasting”; EX1012)
- U.S. Patent No. 8,187,227 to Luzbetak et al. (“Luzbetak”; EX1013)
- U.S. Patent No. 10,046,097 to Thompson et al. (“Thompson”; EX1014)
- U.S. Patent Application Pub. No. 2018/0333523 to Chang et al. (“Chang”; EX1015)
- U.S. Patent No. 6,379,327 to Lundy (“Lundy”; EX1019)
- PCT Application Pub. No. WO2002/102437 to Myers et al. (EX1020)

- PTC Application Pub. No. WO2008/137678 to Myers et al. (EX1021)
- U.S. Patent Application Pub. No. 2016/0082166 to Guthrie et al. (EX1022)

25. All of the opinions contained in this declaration are based on the documents I reviewed and my knowledge and professional judgment. My opinions have also been guided by my appreciation of how a person of ordinary skill in the art would have understood the claims and the specification of the '454 patent at the time of the alleged invention, which I have been asked to initially assume is March 26, 2020.

26. Based on my experience and expertise, it is my opinion that certain references disclose and/or suggest, alone or in combination, all the features recited in the Challenged Claims of the '454 patent, as I explain in detail below.

27. My opinions are based on my years of education, research, and experience, as well as my investigation and study of relevant materials. In forming my opinions, I have considered the materials I identify in this declaration and those listed in the Exhibit List above.

28. I may rely upon these materials and/or additional materials to respond to arguments raised by the Patent Owner. I may also consider additional documents and information in forming any necessary opinions — including documents that may not yet have been provided to me.

29. My analysis of the materials produced in this matter is ongoing and I will continue to review any new material as it is provided. This declaration represents only those opinions I have formed to date.

IV. LEVEL OF ORDINARY SKILL IN THE ART

30. I understand that patents and prior art references are analyzed from the point of view of a person of ordinary skill in the art (“POSITA”) at the time of the invention of, in this case, the ’454 Patent. I understand that “the time the claimed invention was made” is often referred to as the priority or critical date.

31. I have been asked to assume that the priority date for the ’454 patent is March 26, 2020. As such, in this declaration, I adopt this date to be the relevant date to ascertain the perspective of one of ordinary skill in the art.

32. I have been informed that the level of ordinary skill of a POSITA at the time of the invention is based on consideration of factors such as the educational level of the inventor and persons working in the field, the types of problems encountered in the field, prior art solutions to those problems, rapidity with which innovations are made, and the sophistication of technology.

33. Based on my background and experience, a POSITA with respect to the technology of the ’454 patent as of March 26, 2020 would have had at least a bachelor’s degree in mechanical engineering or a similar field and at least two years’

experience designing human breast pump equipment. A POSITA could potentially have higher extent of education and a lower level of work experience or vice versa.

V. TECHNOLOGY BACKGROUND

34. Breast pumps are used to facilitate extraction of milk from the human breast postpartum. They often augment or replace nursing a baby for many reasons. They can be used to address milk supply (either under or over-supply), separation of the mother-baby dyad, milk elimination, building stored milk reserves, donation (i.e., milk banking), breast mastitis, etc.

35. Clinically effective breast pumps typically work on a common principle wherein a localized volume is defined which includes the nipple, vacuum (i.e., negative pressure or suction) is applied to the nipple throughout this volume, then milk is ejected and held within the evacuated volume, and finally the vacuum is released. When the vacuum is released the ejected milk is usually transferred from the localized volume to a separate collection container. This cycle is repeated at a frequency (or frequencies) designed to emulate the sucking of a nursing baby. The milk accumulates in the collection container until the breast is emptied or stops responding to the pump.

36. While many of the reasons to use a breast pump span demographics and are universally needed, the separation of the mother-baby dyad is highly varied around the world. Policies supporting mother-baby health in each market

significantly influence this need. Indeed, the USA is by far the leading market for breast pumps and accessories. While the World Health Organization (WHO) and UNICEF recommend exclusive breastfeeding for the first 6 months of life, the USA does not mandate paid maternity leave for working women. Additionally, protected leave through the FMLA (Family Medical Leave Act of 1993) only covers 12 weeks of job protection for maternity and childbirth, and does not guarantee pay. This disparity between policy, employment and maternity needs in the USA has long fueled a breast pump market for mothers seeking to balance providing optimum nutrition through breastfeeding to their children and keeping their employment. As a result, the USA breast pump market was the largest in the world for some time, far outstripping markets with greater populations. Even then, the size of this market was capped to those women who could choose or afford to invest in a breast pump to support feeding breast milk to their children. This all changed in 2010 with the passage of the Affordable Care Act (“ACA”).

37. The ACA stipulated that health insurance plans must provide breastfeeding support, counseling, and equipment for the duration of breastfeeding. These services may be provided before and after birth. New private insurance plans needed to provide breast pumps with no cost sharing beginning August 2012, and in January 2014 ACA expanded this requirement to Marketplace plans and expanded

Medicaid coverage. In all, this new regulation significantly expanded the commercial market for breast pumps.

38. This expanded market and the influx of revenue to the industry had several significant impacts. Existing breast pump manufacturers needed to scramble to meet significantly increased demand for all types of pumps (e.g., manual, electric, rental) and accessories. Insurance market vendors engaged as a third party to act as sources of pumps to consumers and help them navigate insurance submission. Consumers also wanted choice in their breast pump selection, and looked for both fully covered and upgrade options in their pump selection.

39. The size of the expanded market also attracted new competition, both domestic and foreign. Powered breast pumps are Class II medical devices in the USA, and bringing new products to market requires a pre-market submission process with the FDA before they are allowed to be legally marketed and sold. This process takes time, so the initial response required companies to scale previously cleared products to meet demand. In parallel, significant investment was made by old and new manufacturers to cost optimize, scale, and provide the right portfolio to this market.

40. While the breast pump is a medical device, it is also a very personal device, and many existing designs on the market did not adequately meet user expectations as a mainstream consumer product. With the ACA making the breast

pump accessible to everyone, consumers started to expect and demand more. One significant event highlighting this was the 2014 MIT Hackathon “Make The Breast Pump Not Suck”. This event attracted a variety of participants, including academics, students, researchers, designers, and health providers to rethink what was possible. The topic went viral in the media, and according to the hackathon website “The event received over 90 articles in the global press and viral attention on social media.” This attention continued to pervade the media not just in 2014 but persisted for many years. Focus areas of the hackathon top prize winner identified areas to improve that included achieving a fashionable, discrete, hands-free wearable pump. Other winners focused on areas such as easy to clean, hands-free, ‘smart’ pump / data rich, connected community, low-profile, worn discreetly, etc.

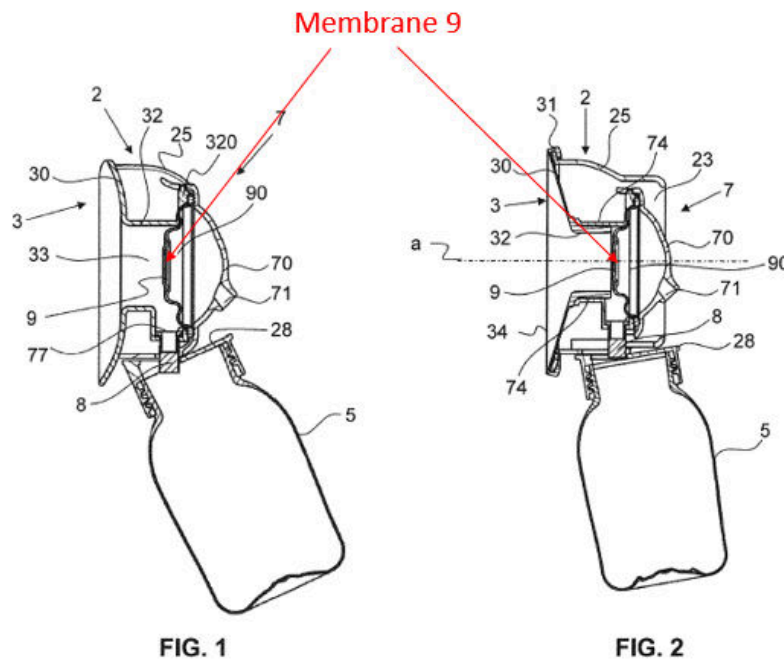
41. Manufacturers started to respond to these demands, and new designs started to roll out. One notable example was shown at the 2017 Consumer Electronics Show (CES) in Las Vegas, NV. Medical devices and specifically breast pumps were not a common focus at CES, but the Willow Breast Pump (a new competitor) was introduced there and garnered significant media attention as an in-bra wearable hands-free breast pump. For example, it was recognized by Engadget as a winner of their ‘Best Digital Health and Fitness Product’ & ‘Best Wearable’ awards. Wearables as a category were of high interest to consumers as a technology at that time, and the Willow pump capitalized on this interest.

42. The preceding history is exemplary in showing the motivation and opportunity breast pump manufacturers had over this period. The ACA significantly boosted overall demand, consumers demanded better product offerings through media and feedback, and manufacturers were reacting to both increased opportunity and competition. Some examples of the consumer demands that motivated improvements in breast pumps were to prioritize unmet needs around discretion, hands-free, wearable, mobile, and the elimination of wires or tubes, and cleanability. Breast pumping is a time-consuming, repetitive task that consumers were looking for a better experience.

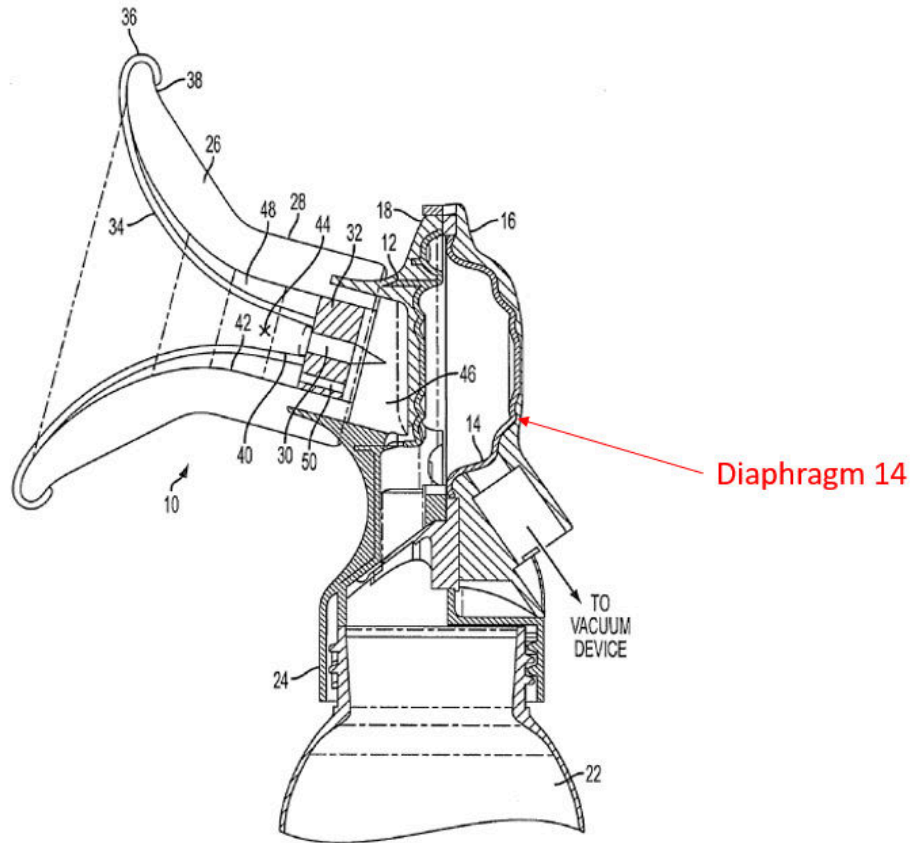
43. As discussed earlier, breast pumps must act upon a localized volume that includes the nipple of a lactating woman. Major components of the pump include the breast shield (often called a funnel) engaging the breast tissue, a pump or actuator to generate negative pressure (i.e., vacuum or suction), and a collection container. Often a one-way valve is used to minimize the size of the localized volume allowing extracted milk to escape between vacuum cycles.

44. Another typical embodiment includes a diaphragm defining one boundary of the localized volume on one side and is in fluid or mechanical communication with the pump on the other. Such a diaphragm is commonly referred to as a media or fluid separation membrane, since it keeps milk away from the pump mechanism for cleaning and sanitary purposes. Use of diaphragms for this purpose

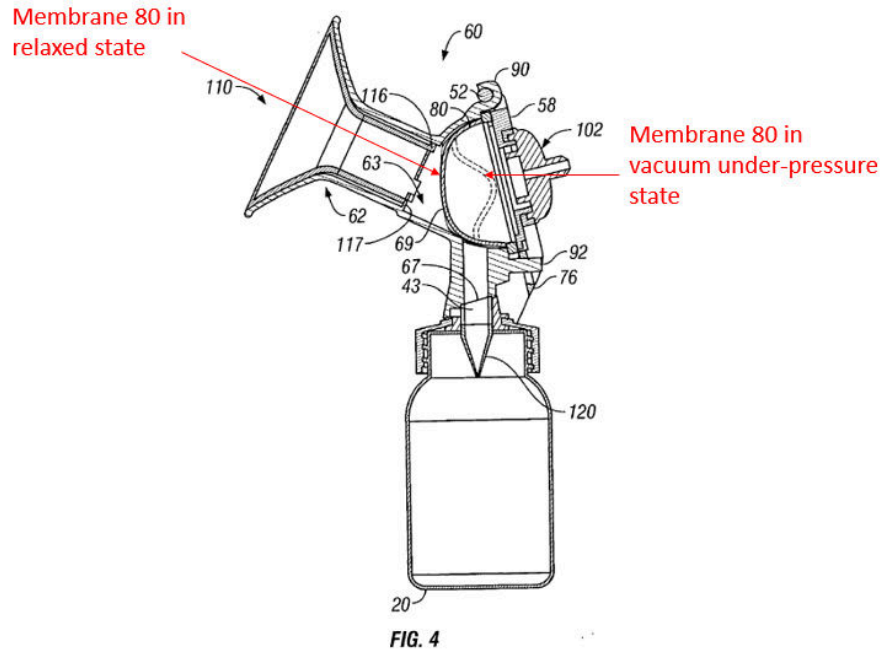
was well-known before the March 2020 priority date of the '454 patent. For example, Furrer, Weniger, Rigert, Park, Silver, and other references discussed below all disclose breast pump systems that utilize such a diaphragm. For example, Furrer discloses a “media separation membrane 9” that “moves to and fro between two positions” to convey underpressure to the nipple. EX1004, 5:59-6:17.



EX1004, FIGs. 1-2. 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.” EX1011, [0059].



EX1011, FIG. 5. In yet another example, Weniger's device includes 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." EX1007, [0033], [0038], [0040].



EX1007, FIG. 4 (annotated).

45. By the time of the '454 patent, it was well-known that breast pumps may be configured in a variety of ways. Of the main components of the pump (pump/actuator, breast shield, and collection container), only the breast shield is required to be at the breast since it forms part of the localized volume for milk extraction. Different pump configurations have combined these components or connected them in various ways, such as through tubing or fittings at various locations on or off the body, as discussed with respect to the below cited prior art references.

46. Many other variations also existed at the time, and would have been known to a POSITA, including hands-free breast pumps with breast shields and collection containers connected to or supported by a nursing bra, wearable breast

pumps with in-bra breast cups and milk container and separate pump, wearable breast pumps with in-bra breast cups and pump but milk container outside bra, and wearable integrated breast pumps with in-bra breast cups and milk container but pump protruded outside bra, among others. *See, e.g.*, EX1006, [0062]-[0068], FIGs. 2, 5; EX1010, [37]-[39], [44]-[46], FIGs. 5, 7; WO 2002/102437 (EX1020), Figs. 20A and 20B, [44]; WO 2008/137678 (EX1021), Fig. 1, pp. 12-13; U.S. 2016/0082166 (EX1022), Fig. 1, [0026].

47. POSITAs recognized that components of breast pumps were freely combined or separated in many different configurations depending on the goals of the designers and/or various commercial considerations. A POSITA would have known how to combine or separate components according to these goals. The selected pump technology and configurations is a matter of design choice to meet commercial and clinical requirements. In particular, breast pump technology at the time of the '454 patent involved relatively simple electromechanical technology that was well understood to a POSITA, and a POSITA would have recognized the various tradeoffs for a particular design, such as cleanability, power consumption, compensation for anatomical variation, lifestyle and expense.

48. For this reason, there were (and are) a large variety of breast pump designs on the market and in the prior art. There was (and is) no single design or configuration that is ideal for all purposes and consumers. Take for example

tradeoffs in a wearable pump design – which can take many forms. One example shown by Chang (U.S. 2018/0333523; EX1015) is a breast pump that is fully supported by the bra at the breast:

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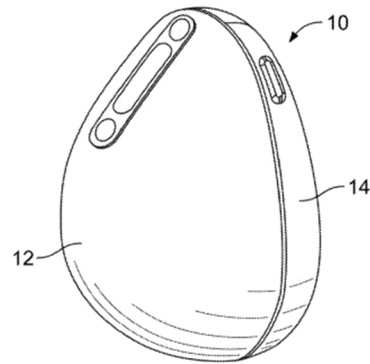


FIG. 1A

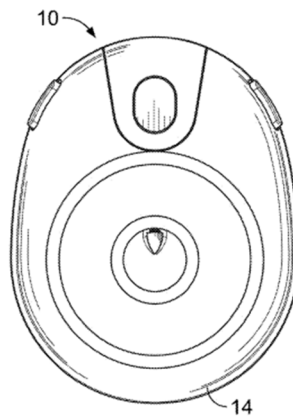


FIG. 1B

Chang, Figs. 1A, 1B. A tradeoff with this configuration is that the full pump weight with electronics, housings, controls, milk container (plus extracted milk), etc. would hang from the front of the user's chest. This may not be comfortable for some women.

49. Chang, for example, recognized the interchangeability of arranging breast pump components into different configurations:

In at least one embodiment, the flange or skin contact member, the conduit, the driving mechanism, the external shell and the milk collection container are all contained within a cup of a brassiere. In other embodiments, the container need not be contained within the housing, and the pump need not be in a cup of a brassiere, but can be unsupported or supported by itself or by other clothing or a nursing tank top or a band surrounding the user's body.

EX1015, [0019]. These alternate embodiments are prevalent in the prior art. As one example, a design for a wearable pump is shown in Lundy (U.S. Patent No. 6,379,327; EX1019), which separated the components of the pump so they could be supported by different parts of the body:

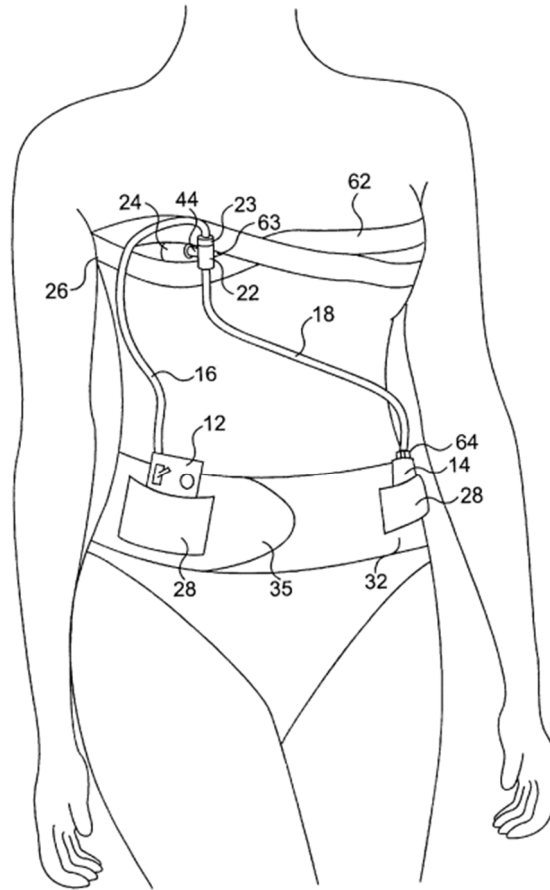


FIG. 3

EX1019, FIG. 3, 3:42-46.

50. In addition to these various alternative configurations of known breast pump components, a POSITA would also know that the diaphragm/fluid separation membrane could be positioned in various ways, with each position having known benefits and tradeoffs. For example, a POSITA would have known that the diaphragm could be positioned at the top of the device (EX1010, [37]-[39], [44]-[46], FIGs. 5, 7; EX1006, [0061]-[0063]) or at the front of the device positioned in front of the nipple (EX1004, 5:59-6:17, FIGs. 1-4, 7; EX1011, [0059], FIG. 5;

EX1007, [0033], [0038], [0040], FIG. 4; EX1008, [0055]-[0058], FIG. 4). For example, with respect to positioning the diaphragm in front of and near the nipple, a POSITA would have recognized that such a configuration reduces or eliminates “dead volume” in the area near the nipple, thereby reducing the amount of power required to produce suction which beneficially led to cost reduction and pump size reduction, and produced a more compact, less conspicuous design. EX1011, [0003], [0013]-[0014], [0018]; EX1004, 2:4-20, 8:28-30.

51. The term ‘dead volume’ is commonly used in the breast pump industry to reference the space within the closed volume surrounding the nipple. This volume is the target space to apply negative pressure in order to extract milk from the breast. A POSITA would have recognized that reducing the dead volume has significant benefit. This includes reduced energy/power requirements, reduced cost, reduced size, reduced pump noise, reduced weight, among other known benefits. Accordingly, as part of the boundary defining the closed volume, the diaphragm positioning can have a significant influence on overall dead volume.

52. It was also known in the art to beneficially include removable fluid separation diaphragms to allow for easy “replacement or cleaning.” EX1008, [0027], [0056].

53. A POSITA would have also been aware of both manual and electric breast pumps, with the electric pumps falling into two options, those powered by a

plug that is plugged into an outlet or those powered by one or more batteries. EX1004, 5:40-41, 5:59-62; EX1005, [0069], [0082], [0112], [0115]. For example, Chang describes “[s]ome powered breast pumps require an AC power source to plug into during use. Some systems are battery driven.” EX1015, [0003], [0020] (“the system is battery powered, the system comprising a battery, wherein the battery is received in the compartment of the external shell”). In another example, Guthrie describes a system in which “external vacuum pump 103 may operate by either battery power or by alternating current (“AC”) power supplied through a standard electrical outlet.” EX1022, [0026]-[0027] (“a battery may be included within the vacuum pump such that the vacuum pump has sufficient power to create enough vacuum pressure to cause a breast to express milk”). A POSITA would have further been aware that use of battery power would have allowed for increased mobility during use of a breast pump.

VI. THE '454 PATENT

A. Specification

54. The '454 patent discloses an in-bra wearable “breast pump system” that includes “at least one wearable milk collection hub” connected to an “external air pump” (or “control unit”) via an “air line” (or “air tube”), such as illustrated in Figure 1B:

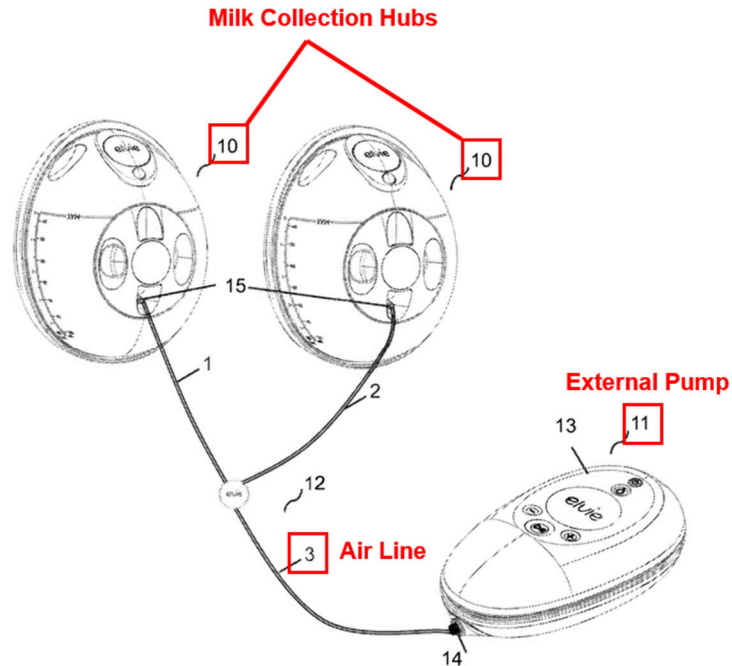


FIGURE 1B

EX1001, FIG. 1B (annotated); e.g., *id.*, Abstract, 5:3-12, 5:41-44 (“The milk collection hubs...are configured to be discreet and to be comfortably held inside a bra”), 15:11-14.

55. The milk collection hub includes a “breast shield” that is removably attached to an “outer shell,” which together form an “interior volume...in which milk is collected.” *Id.*, 5:41-53. The breast shield is “made up of” a “flange” that “contacts the user’s breasts” (*id.*, 5:46-50) and a “nipple tunnel” that is “shaped to receive a nipple” (*id.*, 6:23-24). These features are shown in Figure 3 below:

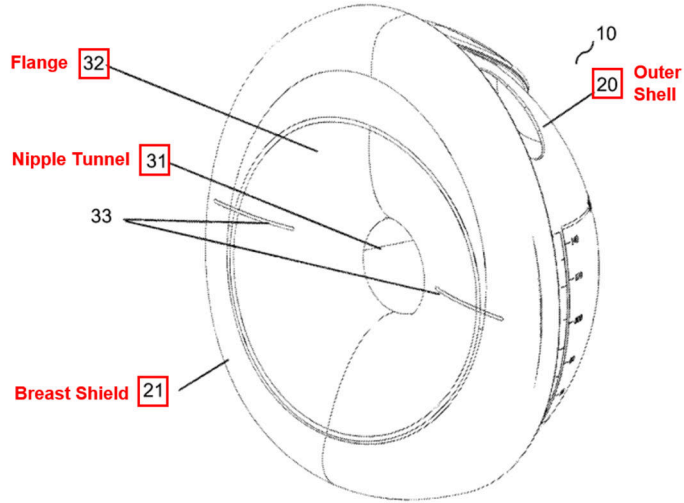


FIGURE 3

Id. Fig. 3 (annotated).

56. The collection hub further includes a “diaphragm” and “diaphragm cap,” shown below in Figure 6 of the ’454 patent:

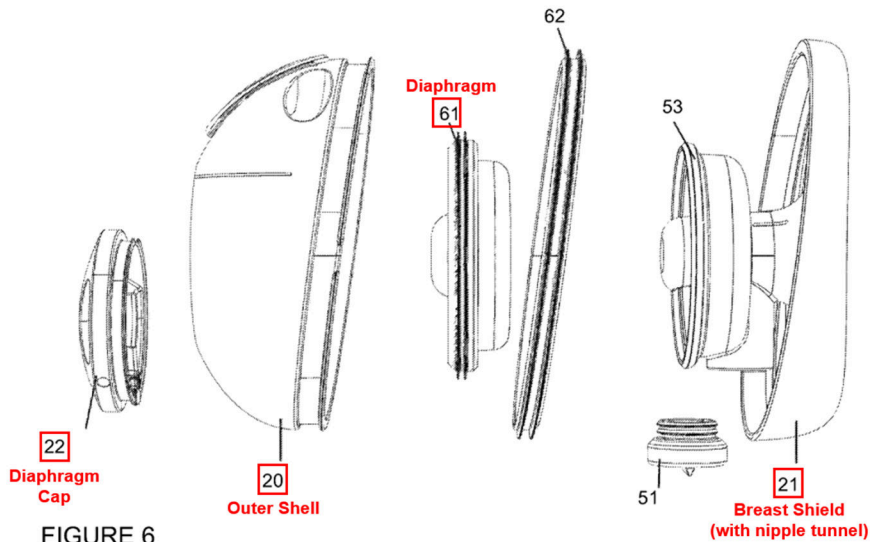


FIGURE 6

Id., Fig. 6 (annotated); *see also* Fig. 7. The diaphragm is “flexible” and designed to move when negative pressure is provided by the external pump. *Id.*, 7:44-61. “The

diaphragm 61 is configured to prevent milk from reaching the pump unit housed inside the control unit 11.” *Id.*, 8:48-51.

57. The external air pump is connected to the “diaphragm cap” to create a negative pressure between the cap and diaphragm, which causes the diaphragm to move, which “reduces the air pressure inside the nipple tunnel 31...and causes milk to be expressed from the nipple.” *Id.*, 7:44-61. The diaphragm cap “forms part of the front face of the outer shell,” as shown below in Figure 2:

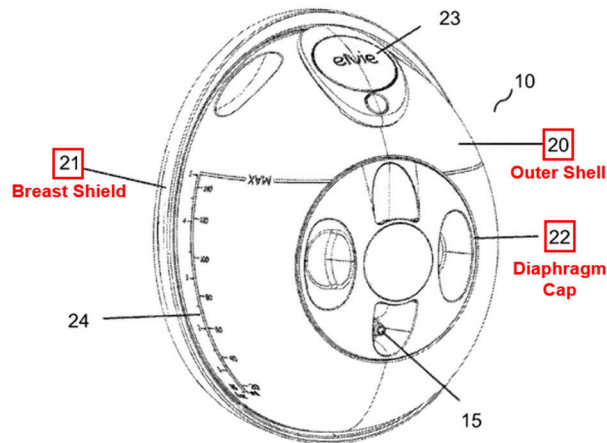


FIGURE 2

Id., Fig. 2 (annotated).

58. The '454 patent acknowledges that wearable breast pumps with diaphragms were known in the art (*id.* 1:30-63), but touts that the benefit of positioning the diaphragm and diaphragm cap at the front of the outer shell improves the mother's view of the milk collection hub:

This arrangement enables the air line to be connected to the front face of the outer shell of the milk collection

hub; prior art devices position the diaphragm and air line on the top of the milk collection hub, which obscures the users view down into device, which in turn makes correct nipple positioning difficult. By having a diaphragm cap that forms part of the front face of the outer shell, the user's view down into the device is not obscured by a diaphragm that sits over the nipple; correct nipple positioning is easier to achieve.

Id., 2:31-39; *see also* 8:4-7, 9:24-27, 10:17-21.

B. Claims

59. The Challenged Claims of the '454 patent have been reproduced below for convenience:

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.
[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.

VII. CLAIM CONSTRUCTION

60. As previously noted, I understand that the words of a claim are generally given their ordinary and customary meaning as understood by a POSITA in light of the patent specification and prosecution history, which I apply herein. Given the significant overlap between the components described and depicted by the various prior art references discussed herein and the preferred embodiment of the system described and claimed in the '454 patent, I do not believe that formal claim

construction is necessary for any of the challenged claim elements. I may be prompted to provide additional insight on how the claims are to be interpreted in response to arguments raised by the Patent Owner.

VIII. PRIOR ART

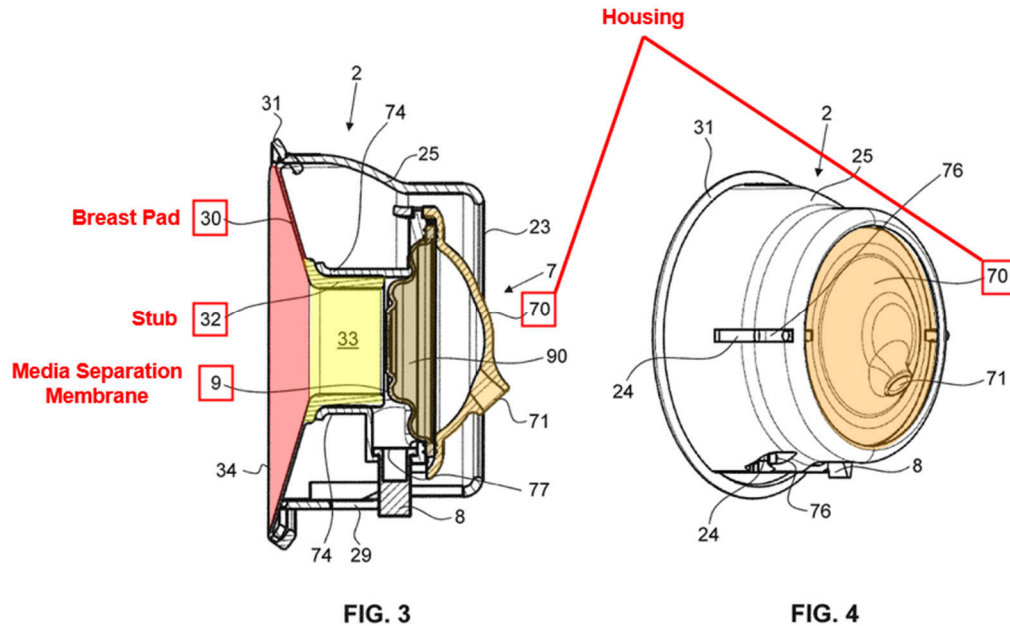
C. Furrer (EX1004)

61. Furrer is directed to “a breastshield unit for use with a breastpump for expressing human breastmilk and to a media separation device.” EX1004, 1:16-18. The breastshield includes a “breast pad 30” that is “in the shape of a funnel” and “merges in one piece into a stub 32” (*id.*, 5:11-18):

The breast pad 30 serves the purpose of being placed onto a mother's breast, with the nipple of the breast extending right into the stub 32. In this way, the stub 32 forms, with its hollow interior, a receiving area 33 for receiving the nipple.

Id., 5:31-34. The breastshield also includes a “media separation membrane 9,” held in place by “housing 70,” that transfers “underpressure” through the stub to express breast milk. *Id.*, 5:62-67 (“When 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 expressed.”); *see also, id.* 5:50-6:12. Furrer describes that the housing 70 “can be arranged movably in the main body 25” or “can also be connected rigidly and immovably

thereto.” EX1004, 4:57-63. The breast pad 30 (in red below), stub 32 (in yellow below), media separation membrane 32 (in brown below) and housing 70 (in light orange below) are shown with respect to Figures 3 and 4 from Furrer below:



Furrer, Fig. 3 (annotated), Fig. 4 (annotated).

62. As can be seen above, Furrer discloses positioning its media separation membrane 9 and housing 70 at the end of stub 32, “approximately perpendicularly with respect to the longitudinal direction...of the breastshield 2 and of the breastshield insert 3.” *Id.*, 7:40-45.

63. Furrer indicated that its design, including positioning the media separation membrane in front of near the nipple, can be “compact” and can reduce the “dead volume”:

Despite the integrated media separation, the breastshield unit according to the invention can be made ***extremely compact*** and ***minimizes the dead volume***.

Furrer, 8:28-30; *see also id.*, Abstract.¹

Since the media separation membrane is arranged in the area of the nipple, the breastshield unit can be made ***extremely compact and small*** despite the media separation device. Another important advantage is that ***the dead volume***, i.e. the volume to be evacuated in the breastshield during the expression of milk, ***is further minimized***.

Id., 2:4-9.

The media separation membrane 9 is arranged such that it is located in the receiving area 33 in at least one of these two [to-and-fro] positions. It usually protrudes into this receiving area 33 at least in the second position directed towards the breast and it thus ***minimizes the dead volume*** in said hollow space.

Id., 6:13-17.

D. Alvarez (EX1005)

64. Alvarez describes “devices for milk expression” including “an interface configured to engage a breast and an actuation assembly operably coupled to the interface” such that “[a]ctuation of the actuation assembly causes the interface to apply vacuum pressure against the breast to express milk from the breast.” EX1005, Abstract. Alvarez’s system includes a controller that “houses the power source and

¹ All emphasis added unless otherwise noted.

drive mechanism for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100, milk production quantification, and communication with other devices.” *Id.*, [0069]. Alvarez describes the conventional configuration in which the controller is powered by “a local battery.” *Id.*, [0082]. Figure 1 shows Alvarez’s system, including breast interfaces 105, a tube 110, and the controller 115:

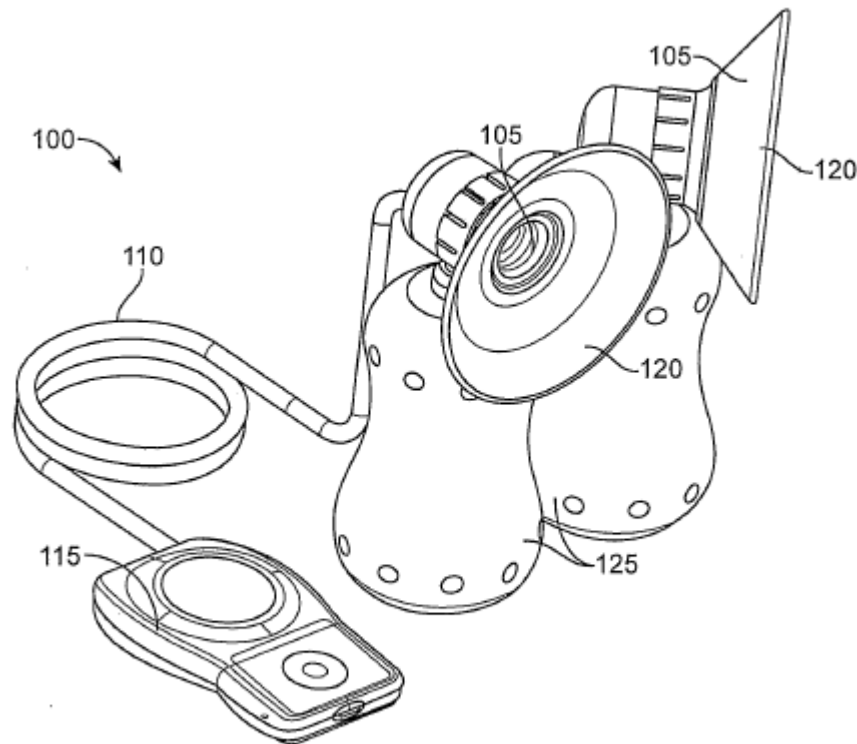


FIG. 1

EX1005, FIG. 1.

65. As can be seen above, the controller is in fluid communication with the breast interfaces (breast shields) via the tube 110 such that “[t]ube 110 transmits

suitable energy inputs, such as mechanical energy inputs from controller 115 over a long distance to breast interfaces 105. Breast interfaces 105 convert the energy inputs into vacuum pressure against the breasts in a highly efficient manner, resulting in the expression of milk into collection vessels 125.” EX1005, [0069]. Alvarez describes several configurations for the hydraulic pump that generates the negative pressure and that the driving mechanism for the pump is “housed within a controller.” *Id.*, [0070]-[0084], [0092], [0115].

66. Alvarez describes collecting measurement data from various sensors that are provided as feed back “to the pumping device in order to optimize fluid expression.” EX1005, [0114]. The controller is thus “configured to control one or more functionalities of the actuation assembly” and can “determine changes to actuation parameters of the actuation assembly in order to achieve and/or maintain optimal fluid expression” using the sensor feedback. *Id.*

E. Pollen (EX1006)

67. Pollen describes “an example breast pump system 10 that includes a milk collection device 12 with means for preventing milk 14 from backflowing to a vacuum pump 16.” EX1006, [0060]. The milk collection device of Pollen’s breast pump system includes 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]. The “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. Fluid exchanger 26 is coupled to breast receiver 22 to provide means for strategically directing milk 14 and air 44 within milk collection device 12.” EX1006, [0062].

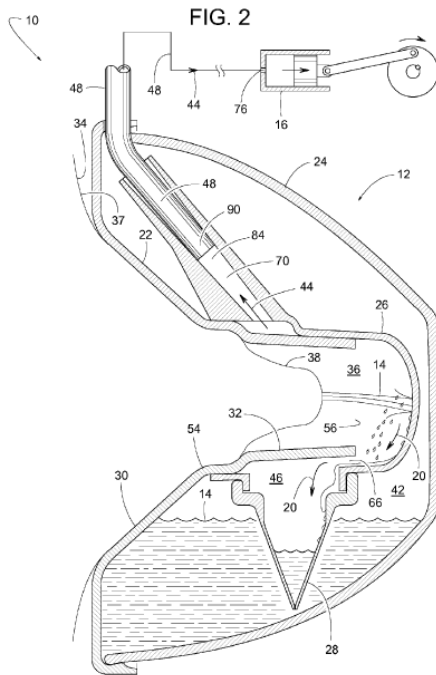
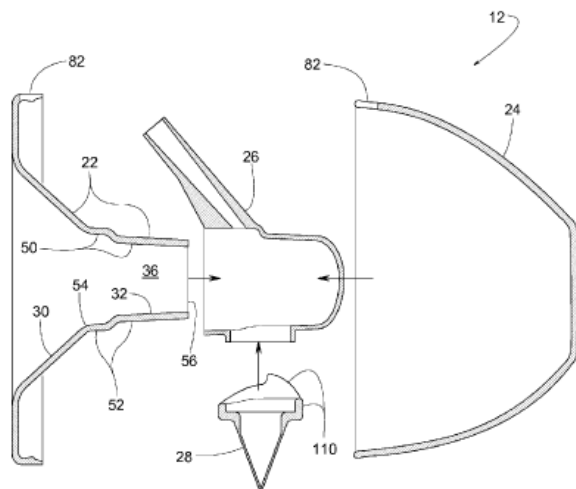


FIG. 5



EX1006, FIGs. 2, 5.

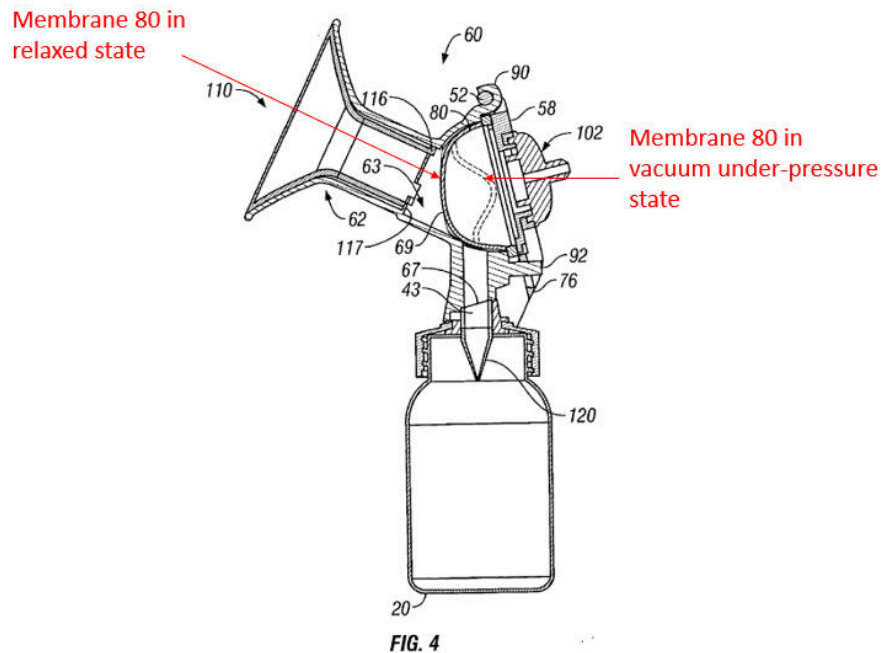
68. A “milk charging chamber” in the area of the user’s nipple “is cycled between positive and negative pressure to draw “discrete quantities of expressed milk from nipple receptacle 36.” *Id.*, [0062]. “During periods of positive pressure, charging chamber 46 discharges each discrete quantity or charge through valve 28 to storage chamber 42.” *Id.* This cycling between positive and negative pressure is

accomplished through use of a vacuum pump 16 coupled to the milk collection device 12 via a suction tube 48. *Id.*, [0063].

F. Weniger (EX1007)

69. Weniger “is directed to a breast pump assembly for expressing milk from the mammary glands of the human female.” EX1007, [0021]. Weniger’s system includes traditional breast pump components such as “an interface connected to a breast shield, a container and a vacuum source.” *Id.* Weniger’s device further includes a “membrane 80” that defines “a cavity 82 complimentary to the vacuum chamber 64 and in communication with the vacuum source includes a shoulder 84 formed about an open end thereof.” *Id.*, [0033]. The membrane 80 “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]. As Weniger describes, a “hose 109 connects the adapter 102 to the vacuum source in order to supply vacuum or negative pressure to the membrane 80.” *Id.*, [0038]. As such, the membrane 80 “communicate[s] a vacuum from the vacuum source to within the funnel portion 62 when in a collapsed state (as shown in phantom) and to isolate the vacuum source from the breast.” *Id.*, [0040], [0047] (“... a negative pressure is generated in the bore 207 which is then communicated through the port of the interface to the recess defined by the hemispherical membrane

and collapses the membrane as discussed above in order to generate a vacuum or negative pressure in the vacuum chamber in order to facilitate the expression of milk.”). Figure 4 shows both relaxed and under-pressure states of the membrane 80:



EX1007, FIG. 4 (annotated).

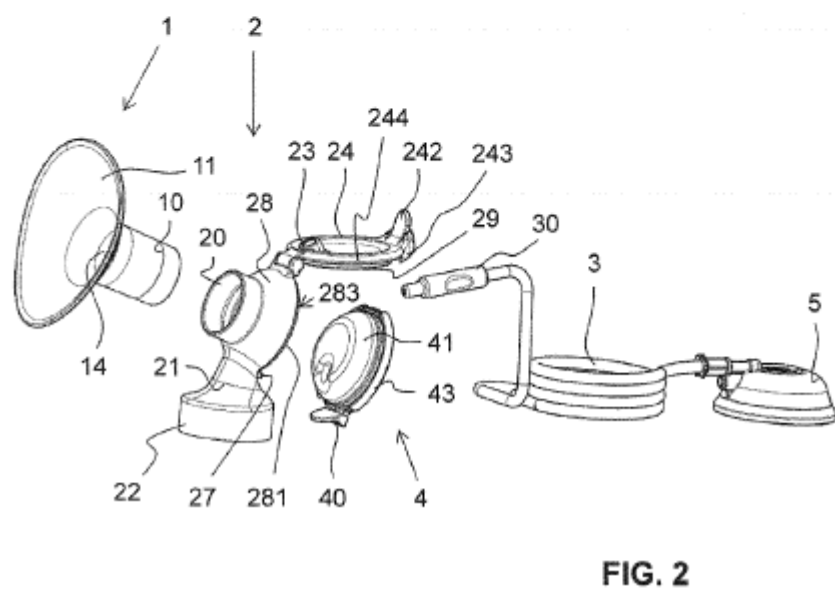
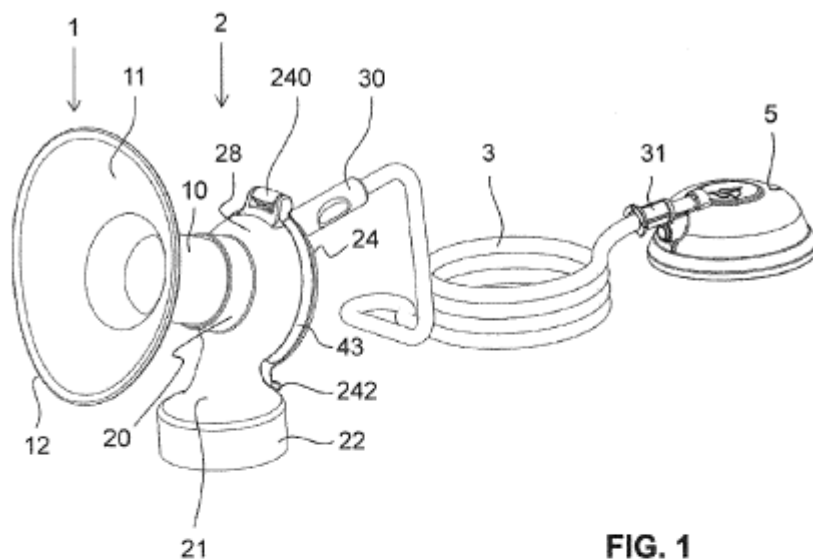
70. Weniger’s vacuum chamber 64 and funnel portion 62 “define a passageway 63 for expressed milk” such that “[t]he *passageway is discontinuous* (as shown in FIG. 4) when the hemispherical membrane 80 is disposed in an unaltered configuration.” EX1007, [0041]. Weniger goes on to describe that “[w]hen 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.

G. Rigert (EX1008)

71. Rigert describes “[a]n adapter for a breast shield of a breast pump for pumping human breast milk has a chamber having a first opening leading to the breast shield and a second opening remote from the breast shield” including “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. As Rigert describes “[t]he breast shield 1 comprises a tubular connection part 10 and a funnel 11, which is integrally moulded thereon in one piece, for receiving a human breast and a supporting edge 12 for supporting the human breast.” *Id.*, [0053]. Vacuum pressure is applied to the media separation diaphragm by a vacuum pump connected to the breast pump via a suction line 3 that couples to a suction connection 23. *Id.*, [0052]. More specifically, the breast pump includes a “suction connection 23 [that] is integrally moulded [*sic*] in the top region of the cover 24.” *Id.*, [0058].



EX1008, FIGs. 1-2.

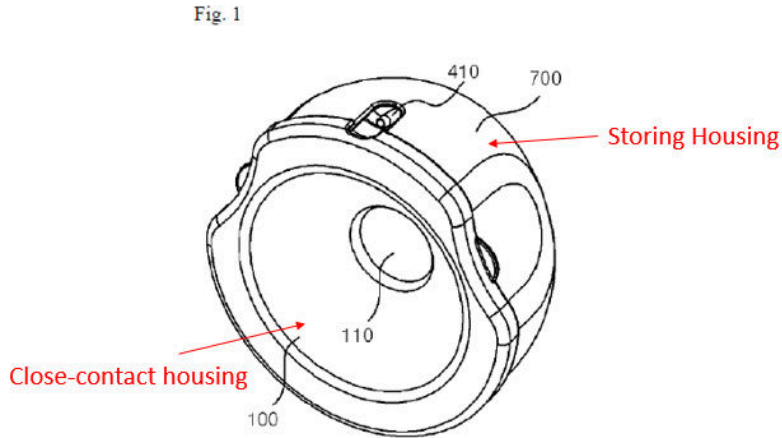
72. Rigert describes that the back cover can open such that “the media separating diaphragm can be changed, cleaned and re-installed again in the chamber in a simple manner.” *Id.*, [0018], [0056].

H. Park (EX1009 (original); EX1010 (certified English translation))

73. Park is a certified English translation of an International Patent Publication No. WO 2016/186452. *See* EX1009 (original Korean publication); EX1010 (certified translation). Park was published on November 11, 2016 based on a PCT application (PCT/KR2016/005271) filed on May 18, 2016.

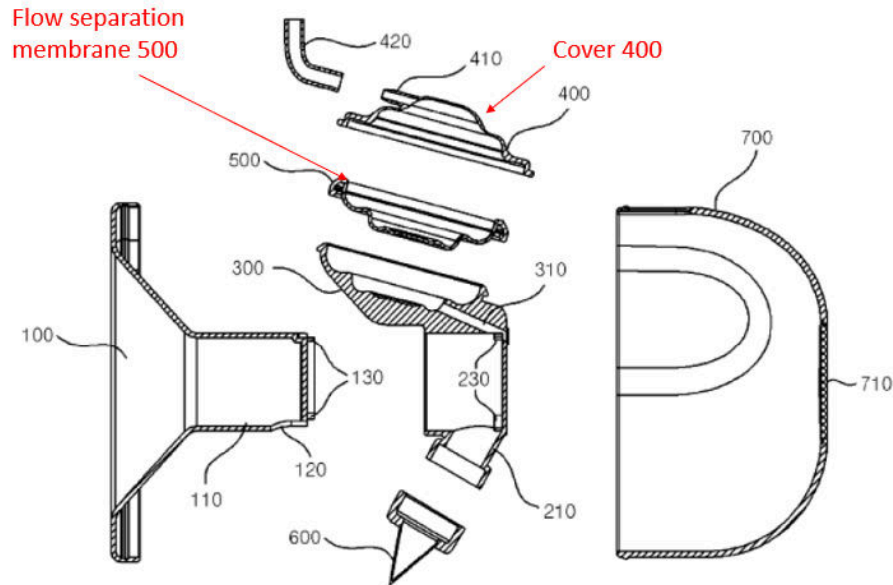
74. Park discloses a breast pump that is “worn on a breast of a lactating woman.” EX1010, [5]. Park’s breast pump “enables a lactating woman to freely use both hands during milking” and is “capable of preventing breast milk flowing backward,” and is thereby “easily cleaned and maintained.” EX1010, [8]; *see id.*, Abstract, [1]. Park describes that its wearable breast pump device addresses limitations of both manual and electric breast pump devices. As to manual breast pumps, Park observes that they “have a very low milk extracting efficiency” and involves “substantial inconvenience in that the user consumes a great amount of power.” *Id.*, [4]. As to electric breast pumps, the application of negative pressure may cause “a portion of the breast milk suctioned into the suctioner [to] occasionally flow[] backward to the pipe passage.” *Id.*, [6].

75. Park’s breast pump includes a “close-contact housing 100” and a “storing housing 700,” such as illustrated in Figure 1. EX1010, [37], [42]-[44].



Id., Fig. 1 (annotated). The close-contact housing is designed to contact a mother's breast and includes a "protruding part 110, which extends forward and is formed in the portion corresponding to nipple of a lactating woman." *Id.*, [37]. The "storing housing 700" includes an "air nozzle 410" to enable the passage of air flow. *Id.*, [39]. The close-contact housing and storing housing are coupled in a "detachable" manner "so as to collect extracted breast milk even without using a separate milk bottle." *Id.*, [42].

76. Park's breast pump device applies suctioning to a breast by using a "flow separation membrane 500" to create negative pressure. EX1010, [6], [39]. The "flow separation membrane 500" is covered and sealed by a "cover 400," such as illustrated in Figure 5 of Park. EX1010, [37].



EX1010, Fig. 5 (annotated), 4:59-65. The flow separation membrane 500 “is formed of a ductile material so as to be easily bendable by external force” and generates “vacuum pressure” such that “breast milk is extracted from the breast 10 of the lactating woman” via the “the protruding part 110” of the “close-contact housing 100.” EX1010, [39]. Specifically, “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 upward.” *Id.* Further, “when the flow separation membrane 500 is moved upward, the space between the flow separation membrane 500 and the funnel connector 300 is expanded to form a vacuum pressure.” *Id.* The vacuum pressure is then “transferred to a breast 10 of a lactating woman through the communication flow passage 310, the spacing space G, the breast milk discharge hole 210, and the inside of the protruding part 110, and thus, breast milk is extracted from the breast 10 of the lactating woman.” *Id.* The flow

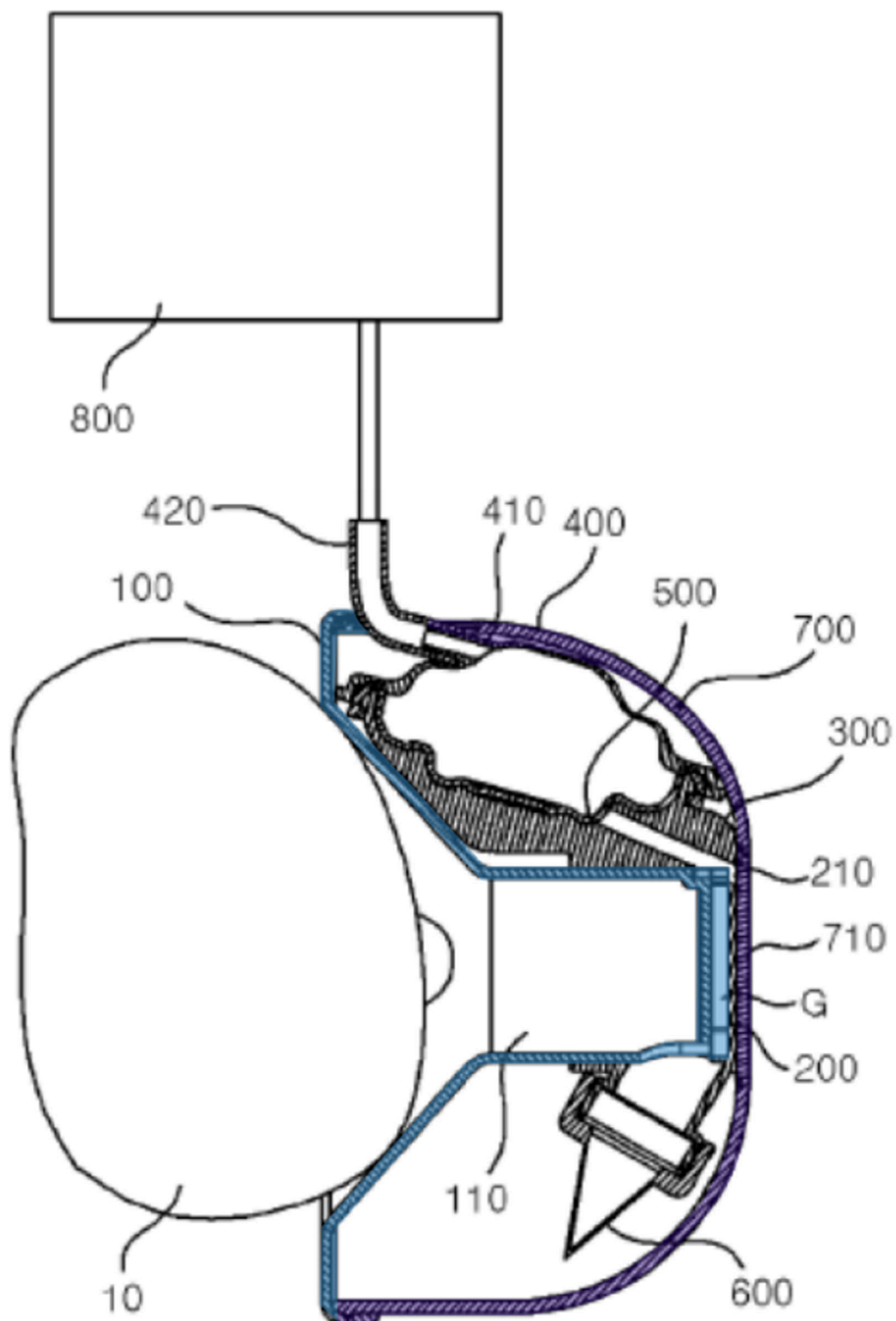
separation membrane further prevents milk from “flow[ing] backward up to the air nozzle 410.” *Id.*, [40].

77. Park discloses that an “electric pump 800” can be connected to the breast pump via an “air tube 420,” to suck out the air between the membrane and lid to deform the membrane and create the resulting vacuum pressure on the protruding part or the contact housing. *Id.*, FIG. 7, [37], [49], [53]-[54].

78. In Park’s breast pump system, the “storing housing 700” is configured “so as to collect extracted breast milk even without using a separate milk bottle.” Appx. E, [42]. In this configuration, “when the storing housing 700 is attached to the close-contact housing 100, 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.* Further, the “storing housing 700 is coupled to the close-contact housing 100 in a detachable structure” so that “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.” *Id.*

79. A cross section of the Park breast pump device when assembled is shown in Figure 7:

Fig. 7



EX1010, FIG. 7 (annotated); *see id.*, [51]-[55].

80. In the state shown in Figure 7, “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,” which causes “flow separation membrane 500” to be “pulled toward the cover 400” (shown in FIG. 8). Appx. E, [54]. Then, “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.” *Id.* Further, the “vacuum pressure generated in the communication flow passage 310 is applied into the protruding part 110 through a spacing distance G and a breast discharge hole 120, a stimulus is transferred to a breast 10 closely contacting a close-contact housing 100, and thus, it is possible to extract milk.” *Id.*

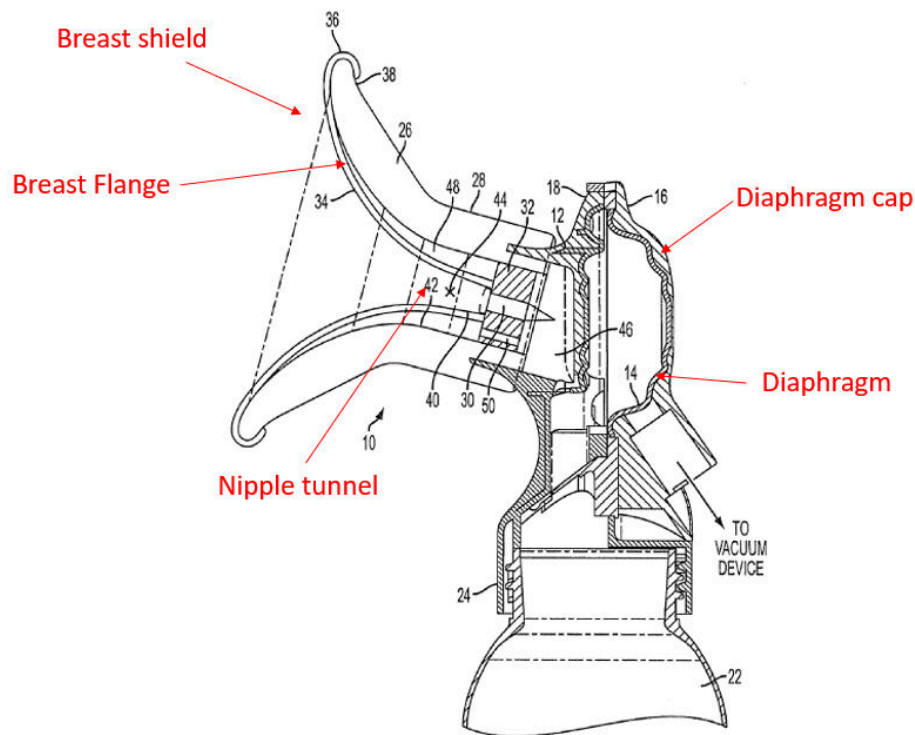
I. Silver (EX1011)

81. Silver describes “a breastshield for use with a breastpump for expressing milk” specifically configured with the air separation diaphragm positioned close to the nipple to “substantially limit[] the amount of air between the breast/nipple and the breastshield surrounding the breast/nipple, and most preferably virtually eliminates any air at least in the area of the breast and nipple.” EX1011, [0013]. Silver describes the known benefits of such a configuration in which the amount of air surrounding the nipple is limited, including that “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.* As such “[l]ess energy is required for the expression of milk, and thus the size of pump used can be decreased, thereby reducing the overall cost of the device.” *Id.* Silver further describes the configuration of its breast pump system:

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, thereby forming a plenum between the sheath member 34 and the inner sidewall 42 of the shield via a channel 50.

EX1011, [0067].



EX1011, FIG. 5 (annotated).

82. Silver describes several additional benefits of this arrangement in which the media separation diaphragm is positioned in front of and as close to the nipple as possible to substantially eliminate air near the nipple (referred to in the art as “dead volume”)

The vacuum pump can therefore be configured to be smaller and lighter, which means that it is in turn less conspicuous to onlookers. The mother can use the vacuum pump more discreetly. In addition, because of the lower energy, the vacuum pump is quieter during use, which in turn increases the comfort and discretion.

EX1011, [0014].

One aspect of the small working volume of the invention includes utilizing sensing of the vacuum pressure applied to the nipple and processing the vacuum level reading, as through a microprocessor control system, for example. The microprocessor then drives the pump in a manner to ensure the appropriate vacuum profile is produced at the nipple. This will allow the invention to perform consistently from mom to mom and will also allow for an improved reproduction of vacuum profiles of an infant.

EX1011, [0015].

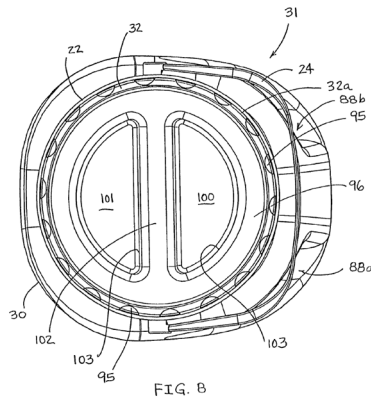
Further, with the breastshield of the present invention, vacuum may act on a smaller portion of the mother's breast, indeed on the nipple alone, as compared to known breastshields.

EX1011, [0017].

83. I discuss additional benefits of this reduction of air near the nipple with respect to the combination of Park with Silver, below.

J. Kasting (EX1012)

84. Kasting “relates in general to the sealing of an interface between two (or more) members, such as between a container body and a container lid.” EX1012. 1:19-21. Kasting discloses a cap/lid for a container that includes “two recessed pockets 100 and 101”:



EX1012, Fig. 8. The two recessed pockets 100 and 101 “enable the cap 32 to be grasped in an ergonomically-convenient manner so as to more easily remove the cap 32 from the spout 22 in order to open container 31 and also to more easily reapply cap 32 to spout 22 to close container 31.” *Id.*, 11:33-43.

IX. THE CHALLENGED CLAIMS OF THE '454 PATENT ARE OBVIOUS

85. It is my opinion that the Challenged Claims of the '454 patent are obvious in view of Furrer either alone or combined with other prior art references as discussed below. In particular, claims 17-18, 21-22, 24-25, 27-28, 30-32 are obvious

in light of Furrer alone. Alternatively, claims 17-18, 21-22, 24-25, 27-28, 30-32 are obvious in light of Furrer and Alvarez. Additionally, claims 17-19, 21-25, 27-32 are obvious in light of Furrer, Alvarez, and Pollen. Dependent claims 22 and 31 are obvious in light of any of the above combinations, with the addition of Weniger. Dependent claim 25 is obvious in light of any of the above combinations, with the addition of Rigert. Dependent claims 26 and 33 are obvious in light of any of the above combinations, with the addition of Kasting.

86. Additionally, claims 17-19, 21, 23-24, 27-30, 32 are obvious in light of Park in combination with Silver. Claims 25, 27-30, 32 are obvious in light of the Park-Silver combination, with the addition of Rigert. Dependent claims 22 and 31 are obvious in light of either of the above combinations, with addition of Weniger. Dependent claims 26 and 33 are obvious in light of either of the above combinations, with addition of Kasting.

**A. Ground 1A: Obviousness of Claims 17-18, 21-22, 24-25, 27-28, 30-32
Based on Furrer**

87. Claims 17-18, 21-22, 24-25, 27-28, 30-32 are obvious in light of Furrer for the reasons discussed below.

1. Claim 17

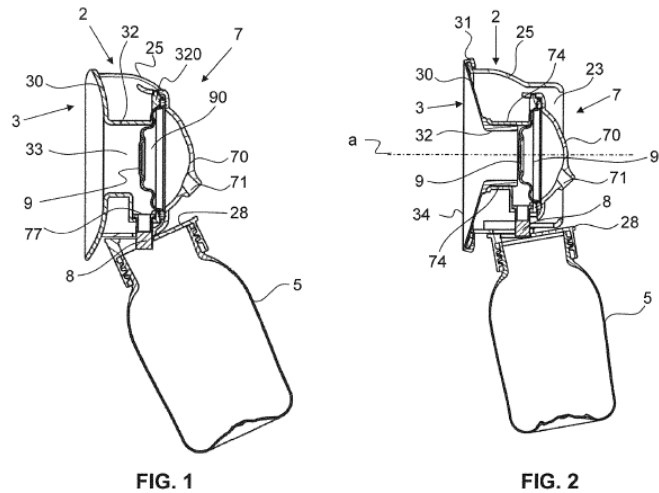
a. [17pre]: A breast pump system comprising:

88. Furrer discloses “[a] breastshield unit for use with a breastpump for expressing human breastmilk has a breastshield for receiving a mother 's breast and

a media separation device for transferring a vacuum into the interior of the breastshield.” EX1004, Abstract. The breastshield includes a “breast pad 30” that is “in the shape of a funnel” and “merges in one piece into a stub 32” (*id.*, 5:11-18):

The breast pad 30 serves the purpose of being placed onto a mother's breast, with the nipple of the breast extending right into the stub 32. In this way, the stub 32 forms, with its hollow interior, a receiving area 33 for receiving the nipple.

89. *Id.*, 5:31-34. The “media separation membrane 9,” is held in place by “housing 70” and transfers “underpressure” through the stub to express breast milk. *Id.*, 5:62-67.



EX1004, FIGs. 1-2.

- b. [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

90. Furrer renders obvious a control unit comprising: a battery, and a pump configured to be powered by the battery and to generate negative air pressure.

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. Furrer also teaches that this pump is a motorized vacuum pump, stating that the pump "can be driven manually or *by motor*" to thereby apply "cyclically changing underpressure" via the vacuum connector 71. *Id.*, 5:40-62. In its background section, Furrer corroborates the knowledge of a POSITA that during the relevant timeframe "motor-driven breastpumps are commercially available." *Id.*, 1:22-25. A POSITA would have recognized that such "motor driven breastpumps" that would have served as the motor driven vacuum pump in Furrer's system are, or at least plainly suggest, control units. Specifically, a POSITA would have recognized that such motorized pumps would have controlled suction to safely and repeatably achieve the "cyclically changing underpressure" described in Furrer and therefore are control units. As such, Furrer discloses or renders obvious the claimed control unit.

91. As discussed above, Furrer discloses that its motorized pump generates "a cyclically changing under pressure" which is "applied via the vacuum connector 71" such that "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 expressed." EX1004, 5:39-42, 5:59-67. As such, Furrer discloses that the pump generates negative air pressure that is applied to the mother's breast via the media separation membrane.

92. Furrer does not expressly state that its electric pump includes and is “powered by” a “battery.” However, this would have been obvious to a POSITA based on Furrer’s disclosure alone. In particular, as discussed above, Furrer discloses that its vacuum pump is motorized and of the type of motor-driven pumps that were commercially available at the time. EX1004, 5:39-42, 1:22-25. There were only two power sources available for commercially-available motor-driven pumps at the time, as was well-known to a POSITA: those powered by a power cord that plugs into an outlet and battery power.

93. As discussed above in the Technology Background Section, breast pumps could be powered either manually or by electricity. For electric-powered breast pumps, the only two options for providing electricity to the pump was either via a wire plugged into an outlet or via a battery, as would have been well-known to a POSITA. *See e.g.*, EX1005, [0082]; EX1011, [0005]; EX1013, 7:52-58, 8:14-17; EX1015, [0003], [0020]; EX1022, [0026]-[0027] (corroborating the knowledge of a POSITA that motorized breast pumps were powered by a cord plugged into an outlet or by battery). It would have been obvious for a POSITA to utilize a battery as the power source for Furrer’s pump as it was one of the two available options and would have provided known benefits. Selection of battery power for Furrer’s pump would have beneficially provided a portable system that was usable during travel. Additionally, such a configuration would have allowed the user to move freely about

a room, or be positioned in a location within a room without being tethered to a wall plug, allowing the user to, for example, sit or lay in the most convenient location while using the system without having to worry about being close to an outlet. Such mobility provided by selecting battery power for Furrer's pump would have particularly aligned with Furrer's suggestion for a "hands-free" and discrete solution. EX1004, 3:7-9.

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

94. Furrer discloses a wearable milk collection hub configured to connect to the control unit via an air line. For example, Figures 3 and 4 show a cross-section and perspective view, respectively, of Furrer's wearable milk collection hub.

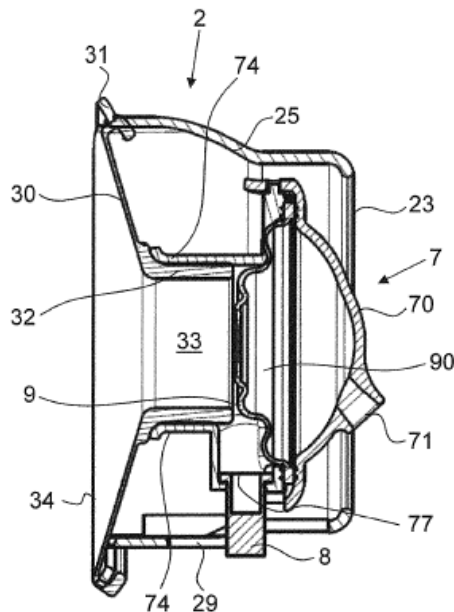


FIG. 3

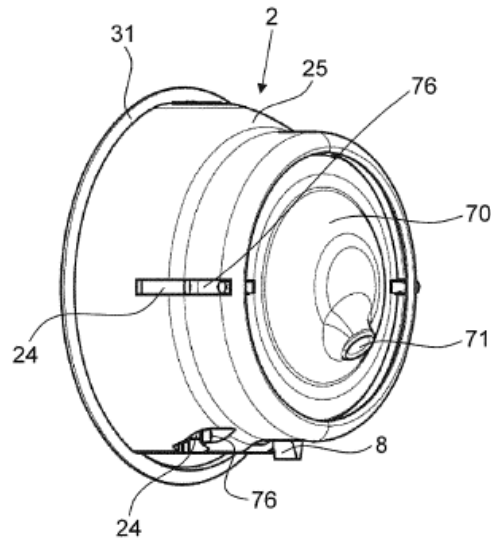


FIG. 4

EX1004, FIGs. 3-4.

95. Furrer is also express that this milk collection hub is wearable, describing that it provides a “‘hands-free’ solution[], in which the breastshield is worn in a bra under the clothes.” EX1004, 1:47-52. In another example, Furrer describes that this milk collection hub is “worn under a bra.” *Id.*, 3:5-10, 7:25-31.

96. The milk collection hub is also connected to the control unit (Furrer’s motorized pump) via a suction line:

A vacuum connector 71 for connection to a vacuum pump (not shown) is present on the housing 70 of the media separation device 7. The connection can be made directly or via a suction line. The vacuum pump can be driven manually or by motor.

EX1004, 5:35-41. 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 expressed.” EX1004, 5:59-67.

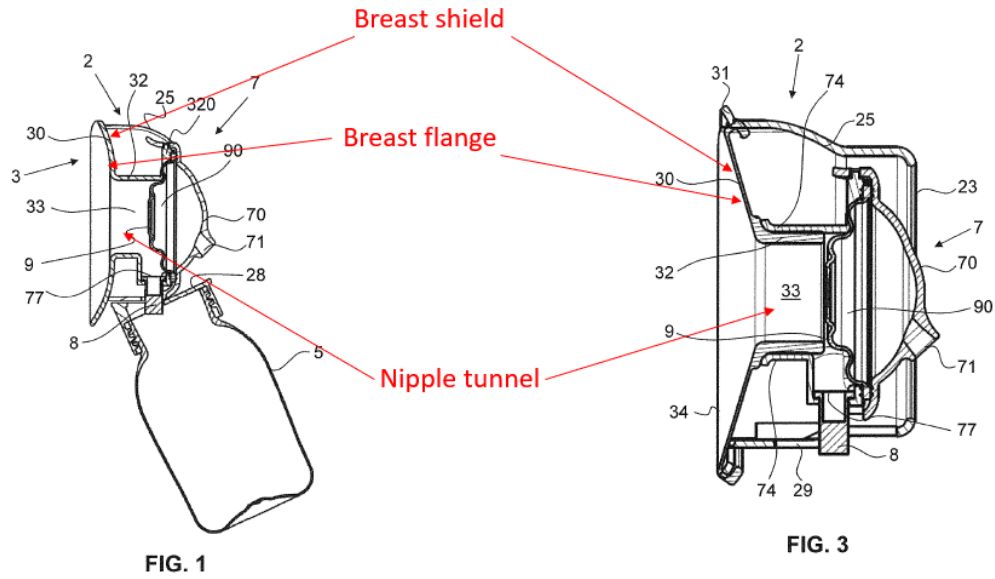
d. [17c-1]-[17c-3]: a breast shield comprising: a breast flange; and a nipple tunnel extending from the breast flange;

97. Furrer discloses a breast shield comprising: a breast flange and a nipple tunnel extending from the breast flange.

98. Furrer’s “breastshield unit for use with a breastpump” includes a “breast pad 30” that is “in the shape of a funnel” and “merges in one piece into a stub 32” (EX1004, 1:16-18, 5:11-18):

The breast pad 30 serves the purpose of being placed onto a mother's breast, with the nipple of the breast extending right into the stub 32. In this way, the stub 32 forms, with its hollow interior, a receiving area 33 for receiving the nipple.

Id., 5:31-34. A POSITA would have recognized that the breast pad 30 of the breastshield insert 3 provides the claimed breast flange while the stub 32 that extends from the breast pad 30 defines the “receiving area 33 for receiving the nipple” which is the claimed nipple tunnel extending from the breast flange. *Id.*



EX1004, FIGs. 1, 3 (annotated).

99. These components are highly similar to the breast shield, flange, and nipple tunnel of the preferred embodiment of the '454 patent. For example, the '454 patent discloses that a “breast shield” “is made up of a “breast flange” and “a nipple tunnel” (EX1001, 5:46-49), where the breast flange “contacts the user’s breasts” (*id.*, 5:49-50) and the nipple tunnel is “shaped to receive a nipple” (*id.*, 6:23-24). The '454 patent illustrates its breast shield 21 in Figure 3, with the flange 32 and nipple tunnel 31:

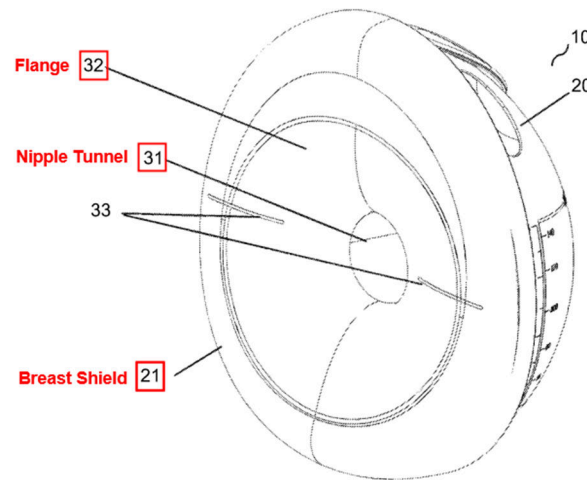


FIGURE 3

EX1001, FIG. 3 (annotated).

100. As can be seen, in comparing Figures 1 and 3 of Furrer to Figure 3 of the '454 patent, each of these claimed structures is provided by Furrer.

- e. **[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;**

101. Furrer discloses a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel. The '454 patent interchangeably refers to a “diaphragm” as a “membrane”: “Diaphragm cap 22 sits over the flexible diaphragm or membrane 61 and a negative pressure chamber is hence formed between diaphragm cap 22 and one side of the flexible diaphragm 61.” EX1001, 7:41-45 (referring to diaphragm and membrane by reference number 61); *see also id.*, 7:32-43, Fig. 6 (diaphragm 61).

102. Furrer discloses the claimed “diaphragm” configured to “deform” in the form of “media separation membrane 9.” EX1004, 5:50-6:17. The “media separation membrane 9” is held in place by “housing 70,” that transfers “underpressure” through the stub to express breast milk. *Id.*, 5:50-6:12.

When 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 expressed.

EX1004, 5:62-67. Furrer goes on to describe that:

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.

103. Furrer describes 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.*, 5:59-6:12.

- f. **[17e]: 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**

104. Furrer discloses 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.

105. The '454 patent describes the “outer shell” as “having a curved shape that is configured to contact the inner surface of the bra” and that it “fits or latches onto a breast shield 21 that forms the rear surface of the hub 10” (EX1004, 5:40-46), as shown below in Figure 3 of the '454 patent:

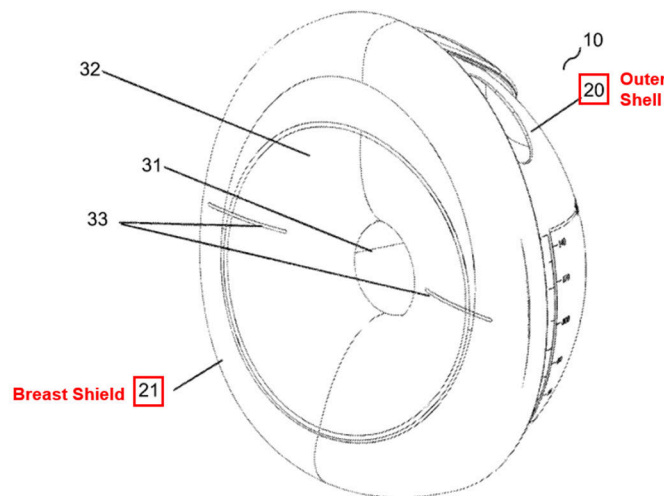
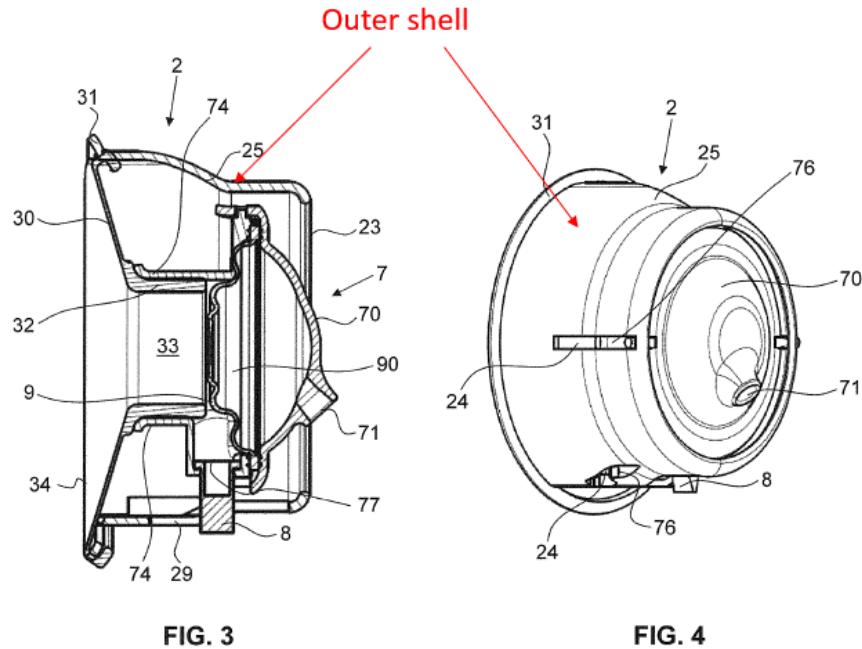


FIGURE 3

EX1004, FIG. 3 (annotated).

106. Furrer discloses this same configuration for the outer shell in the form of the main body 25 and housing 70 (which acts as a cap for media separation membrane 9 by sealing and securing the membrane) which together form an outer

shell having the claimed configuration in which the main body 25 includes a rear end configured to removably attach to the breast pad 30 of breastshield insert 3 (the claimed breast shield).



EX1004, FIGs. 3-4 (annotated). This configuration in Furrer's device is similarly shown in FIG. 1 of Furrer, which shows the diaphragm cap (housing 70) positioned at the front and center of the main body 25:

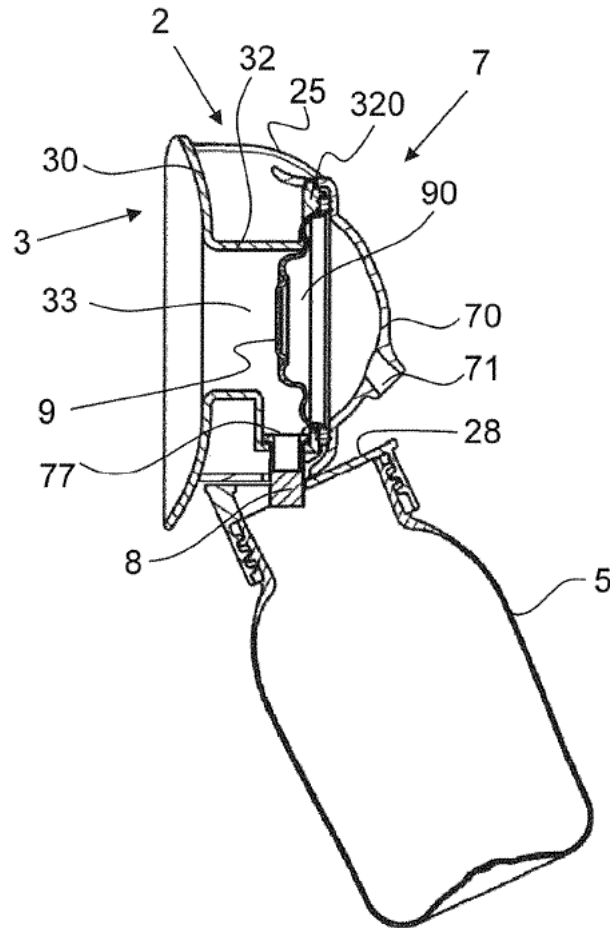


FIG. 1

EX1004, FIG. 1. As Furrer describes, in some implementations, the housing 70 “can also be connected rigidly and immovably” to the main body 25. *Id.*, 4:59-63.

107. Furrer expressly describes the removable coupling between the main body 25 and the breast pad 30 of breastshield insert 3, stating that the breast pad 30 “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. According to the ’454 patent, the “rear end” is the

side of the milk collection hub that is directed towards the mother's breast and the "front end" is the side that is directed away from the mother's breast. *See, e.g.*, EX1001 at 5:56-58 (describing Figure 2 as "a perspective front view of a milk collection hub" and Figure 3 as "a perspective rear view of a milk collection hub"); *id.* Figs. 2, 3. As shown in Figure 3 of Furrer, Furrer discloses that it is the "rear end" of its main body 25 that couples to breastshield insert 3:

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

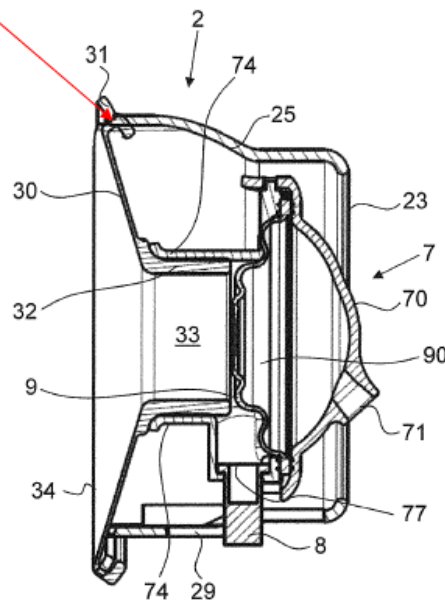


FIG. 3

EX1004, FIG. 3 (annotated).

108. Figure 3 of Furrer also shows an interior volume between the main body 25 and the breastshield insert 3 defining a chamber to receive expressed milk.

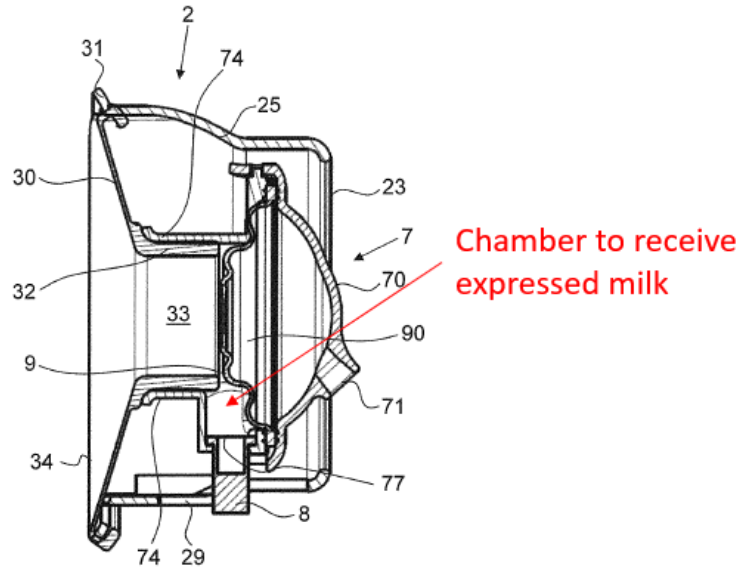


FIG. 3

EX1004, FIG. 3 (annotated).

109. As Furrer describes, when milk is expressed from the breast, “the 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 chamber that I identified above in Figure 3 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.

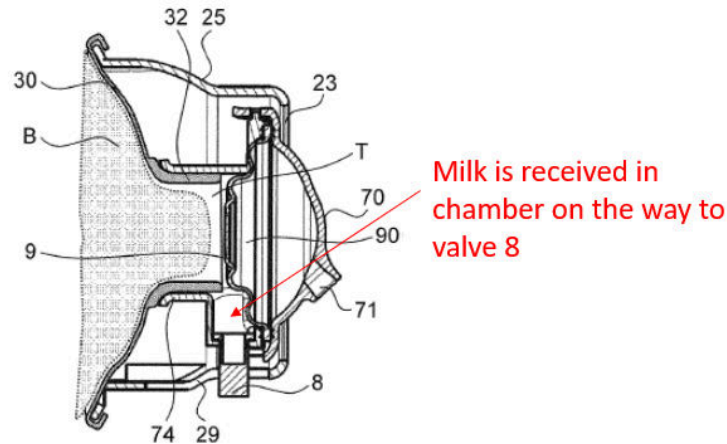


FIG. 7

EX1004, FIG. 7 (annotated). As such, this chamber provides the claimed chamber to receive expressed milk that is defined between the outer shell and the breast shield.

- g. [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.**

110. Furrer discloses 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.

111. As previously discussed, according to the '454 patent, the “rear end” is the side that is directed towards the mother’s breast and the “front end” is the side that is directed away from the mother’s breast. *See, e.g.*, EX1001 at 5:56-58 (describing Figure 2 as “a perspective front view of a milk collection hub” and Figure 3 as “a perspective rear view of a milk collection hub”); *id.*, Figs. 2, 3. The

'454 patent describes the diaphragm cap as "located at the front of the outer shell 20, and form[ing] a central region on the front surface of the outer shell 20" (*id.*, 5:56-58):

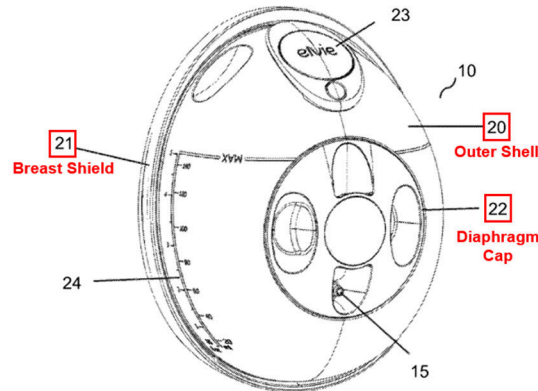


FIGURE 2

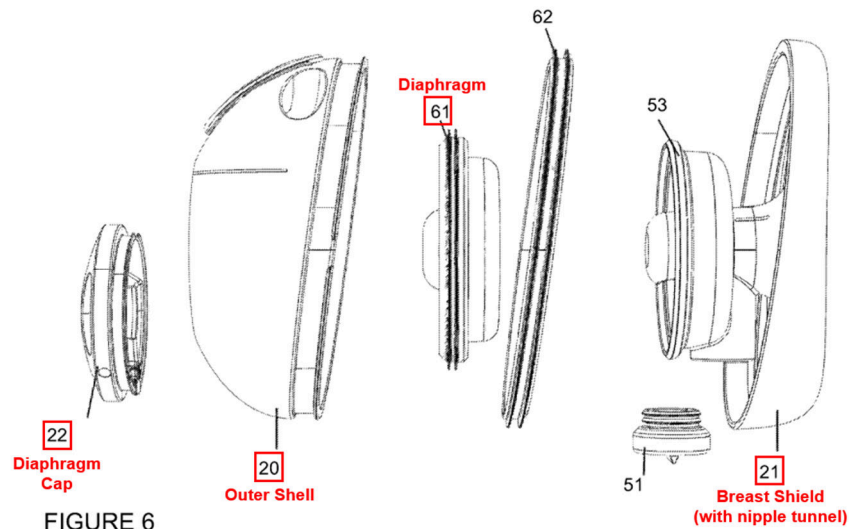


FIGURE 6

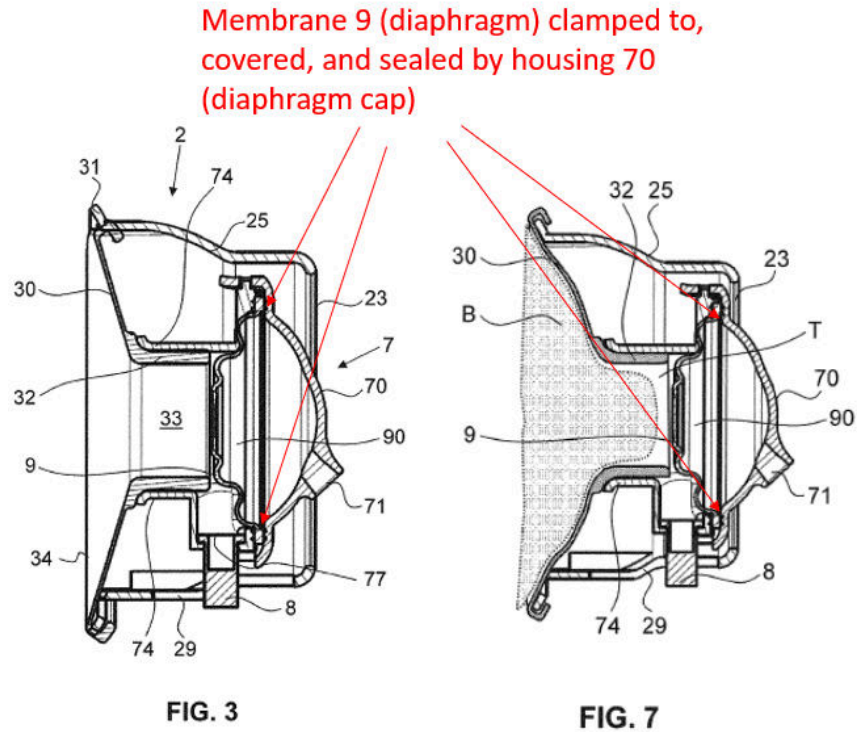
Id., Fig. 2 (annotated), Fig. 6. As can be seen, in this position, the diaphragm 61 and diaphragm cap 22 are located at the end of the nipple tunnel, away from the mother's breast.

112. Furrer discloses this exact configuration. Specifically, as previously discussed, Furrer's a breastpump system includes "media separation membrane 9" (the claimed diaphragm) which is covered and sealed at a front end of the outer shell by a "housing 70 (the claimed diaphragm cap):

The media separation device 7 has a media separation membrane 9, which is held movably in the housing 70. In this example, it is clamped between the housing 70 and a flange 320 at the end of the stub 32 directed away from the breast. The media separation membrane 9 forms a breast-side wall of a pump chamber 90, and the housing 70 forms the wall of the pump chamber 90 directed away from the breast.

EX1004, 5:50-54. Furrer describes that the housing 70 "can be arranged movably in the main body 25" or "can also be connected rigidly and immovably thereto."
EX1004, 4:57-63.

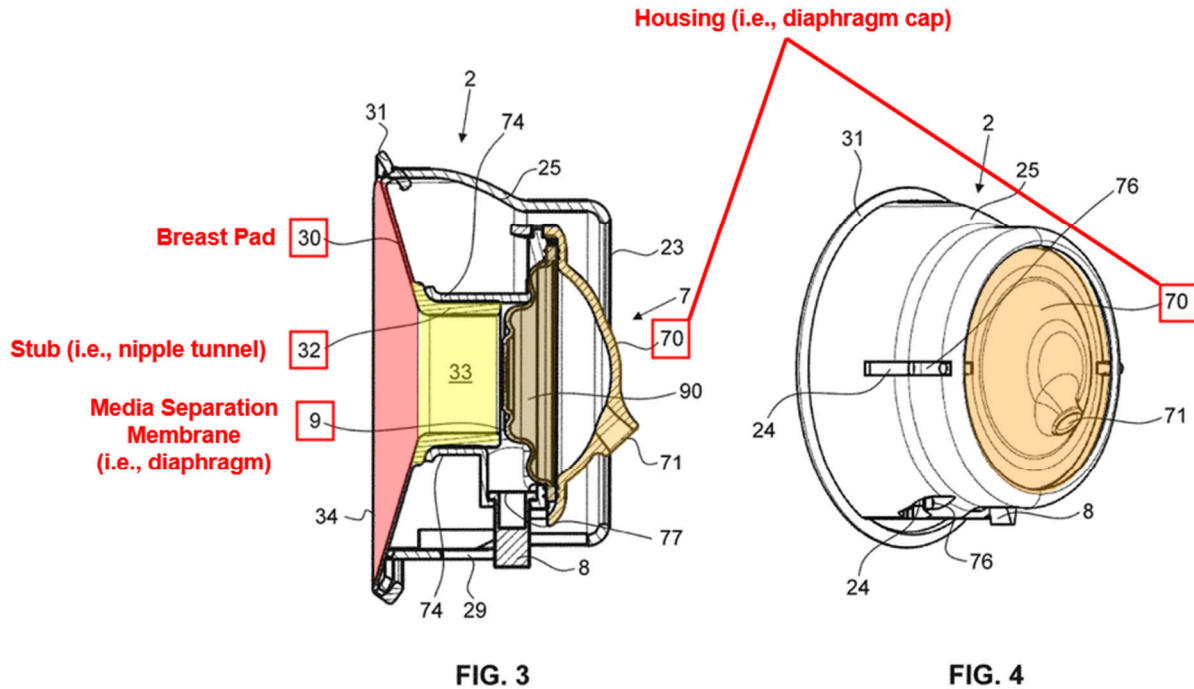
113. As would have been understood by POSITA, to convey the vacuum underpressure described in Furrer, the membrane 9 would be sealed in place by the housing 70 to prevent air from leaking into that space, which would prevent operation of the device by equalizing the pressure. EX1004, 5:35-42, 5:59-67, 6:5-12. 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.



EX1004, FIGs 3, 7 (annotated).

114. Furrer discloses positioning and orienting the diaphragm and diaphragm cap in the same manner described and claimed in the '454 patent. For example, Furrer discloses positioning its media separation membrane 9 (i.e., diaphragm) and housing 70 (i.e., diaphragm cap) at the end of the nipple tunnel—the receiving area 33 defined by stub 32 (*id.* 5:33-34 (“the stub 32 forms, with its hollow interior, a receiving area 33 for receiving the nipple”))—away from the mother’s breast and in an orientation that is perpendicular to the nipple tunnel. *Id.*, Figs. 3, 4; *see also id.*, 5:50-54 (“the housing 70 forms the wall of the pump chamber 90 directed away from the breast”).

115. Furrer's media separation membrane 9 (in brown), stub 32 (in yellow) and housing 70 (in light orange) are shown in Figures 3 and 4 of Furrer below:



Furrer, Fig. 3 (annotated), Fig. 4 (annotated).

116. Figure 7 of Furrer shows another example of the housing 70 positioned at a front end of the main body 25 such that the housing 70 forms a central region on a front surface of the outer shell (made up of main body 25 and housing 70).

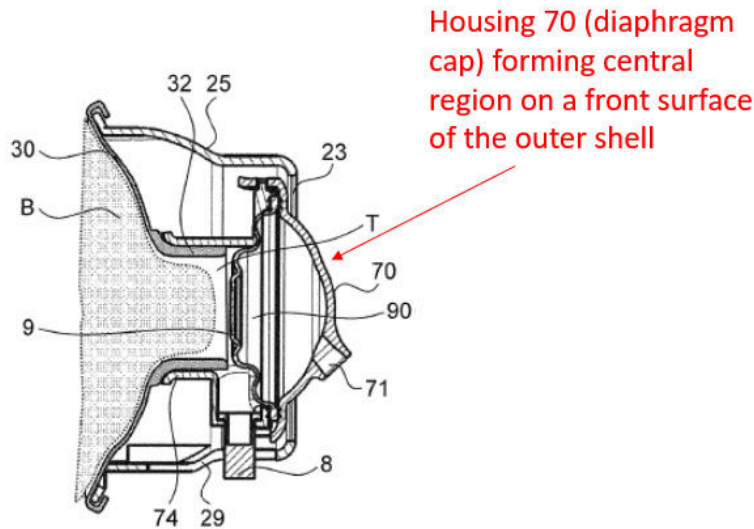


FIG. 7

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.

2. Claim [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.

117. Furrer discloses that the breast shield comprises an outer edge configured to be received by the rear end of the outer shell. Specifically, Furrer discloses several arrangements for its breastpump system in which the breastshield insert 3 (the claimed breast shield) has an outer edge received by the rear end of the main body 25 (which forms a portion of the claimed outer shell), as demonstrated, for example, in Figures 2, 3, 5, and 7.

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

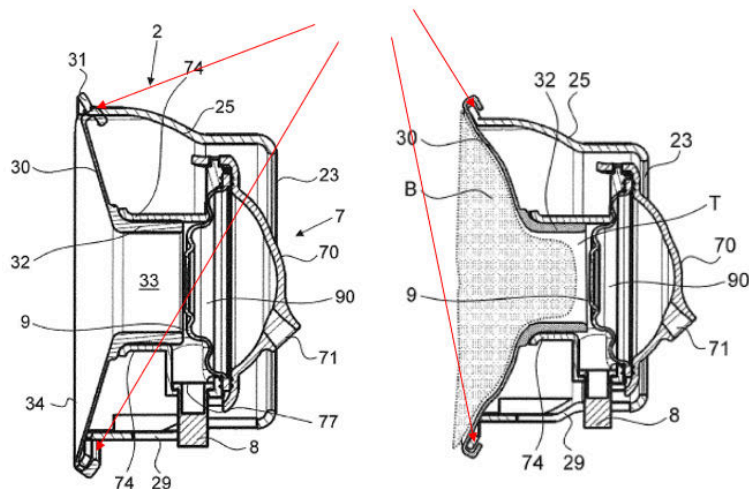


FIG. 3

FIG. 7

EX1004, FIGs. 3, 7 (annotated).

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

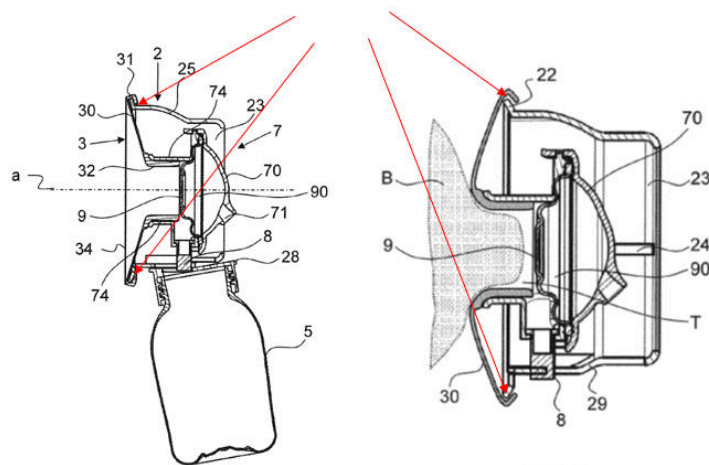


FIG. 2

FIG. 5

EX1004, FIGs. 2, 5 (annotated).

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

118. Furrer discloses that its breast pump system includes a milk port through which the expressed milk flows into the chamber. Specifically, Furrer's device includes a milk port formed between the stub 32 and membrane 9 through which the expressed milk flows into the chamber. EX1004, 5:59-6:4. A POSITA would have recognized that the milk flows through this milk port at the distal nipple tunnel opening where it is received in the above identified chamber of Furrer's device prior to reaching Furrer's valve. After it is held in this chamber (while the valve 8 is closed during underpressure) "the milk flows through the milk outlet opening 77, arranged before the membrane 9, into the milk collection container 5." *Id.* Furrer describes the movement of the membrane in response to the cyclical changing underpressure from the vacuum pump that elicits this milk flow:

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. Furrer goes on to describe:

The media separation membrane 9 is arranged such that it is located in the receiving area 33 in at least one of these two positions. It usually protrudes into this receiving area

33 at least in the second position directed towards the breast and it thus minimizes the dead volume in said hollow space.

EX1004, 6:13-17.

119. Figure 7 of Furrer shows the second position described by Furrer in which the membrane protrudes into receiving area 33 such that it extends in the direction of the nipple:

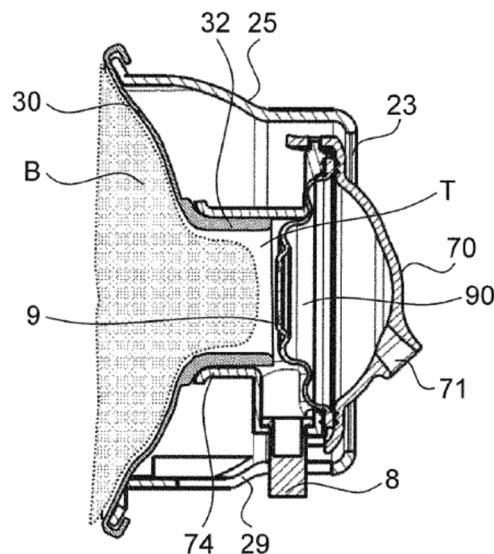
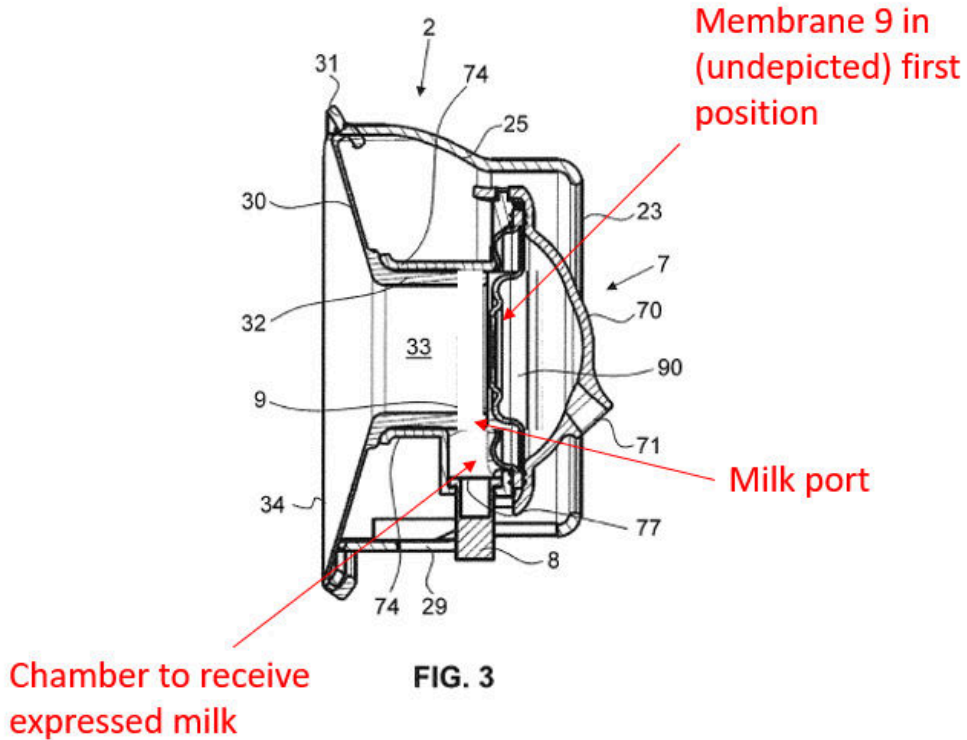


FIG. 7

EX1004, FIG. 7.

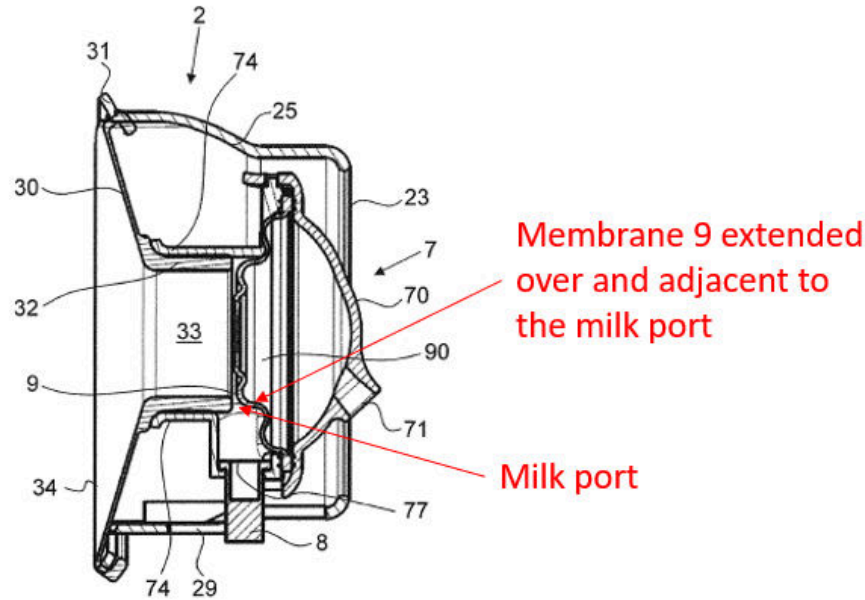
120. Furthermore, a POSITA would have recognized that in the undepicted “first position” in which the membrane 9 is in the under-pressure state, the membrane 9, together with the stub 32, defines a milk port through which the expressed milk flows into the chamber.



EX1004, FIG. 3 (modified and annotated).

- 4. Claim [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.**

121. Furrer discloses that the diaphragm is configured to extend over and adjacent to the milk port in a relaxed state. This configuration is expressly depicted in Figure 3 of Furrer which shows the “second position” for the membrane 9 in which it “protrudes into th[e] receiving area 33” to extend over and adjacent to the milk port. EX1004, 6:11-17.



EX1004, FIG. 3 (annotated). Furrer describes that the cyclical extending and retracting of the membrane 9, that includes extending 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.

5. Claim [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.

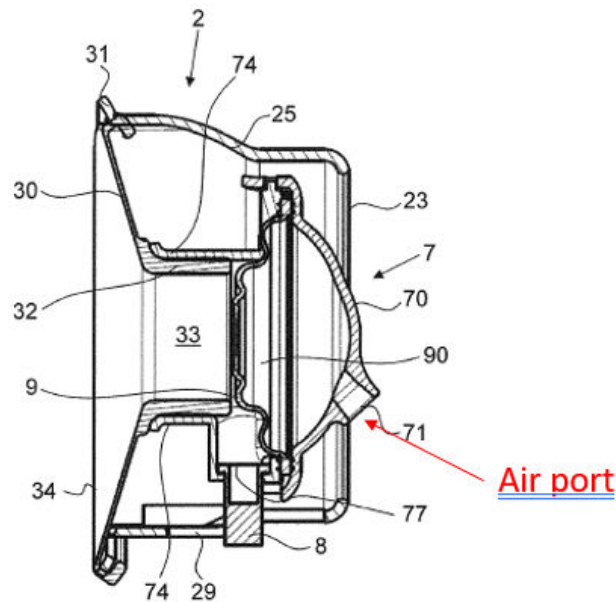
122. Furrer discloses that the diaphragm cap comprises an air port configured to receive an end of the air line. Specifically, Furrer’s vacuum connector 71 provides the claimed air port:

A vacuum connector 71 for connection to a vacuum pump (not shown) is present on the housing 70 of the media separation device 7. The connection can be made directly or via a suction line. The vacuum pump can be driven manually or by motor.

EX1004, 5:35-41.

When 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 expressed.

EX1004, 5:62-67.



EX1004, FIG. 3 (annotated).

6. **Claim [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.

123. As a POSITA would have recognized, Furrer's diaphragm cap (housing 70) is configured such that the air port (vacuum connector 71) can be located above the nipple tunnel by disclosing a circular shape for both the housing 70 and

membrane 9 along with guide slits 24 that are positioned symmetrically across from each other in the main body 25. EX1004, FIGS. 4 and 6. As such, the housing 70 is **configured** such that the air port **can be** located above the nipple tunnel because the housing 70 could be just as easily inserted such that opposite guide lugs of housing 70 are inserted in opposite guide slits 24 such that the housing 70 is rotated 180 degrees from the depicted configuration and the vacuum connector 71 is positioned above rather than below the nipple tunnel.

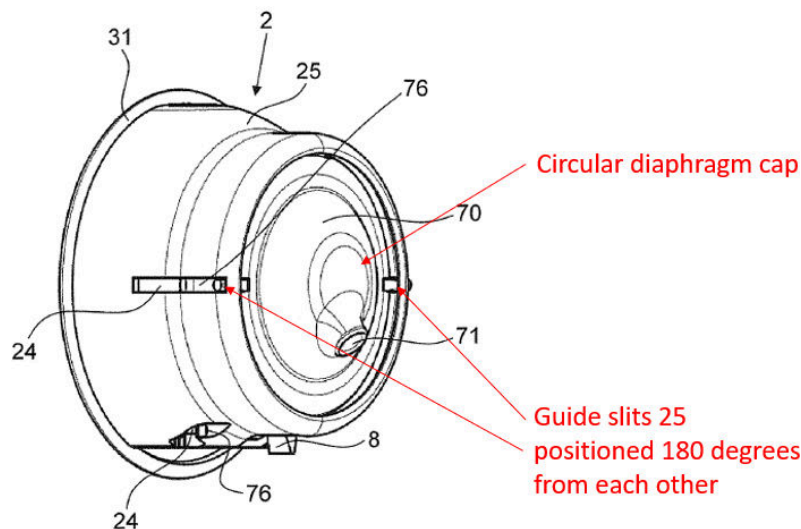


FIG. 4

EX1004, FIG. 4 (annotated).

124. A POSITA would have readily understood from Furrer's depictions in Figures 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 thus that the vacuum connector 71 “can be” positioned above the nipple tunnel 33.

125. Alternatively, a POSITA would have found it obvious to implement Furrer’s device such that the vacuum connector 71 is positioned above (rather than below) the nipple tunnel 33 and would have been prompted to do so to achieve known benefits. As I discussed above, Furrer describes that its device is designed to be “worn under a bra.” EX1004, 1:47-52, 3:5-10, 7:25-31. A POSITA would have recognized that modifying Furrer’s system to position the vacuum connector 71 above the nipple tunnel 33 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. Positioning the suction line to protrude from the bottom of the bra would have been uncomfortable for users with respect to many bra designs (such as those having an underwire). Positioning the vacuum connector 71 above the nipple tunnel 33 also would have allowed the suction lines to exit the mother’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. As such, the resulting device could be implemented with shorter suction lines which would have reduced the strain on the vacuum pump. Additionally, 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.

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

126. Furrer's diaphragm (media separation membrane 9) is arranged concentric with the nipple tunnel 33 as shown, for example, in Figure 3.

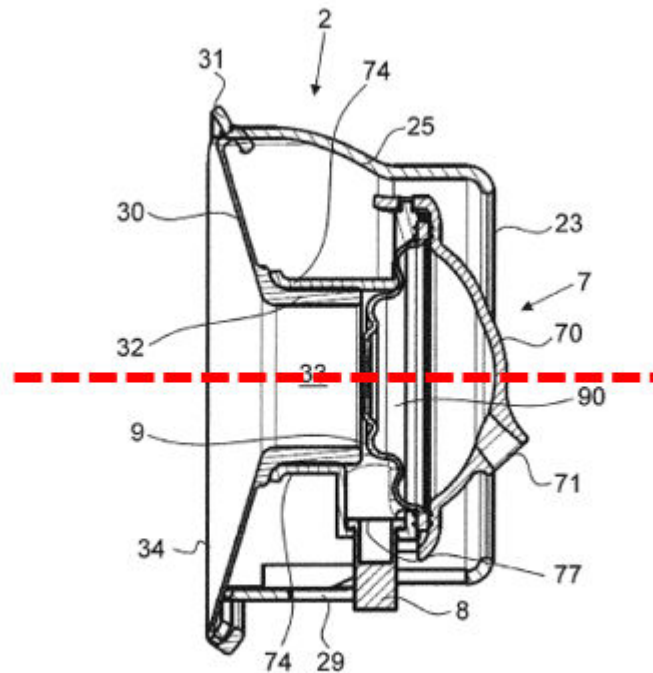


FIG. 3

EX1004, FIG. 3 (annotated). The other figures of Furrer confirm this arrangement in which the media separation membrane 9 is concentric with the nipple tunnel 33.

8. Claim 28

a. [28pre]: A breast pump system comprising:

127. Furrer provides this preamble for the reasons discussed with respect to preamble [17pre], above.

b. [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

128. Furrer provides these claim elements for the reasons discussed with respect to elements [17a-1]-[17a-3], above.

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

129. Furrer provides this claim element for the reasons discussed with respect to element [17b], above.

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

130. Furrer provides these claim elements for the reasons discussed with respect to elements [17c-1]-[17c-3], above.

e. [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;

131. Furrer provides this claim element for the reasons discussed with respect to element [17d] and claim [27], above.

- f. **[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**

132. Furrer provides this claim element for the reasons discussed with respect to element [17e], above.

- g. **[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.**

133. Furrer provides this claim element for the reasons discussed with respect to element [17f], above.

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

134. Furrer provides claim [30] for the reasons discussed with respect to element [17f], above.

- 10. **Claim [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.**

135. Furrer provides claim [31] for the reasons discussed with respect to claims [21]-[22], above.

11. Claim [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.

136. Furrer provides claim [32] for the reasons discussed with respect to claim [24], above.

B. Ground 1B: Obviousness of Claims 17-18, 21-22, 24-25, 27-28, 30-32 Based on Furrer and Alvarez

137. Claims 17-18, 21-22, 24-25, 27-28, 30-32 are obvious in light of Furrer in view of Alvarez for the reasons discussed below.

1. Motivation To Combine Furrer and Alvarez

138. As discussed above, Furrer describes a breast pump system that is provides a “‘hands-free’ solution[], in which the breastshield is worn in a bra under the clothes.” EX1004, 1:47-52; 3:5-10, 7:25-31. Given Furrer’s motivation to allow a user to utilize the device “hands-free” and to be able to move about during use, a POSITA seeking to implement its teachings would have sought opportunities to improve user convenience when the Furrer breast pump device is used for milk extraction. As such, a POSITA would have turned to the teachings of Alvarez to implement Furrer’s vacuum pump using a conventional pump controller having a portable, battery-powered pump to not only increase portability and to allow the user to move about when using the device but also to provide improved control for the system.

139. As I discussed above, Furrer expressly describes using a motorized vacuum pump that is connected to the wearable milk collection hub via a suction line connected to the vacuum connector 71 of housing 70. EX1004, 5:35-41, 5:59-67. Furrer further describes that such motor-driven pumps were “commercially available” at the time. EX1004, 5:37-41, 1:22-25. However, Furrer does not include further details for control of the vacuum pump as such devices were well-known in the art at the time. Therefore, as a first reason that a POSITA would have applied the teachings of Alvarez to Furrer, a POSITA would have recognized that 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 for pumping device 100, and also contains hardware for various functions, such as controlling pumping device 100, milk production quantification, and communication with other devices.” EX1005, [0069]. Alvarez provides details on “a driving mechanism residing in controller 115” that a POSITA would have recognized as being directly applicable to Furrer to provide a simple to use control unit for Furrer’s vacuum pump. *Id.*, [0070]-[0084]. As would have been known to a POSITA, and as expressly described in Alvarez, “a pump unit 2100 preferably include[es] a controller and processor 2104 as well as a motor 2102 for actuating the device.” *Id.*, [0115]. Alvarez provides helpful disclosure that predictably and beneficially aligns 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). Such portability would have allowed the resulting device to be easier to transport and would have allowed for use of the device in more locations. Use of a battery powered control unit, as suggested by Alvarez, for Furrer’s pump would have beneficially provided a portable system that was usable during travel. Additionally, such a configuration would have allowed the user to move freely about a room, or be positioned in a location within a room without being tethered to a wall plug, allowing the user to, for example, sit or lay in the most convenient location while using the system without having to worry about being close to an outlet.

140. As a second reason, a POSITA would have been motivated to implement Furrer’s vacuum pump in accordance with Alvarez’s suggestion for a battery-powered pump controller so as to advantageously provide 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”). Alvarez describes a pump controller that compactly houses the battery and the motor-driven pump unit along with additional hardware that provides the resulting system with added functionality to thereby increase user convenience. This includes functionality for communicating with

other computing devices and providing and helpful information to the user, such as milk production quantification information. EX1005, [0069], [0082], [0118]. A POSITA would have recognized that each of these suggestions of Alvarez would improve the resulting Furrer-Alvarez system to provide known benefits.

141. As a third reason, a POSITA would have been motivated to implement Furrer's vacuum pump in accordance with Alvarez's suggestion for a battery-powered pump controller having improved control functionality so that the resulting system includes a pump controller unit that beneficially monitors feedback on the use of the device to improve functionality of the pump. EX1005, [0098], [0114]-[0116]. Alvarez describes collecting measurement data from various sensors that are provided as feed back "to the pumping device in order to optimize fluid expression." EX1005, [0114]. The controller is thus "configured to control one or more functionalities of the actuation assembly" and can "determine changes to actuation parameters of the actuation assembly in order to achieve and/or maintain optimal fluid expression" using the sensor feedback. *Id.* A POSITA would have recognized that implementing Furrer's system to include a control unit having some or all of this functionality would have improved overall performance of the resulting system.

142. As a fourth reason, a POSITA would have been motivated to combine the designs of Furrer and Alvarez to beneficially implement Furrer's device to utilize

a battery-powered control unit because the use of Furrer's vacuum pump within a battery-powered control unit applies a known technique to wearable breast pump systems. Furrer's breast pump system already uses a motorized pump to generate vacuum forces and recognized that such motor driven pumps were "commercially available" at the time. EX1004, 5:40-62, 1:22-25. Alvarez describes a conventional example of such a vacuum pump unit that would similarly connect (via a suction line) to a vacuum connector that a POSITA would have recognized as being directly applicable to Furrer to implement Furrer's system. EX1005, FIG. 1, [0069] The Furrer-Alvarez combination produces predictable outcomes, as discussed earlier. The modification involves a relatively simple adjustment to implement Furrer's vacuum pump to run on battery power and include additional functionality as described above, and a person skilled in the art would have reasonably expected success in making these modifications. This expectation is based on the similarity between the devices, and the fact that the changes would primarily involve straightforward adjustments that would not significantly alter the overall function of the underlying device.

2. Claim 17

143. As discussed above, elements [17a-1]-[17a-3] recite "a control unit comprising: a battery, and a pump configured to be powered by the battery and to generate negative air pressure." Alvarez provides additional teachings that, when

applied to Furrer as discussed above, render obvious these claim elements. As I previously discussed, Alvarez demonstrates that in the predictable Furrer-Alvarez combination, the resulting device includes 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]. In another example, Alvarez discloses “a pump unit 2100 preferably including a controller and processor 2104 as well as a motor 2102 for actuating the device.” *Id.*, [0115]. For example, a POSITA would have readily applied the teachings of Alvarez to utilize a suction line, such as the tube 110 of Alvarez, to convey negative air pressure from the vacuum pump control unit to the vacuum connector 71 of Furrer in the resulting combination. EX1005, [0069], [0074]-[0075] (“such as air”); EX1004, 5:37-41. 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.

144. With respect to the remaining recitations of claim 17, all of these elements are provided by the Furrer-Alvarez combination for the reasons discussed with respect to Ground 1A, above.

3. Claim 28

145. The Furrer-Alvarez combination provides elements [28a-1]-[28a-3] of claim 28 for the reasons discussed with respect to elements [17a-1]-[17a-3], above. All remaining recitations of claim 28 are provided by the Furrer-Alvarez combination for the reasons discussed with respect to Ground 1A, above.

4. Claims, 18, 21-22, 24-25, 27, 30-32

146. The additional recitations of claims 18, 21-22, 24-25, 27, 30-32 are provided by the Furrer-Alvarez combination for the reasons discussed with respect to Ground 1A, above.

147.

C. Ground 1C: Obviousness of Claims 17-19, 21-25, 27-32 Based on Furrer, Alvarez, and Pollen

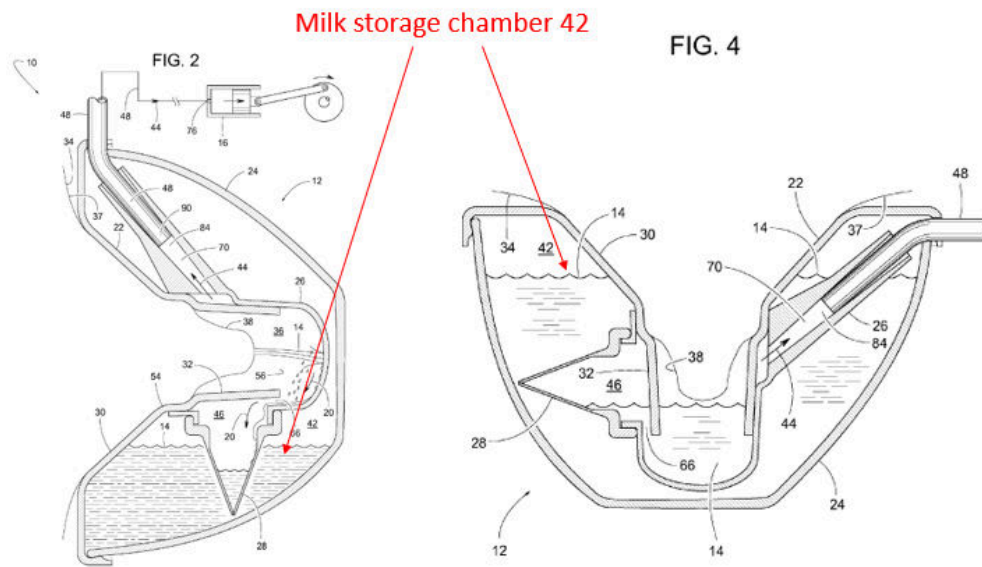
148. Claims 17-19, 21-25, 27-32 are obvious in light of Furrer in view of Alvarez and Pollen for the reasons discussed below.

1. Motivation To Combine Furrer and Alvarez with Pollen

149. As discussed above, Furrer describes a breast pump system that is provides a “‘hands-free’ solution[], in which the breastshield is worn in a bra under the clothes.” EX1004, 1:47-52; 3:5-10, 7:25-31. Given Furrer’s motivation to allow a user to utilize the device “hands-free” and to be able to move about during use, a POSITA seeking to implement its teachings would have sought opportunities to improve user convenience when the Furrer breast pump device is used for milk

extraction. As such, a POSITA would have turned to the teachings of Pollen to implement Furrer's system to collect the expressed breast milk within the wearable milk collection hub itself rather than in a separate bottle. As I previously discussed when summarizing the teachings of Pollen, 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.*" EX1006, [0062].

Pollen shows one possible configuration for such a milk storage chamber:



EX1006, FIG. 2, 4.

150. A POSITA would have recognized that this suggestion for storing expressed milk in the wearable milk collection hub itself rather than in a separate bottle would have been predictably applied to Furrer in a number of predictable ways without requiring bodily incorporation of Pollen's specific structures. Multiple

reason would have prompted a POSITA to predictably applied this suggestion of Pollen to Furrer to implement the resulting Furrer-Alvarez-Pollen system to store expressed milk in a chamber defined by the outer shell and breast shield.

151. As a first reason, a POSITA would have recognized that configuring Furrer's system to include 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. As would have been known to a POSITA, use of separate bottles attached to a user-worn portion of a breast pump system required users to hold the bottles by hand or otherwise support the milk collection bottles. This knowledge of POSITA is corroborated by, Park, which describes that 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]. Application of Pollen's suggestion to Furrer (as modified by Alvarez) would eliminate this disadvantage of such systems by collect[ing] extracted breast milk even without using a separate milk bottle." EX1010, [42]. In the resulting system, as a POSITA would have recognized, "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.*

152. As a second reason, Furrer describes a breast pump system that is provides a “‘hands-free’ solution[], in which the breastshield is worn in a bra under the clothes.” EX1004, 1:47-52; 3:5-10, 7:25-31. Application of Pollen’s suggestion to store the expressed milk in the wearable milk collection hub itself would have furthered this “hands-free” goal of Furrer’s design by eliminating the need for separate bottles hanging from the bottom of Furrer’s outer shells (main body 25). As such, the resulting system have allowed the wearable milk collection hub 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.

153. As a third reason, a POSITA would have recognized that configuring Furrer’s system to include a milk storage chamber between the outer shell and breast shield would have provided a simpler and less costly design. Specifically, Pollen teaches that application of the “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]

154. As a fourth reason, a POSITA would have recognized that the resulting configuration would have increased usability of the resulting system thereby increasing user satisfaction. Specifically, configuring Furrer’s system to collect milk 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. Providing a configuration that is less intrusive to the normal daily activities of the mother would have allowed the mother to go about her ordinary tasks while expressing and collecting milk in a discrete manner.

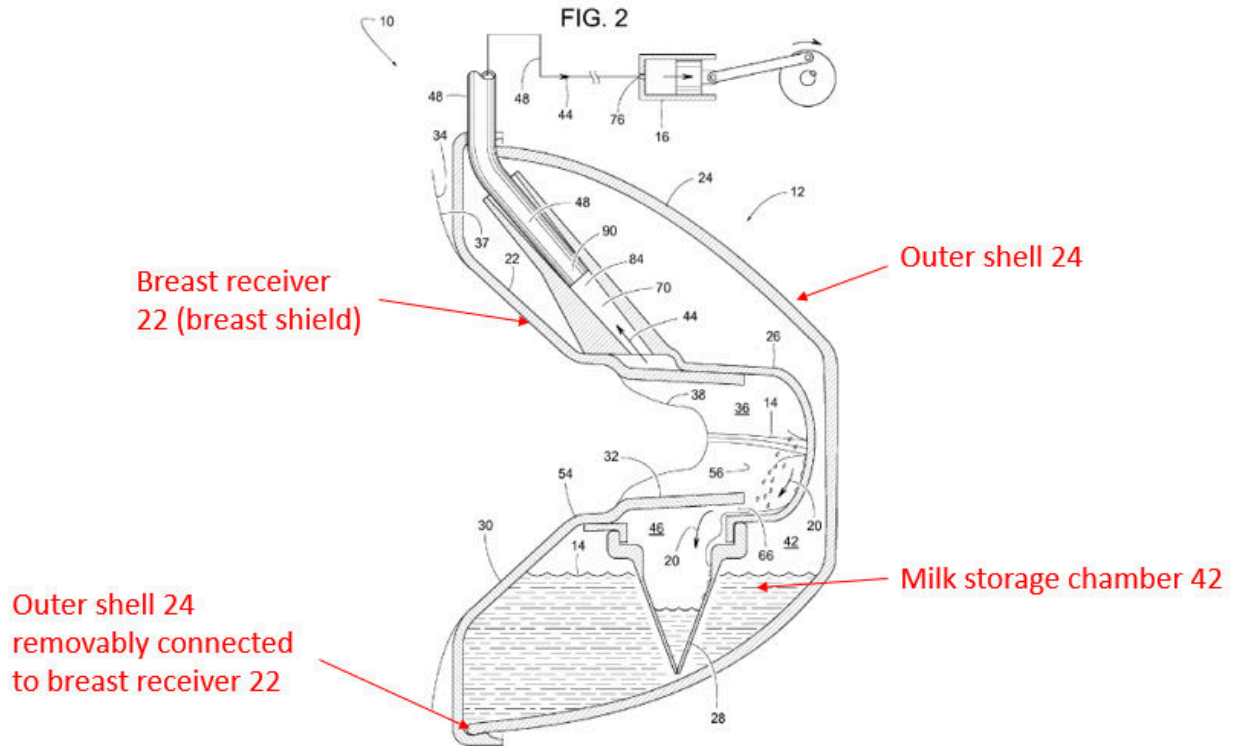
155. As a fifth reason, a POSITA would have been motivated to apply Pollen’s teachings to the Furrer-Alvarez system to beneficially implement Furrer’s device to include a milk storage chamber defined by the outer shell and breast shield because such a configuration for Furrer’s device applies a known technique to wearable breast pump systems. The Furrer-Alvarez-Pollen combination produces predictable outcomes, as discussed earlier. Due to the similarities of the systems described by Furrer, Alvarez, and Pollen, a person skilled in the art would have recognized that such a modification would be relatively straight forward and would have reasonably expected success in making these modifications. This expectation is based on the similarity between the devices, and the fact that the changes would primarily involve straightforward adjustments that would not significantly alter the overall function of the underlying device.

2. Claim 17

156. Element [17e] recites “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.” The

disclosures of Pollen demonstrate that the predictable combination of Furrer with Alvarez and Pollen that I described above provides this recitation of claim 17. As I previously discussed with respect to Ground 1A, Furrer describes 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. Pollen describes a similar releasable configuration for its outershell 24 and breast receiver 22, stating 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]. In another example, Pollen describes that the user can “remove breast receiver 22 from outer shell 24” to allow the user to “pour milk 14 out from shell 24.” *Id.*, [0068].

157. Furthermore, as I discussed above, Pollen demonstrates that in the predictable Furrer-Alvarez-Pollen combination, the outer shell and breast shield define a milk storage chamber for storing the expressed milk:



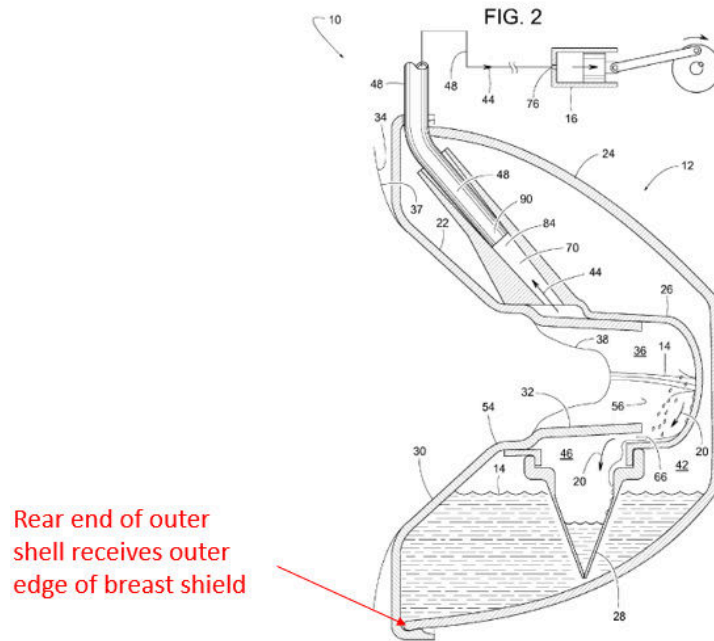
EX1006, FIG. 2 (annotated). Pollen describes a similar flow path to that of Furrer, describing that “[t]he expressed milk 14 flows from nipple chamber 36, flows through milk passage 66, and collects at the bottom of charging chamber 46.”

EX1006, [0066]. Pollen goes on to describe that “air pressure in charging chamber 46 forces milk 14 (collected during the previous suction period) from charging chamber 46, down through valve 28, and into storage chamber 42.” *Id.*, [0067].

158. With respect to the remaining recitations of claim 17, all of these elements are provided by the Furrer-Alvarez-Pollen combination for the reasons discussed with respect to Grounds 1A and 1B, above.

3. Claim [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.

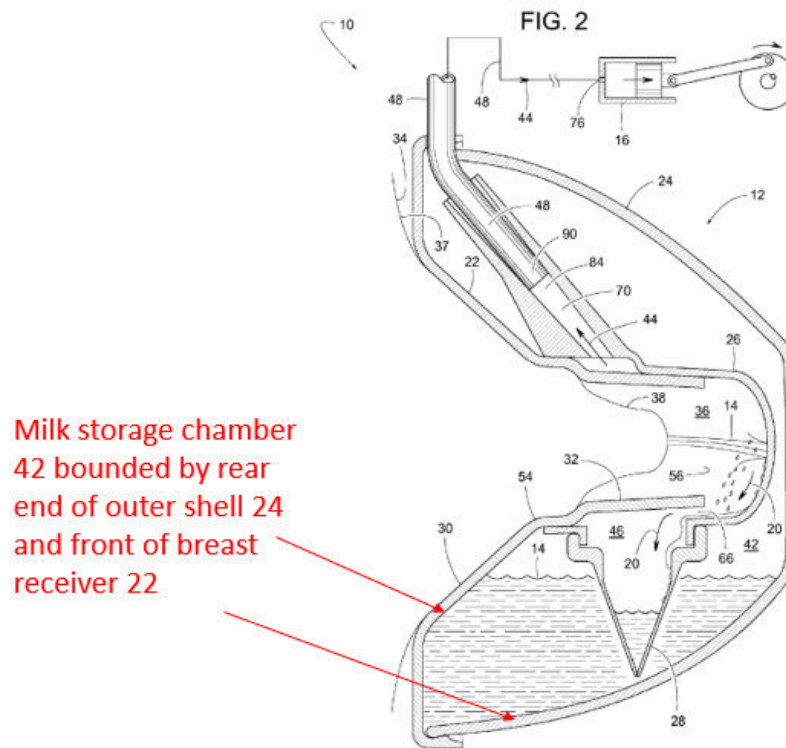
159. Furrer discloses this claim for the reasons discussed in Ground 1A, above. Additionally, Pollen provides further teachings that demonstrate that the predictable Furrer-Alvarez-Pollen combination renders this claim obvious. As I discussed above, Pollen discloses that “outer shell 24 ***removably connects*** to a flange 40 of breast receiver 22.” EX1006, [0062], [0068].



EX1006, FIG. 2 (annotated). In another example, Pollen describes that the user can “remove breast receiver 22 from outer shell 24” to allow the user to “pour milk 14 out from shell 24.” *Id.*, [0068].

4. **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.**

160. The Furrer-Alvarez-Pollen combination provides that the interior volume is bounded by the rear end of the outer shell and a front end of the breast shield as demonstrated, for example, by Figure 2 of Pollen.

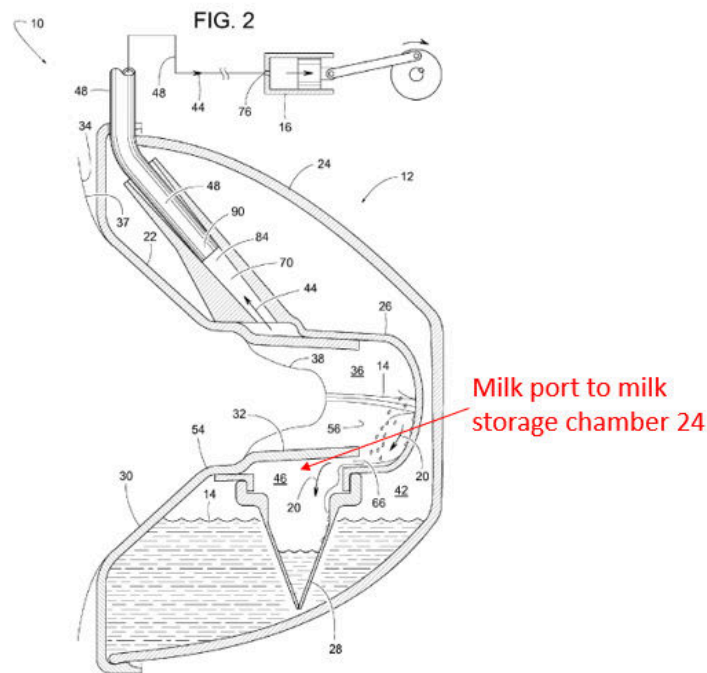


EX1006, FIG. 2 (annotated).

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

161. Furrer discloses this claim for the reasons discussed in Ground 1A, above. Additionally, Pollen provides further teachings that demonstrate that the predictable Furrer-Alvarez-Pollen combination renders this claim obvious. Pollen

describes a similar flow path to that of Furrer, describing that “[t]he expressed milk 14 flows from nipple chamber 36, flows through milk passage 66, and collects at the bottom of charging chamber 46.” EX1006, [0066]. Pollen goes on to describe that “air pressure in charging chamber 46 forces milk 14 (collected during the previous suction period) from charging chamber 46, down through valve 28, and into storage chamber 42.” *Id.*, [0067]. Figure 2 of Pollen shows the milk port through which the milk flows prior to passing through valve 28 into storage chamber 42.



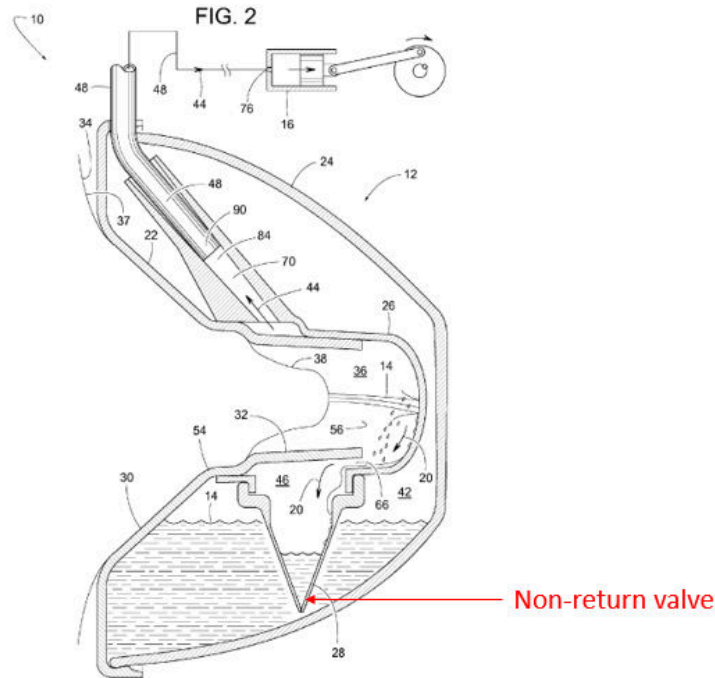
EX1006, FIG. 2.

6. **Claim [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.**

162. The Furrer-Alvarez-Pollen combination provides this claim for the reasons discussed in Ground 1A, above.

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

163. Pollen demonstrates that the predictable Furrer-Alvarez-Pollen combination provides that the breast pump system further includes a non-return valve configured to be mounted to the milk port. For example, 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]. As would have recognized by a POSITA, this description of a “unidirectional” valve indicates that the valve is a non-return valve.



EX1006, FIG. 2 (annotated).

164. Furrer includes similar disclosure, emphasizing the importance of a non-return valve positioned along the flow path between the nipple tunnel and the ultimate milk collection receptacle, thus providing additional disclosures that render obvious this claim. For example, Furrer describes “a check valve is present which separates the receiving area from an attachment for connection to a milk collection container.” EX1004, 3:13-15. In another example, Furrer describes that the breast pump system includes “[a] valve 8, preferably a check valve...arranged on the housing 70 of the media separation device or also on the milk attachment part 28, in order to limit the dead volume when expressing milk and to prevent the expressed milk from flowing back.” EX1004, 4:36-5:4; *see also*, 5:41-49, 6:31-33, FIGs. 1-3,

- 8. Claim [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.**

165. The Furrer-Alvarez-Pollen combination provides this claim for the reasons discussed in Ground 1A, above.

- 9. Claim [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.**

166. The Furrer-Alvarez-Pollen combination provides this claim for the reasons discussed in Ground 1A, above.

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

167. The Furrer-Alvarez-Pollen combination provides this claim for the reasons discussed in Ground 1A, above.

11. Claim [28]

168. The Furrer-Alvarez-Pollen combination provides this claim for the reasons discussed with respect to Claim 17 in Ground 1C (specifically Element [17e], which applies similarly to Element [28e]), above; the reasons discussed in Ground 1B, above, with respect to the Furrer-Alvarez combination; and the reason discussed in Ground 1C, above, regarding the applicability of the analysis of Furrer with respect to claims 17 and 27 to claim 28.

- 12. Claim [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.**

169. The Furrer-Alvarez-Pollen combination provides this claim for the reasons discussed with respect to claim [19] (Ground 1C), above.

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

170. The Furrer-Alvarez-Pollen combination provides this claim for the reasons discussed in Ground 1A, above.

- 14. Claim [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.**

171. The Furrer-Alvarez-Pollen combination provides this claim for the reasons discussed in Ground 1A, above, and the discussion of claim [21] in Ground 1C, above.

- 15. Claim [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.**

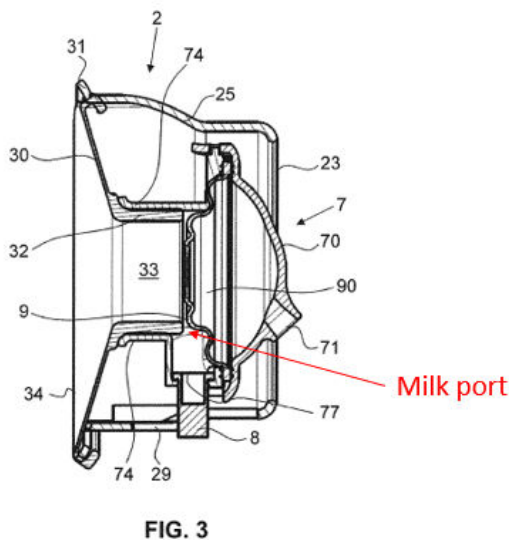
172. The Furrer-Alvarez-Pollen combination provides this claim for the reasons discussed in Ground 1A, above.

D. Ground 1D: Obviousness of Claims 22 and 31 Based on Furrer, Alvarez, Pollen, and Weniger

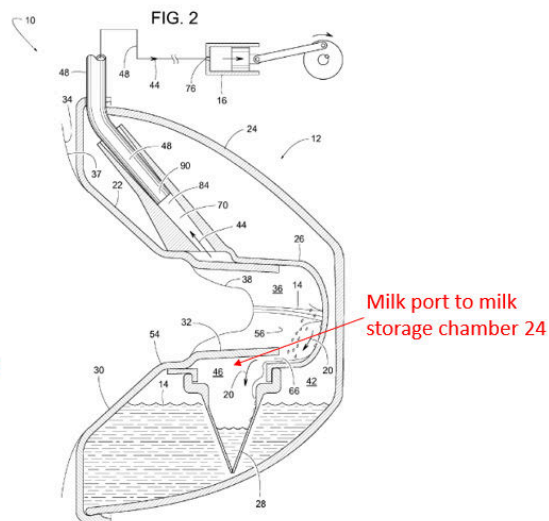
173. Claims 22 and 31 are obvious in light of Furrer in view of Alvarez, Pollen, and Weniger for the reasons discussed below.

1. Motivation To Combine Furrer, Alvarez, and Pollen with Weniger

174. As I discussed above, the breast pump system resulting from the predictable combination of Furrer with Alvarez and Pollen includes a milk port through which expressed milk flows from the area around the nipple to the storage chamber defined by the outer shell and breast shield. EX1006, [0061]-[0063], [0066]-[0067], FIGs. 2, 4; EX1004, 5:59-6:17, FIGs. 3, 7.

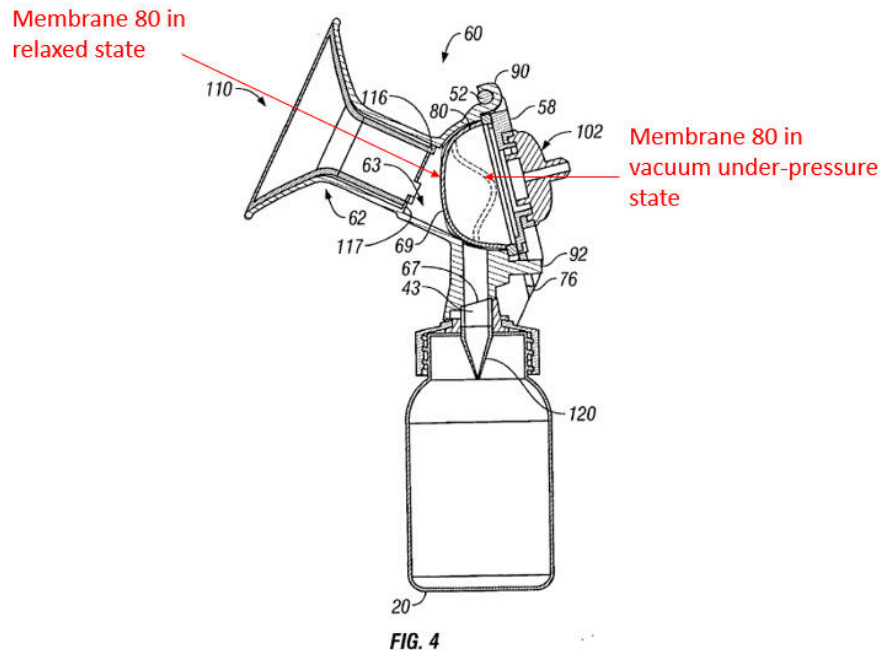


EX1004, FIG. 3



EX1006, FIG. 2

175. Additionally, as I discussed in the overview of Weniger, above, similar to the device of Furrer, Weniger's device includes 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." EX1007, [0033], [0038], [0040]. Figure 4 of Weniger shows this membrane 80 in both relaxed and vacuum under-pressure states.



EX1007, FIG. 4 (annotated).

176. 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]. Weniger goes on to describe that

“[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.

177. Regardless of whether the system of the resulting combination uses the milk port of Pollen or Furrer, a POSITA would have been prompted to apply the suggestion in Weniger to configure the membrane/diaphragm (e.g., Furrer’s “media separation membrane 9”) to extend over and adjacent to the milk port to make the milk passageway “discontinuous” to the Furrer-Alvarez-Pollen system for multiple reasons. As a first reason, a POSITA would have recognized that configuring the membrane 9 to extend over the milk port in the predictable combination to cause the milk flow path to be discontinuous when the membrane 9 is in a relaxed state while opening the passageway to make the milk flow path continuous in the underpressure state (based on the teachings of Weniger) would have prevented milk that has passed through the milk port from returning to the nipple tunnel. EX1007, [0041]. A POSITA would have recognized that it would be desirable to prevent milk from returning to the nipple tunnel as such a back flow of milk could cause discomfort for the user or potentially cause the nipple tunnel to overflow with expressed milk. Such

a scenario could disrupt the seal between the breast shield and breast or could create a mess. A POSITA would have further recognized that 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.

178. As a second reason, a POSITA would have recognized that configuring the membrane 9 to extend over the milk port in the predictable combination to cause the milk flow path to be discontinuous when the membrane 9 is in a relaxed state while opening the passageway to make the milk flow path continuous in the underpressure state (based on the teachings of Weniger) would have resulted in the membrane creating 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. As would have been recognized by a POSITA, the application of such additional pressure by extending the membrane over and adjacent to the milk port in the relaxed state 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.

179. As a third reason, as recognized by Furrer itself, and as would have been known to a POSITA, cyclically interrupting and re-opening the milk flow path “according to a cyclically applied underpressure” by implementing the membrane/diaphragm to extend over and adjacent the milk port in a relaxed state would have “reduce[d] the dead volume” in the resulting device. EX1004, 2:49-56, 6:13-17. A POSITA would have recognized that reduction in dead volume would have resulted in numerous benefits, including reducing the strain on the vacuum pump of the resulting system, which would lead to reduced energy usage requirements, reduced cost, and reduced pump noise, among other known benefits. *See e.g.*, EX1011, [0013]-[0014].

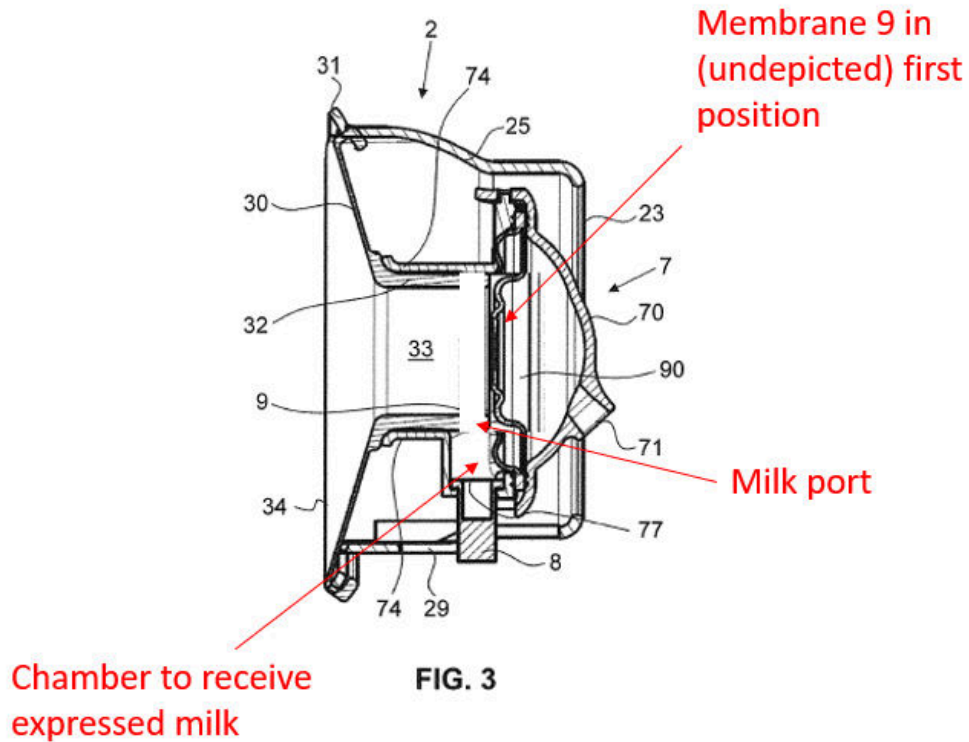
180. As a fourth reason, a POSITA would have been motivated to apply Weniger’s teachings to the Furrer-Alvarez-Pollen system to beneficially implement the resulting device such that the media separation membrane extends over and adjacent to the milk port in a relaxed state because such a configuration for Furrer’s device (as modified by Alvarez and Pollen) applies a known technique to wearable breast pump systems. The Furrer-Alvarez-Pollen-Weniger combination produces predictable outcomes, as discussed earlier. Due to the similarities of the systems described by Furrer, Alvarez, Pollen, and Weniger, including the use of very similar media separation membranes in Furrer and Weniger, a person skilled in the art would have recognized that such a modification would be relatively straight forward and

would have reasonably expected success in making these modifications. This expectation is based on the similarity between the devices, and the fact that the changes would primarily involve straightforward adjustments that would not significantly alter the overall function of the underlying device.

2. Claims [22] and [31]

181. As I discussed above, the teachings of both Furrer and Pollen demonstrate that the resulting breast pump system includes a milk port through which expressed milk flows from the area around the nipple to the storage chamber defined by the outer shell and breast shield. EX1006, [0061]-[0063], [0066]-[0067], FIGs. 2, 4; EX1004, 5:59-6:17, FIGs. 3, 7.

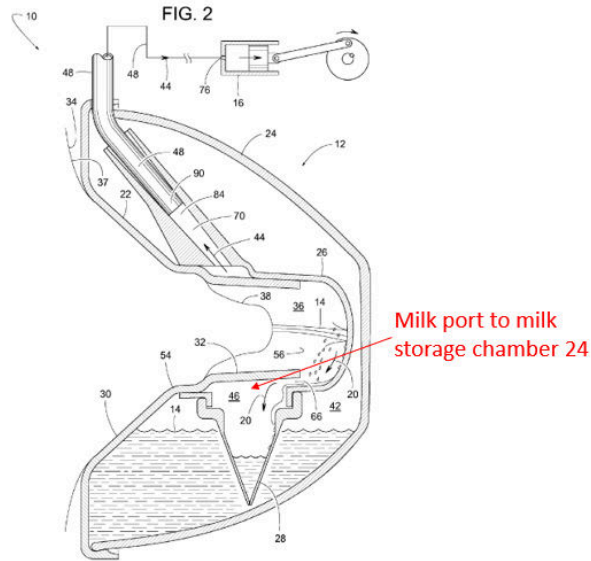
182. For example, Furrer describes a “first position” for the membrane 9 in which membrane 9 is located “at the rear wall of the housing 70” during underpressure “is not shown in the figures.” EX1004, 6:5-12. In this undepicted “first position” in which the membrane 9 is in the under pressure state, the membrane 9, together with the stub 32, defines a milk port through which the expressed milk flows into the chamber.



EX1004, FIG. 3 (modified and annotated).

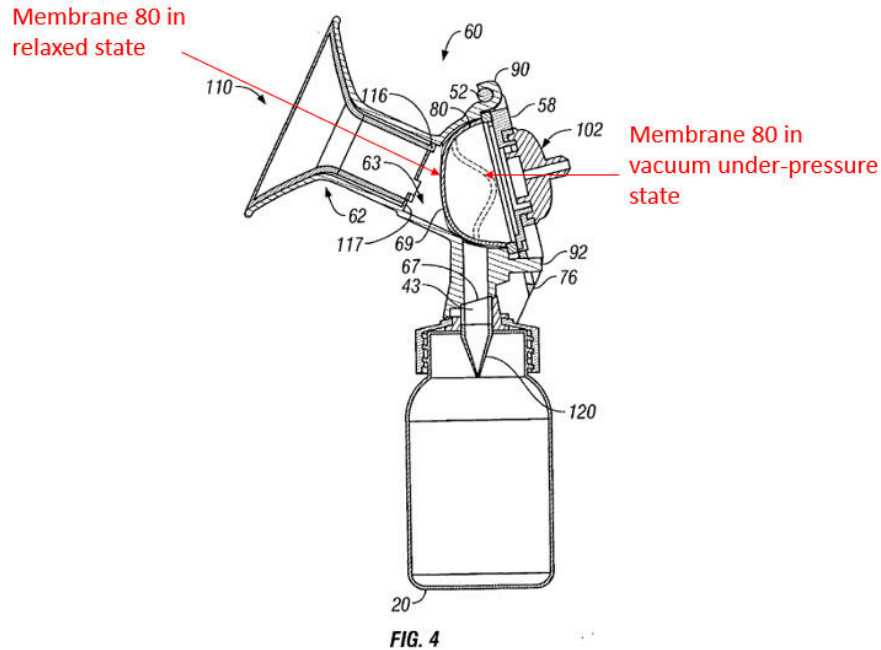
183. Pollen provides similar teachings further confirming that the predictable Furrer-Alvarez-Pollen-Weniger combination includes a milk port to allow expressed milk to flow from the nipple tunnel into the milk storage chamber.

EX1006, [0066]-[0068].



EX1006, FIG. 2 (annotated)

184. Regardless of whether the milk port of Furrer or Pollen is used in the predictable combination, a POSITA would have predictably applied the teachings of Weniger to the Furrer-Alvarez-Pollen system to achieve the benefits discussed above such that the media separation membrane extends over and adjacent to the milk port in a relaxed state. Similar to the disclosure of Furrer, Weniger describes 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.” EX1007, [0033], [0038], [0040]. Figure 4 of Weniger shows this membrane 80 in both relaxed and vacuum under-pressure states.



EX1007, FIG. 4 (annotated).

185. 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]. Weniger goes on to describe that "[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.* As such, as shown above in Figure 4 of Weniger, in the predictable Furrer-

Alvarez-Pollen-Weniger combination, the media separation membrane (diaphragm) extends over and adjacent the milk port when in a relaxed state.

E. Ground 1E: Obviousness of Claim 25 Based on Furrer, Alvarez, Pollen, and Rigert

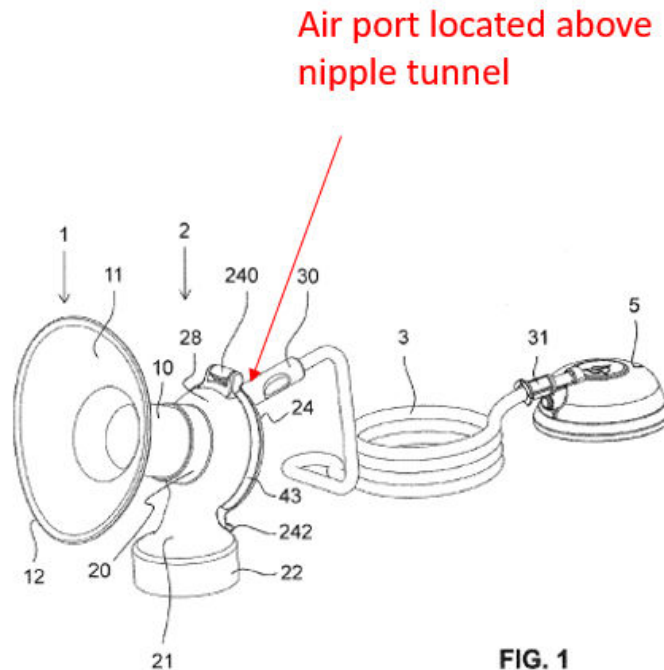
186. Claim 25 is obvious in light of Furrer in view of Alvarez, Pollen, and Rigert for the reasons discussed below.

1. Motivation To Combine Furrer, Alvarez, and Pollen with Rigert

187. As discussed in Ground 1A, above, Furrer discloses that the breast pump system includes “[a] *vacuum connector 71* for connection to a vacuum pump (not shown)” via “a suction line.” EX1004, 5:37-62. The vacuum connector 71 is positioned on the housing 70 (the claimed diaphragm cap). 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 an 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.

188. Rigert describes a similar design for a breast pump that, like the system of Furrer, includes a media separation diaphragm that receives vacuum pressure from a vacuum pump connected to the breast pump via a suction line 3 that couples to a suction connection 23. EX1008, [0052]. More specifically, the breast pump includes a “suction connection 23 [that] is integrally moulded [*sic*] in the top region

of the cover 24.” *Id.*, [0058]. Furthermore, in Rigert’s design, the air port (suction connection 23) is located above the nipple tunnel:



EX1008, FIG. 1.

189. Multiple reasons would have motivated a POSITA to apply Rigert’s suggestion to position the air port (e.g., Furrer’s vacuum connector 71) above the nipple tunnel in the resulting Furrer-Alvarez-Pollen-Rigert combination. EX1008, [0052]-[0058], FIGs. 1-4, 7, 13. As a first reason, a POSITA would have recognized that modifying Furrer’s system to position the vacuum connector 71 above the nipple tunnel 33 (based on the suggestion of Rigert) 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. EX1004, 3:5-12 (Furrer discussing

that its wearable milk collection hub is intended to be “worn under a bra.”)

Positioning the suction line to protrude from the bottom of the bra would have been uncomfortable for users with respect to many bra designs (such as those having an underwire).

190. As a second reason, positioning the vacuum connector 71 above the nipple tunnel 33 (based on Rigert’s suggestion) would have allowed the suction lines to exit the mother’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. As such, the resulting device could be implemented with shorter suction lines which would have reduced the strain on the vacuum pump.

191. As a third reason, positioning the vacuum connector 71 above the nipple tunnel 33 (based on Rigert’s suggestion) such that the suction tube exits through the top of the bra would have allowed the wearer to more easily visually observe the vacuum lines which would allow the wearer to identify kinks or other obstructions that could prevent or diminish suction. Additionally, 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.

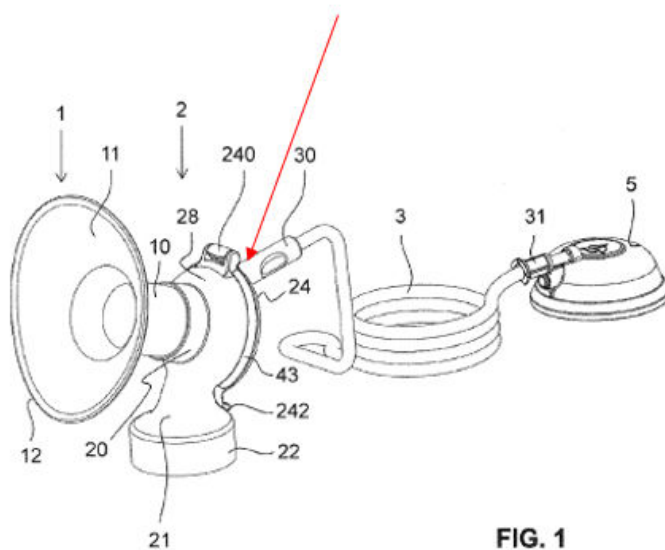
192. As a fourth reason, a POSITA would have been motivated to apply Rigert’s teachings to the Furrer-Alvarez-Pollen system to beneficially implement the resulting device such that the vacuum connector 71 is positioned above (rather than

below) the nipple tunnel 33 because such a configuration for Furrer's device (as modified by Alvarez and Pollen) applies a known technique to wearable breast pump systems. The Furrer-Alvarez-Pollen-Rigert combination produces predictable outcomes, as discussed earlier. Due to the similarities of the systems described by Furrer, Alvarez, Pollen, and Rigert, including the use of very similar media separation membranes and suction line connectors in Furrer and Rigert, a person skilled in the art would have recognized that such a modification would be relatively straight forward and would have reasonably expected success in making these modifications. This expectation is based on the similarity between the devices, and the fact that the changes would primarily involve straightforward adjustments that would not significantly alter the overall function of the underlying device.

2. Claim [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.

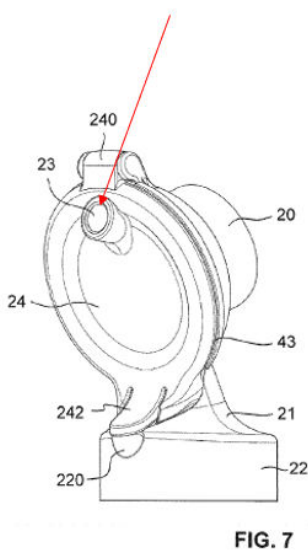
193. The Furrer-Alvarez-Pollen-Rigert combination provides that the diaphragm cap is configured such that the air port can be located above the nipple tunnel. This is demonstrated, for example, by Figures 1 and 7 of Rigert. EX1008, [0056]-[0058].

Air port located above
nipple tunnel



EX1008, FIG. 1.

Air port located above
nipple tunnel



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

F. Ground 1F: Obviousness of Claims 26 and 33 Based on Furrer, Alvarez, Pollen, and Kasting

194. Claims 26 and 33 are obvious in light of Furrer in view of Alvarez, Pollen, and Kasting for the reasons discussed below.

1. Motivation To Combine Furrer, Alvarez, and Pollen with Kasting

195. A POSITA would have been motivated to apply the suggestions of Kasting to the Furrer-Alvarez-Pollen combination to include a pair of recessed finger grips on Furrer's housing 70 in the resulting system for multiple reasons. As a first reason, applying Kasting's suggestion for including two recessed pockets to allow for the cap/cover "to be grasped in an ergonomically-convenient manner" would allow for more easy gripping and movement of Furrer's housing 70. EX1012, 11:33-43. Furrer is express that "the housing 70 can be arranged moveably in the main body 25." EX1004, 4:60-63. As such, a POSITA would have recognized that it would have been beneficial to improve the device (based on Kasting's suggestion) to make the housing 70 easier to grip "by the hand of user" such as by the user's fingers. EX1012, 11:24-32. This would have facilitated easy sliding of the housing 70 along the slits 24. EX1004, 7:25-31.

196. As a second reason, implementing Kasting's suggestion to include recessed gripping features on the housing 70 of Furrer's device would have allowed the user to more easily manipulate the device as a whole when applying the device

to the breast of the user or removing the device from the breast. A POSITA would have recognized that dropping and potential damage to the device could be more easily prevented by providing better gripping surface through the use of recessed finger grip features as suggested by Kasting.

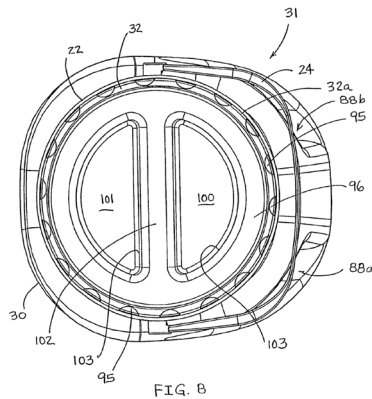
197. As a third reason, inclusion of recessed finger grips on the housing 70 of Furrer, as suggested by Kasting, would have allowed the user to “more easily reapply” the diaphragm cap after, for example, disassembling to clean the inside of the device. EX1012, 11:38-43.

198. As a fourth reason, a POSITA would have been motivated to apply Kasting’s teachings to the Furrer-Alvarez-Pollen system to beneficially implement the resulting device such that the housing 70 (the claimed diaphragm cap) includes recessed finger grip features because such a configuration for Furrer’s device (as modified by Alvarez and Pollen) applies a known technique to a known wearable breast pump system. The Furrer-Alvarez-Pollen-Kasting combination produces predictable outcomes, as discussed earlier. Due to the straightforward nature of the teachings of Kasting, for improving the ability to grip covers/caps of various devices, and the shared goal of improving sealing for various devices, a person skilled in the art would have recognized that such a modification would be relatively straightforward and would have reasonably expected success in making these modifications. This expectation is based on the simple nature of Kasting’s suggestion and the fact

that the changes would primarily involve straightforward mechanical adjustments that would not significantly alter the overall function of the underlying device.

2. Claims [26] and [33]

199. As I discussed above, the breast pump system resulting from the combination of Furrer with Alvarez, Pollen, and Kasting 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. *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.

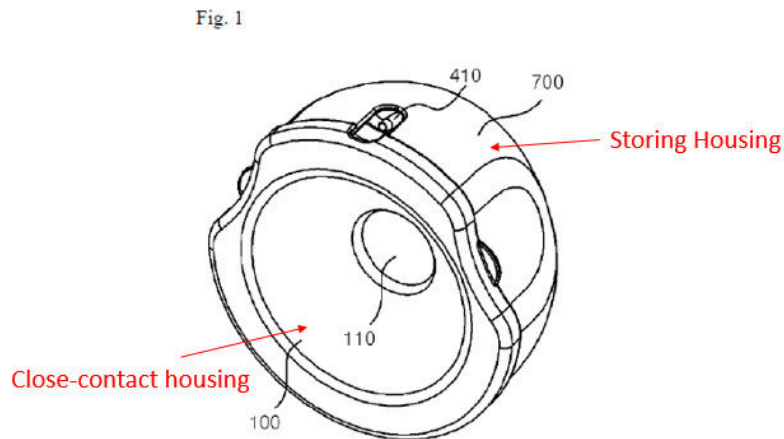
G. Ground 2A: Obviousness of Claims 17-19, 21, 23-24, 27-30, and 32 Based on Park and Silver

200. Claims 17-19, 21, 23-24, 27-30, and 32 are obvious in light of Park in view of Silver for the reasons discussed below.

1. Motivation To Combine Park and Silver

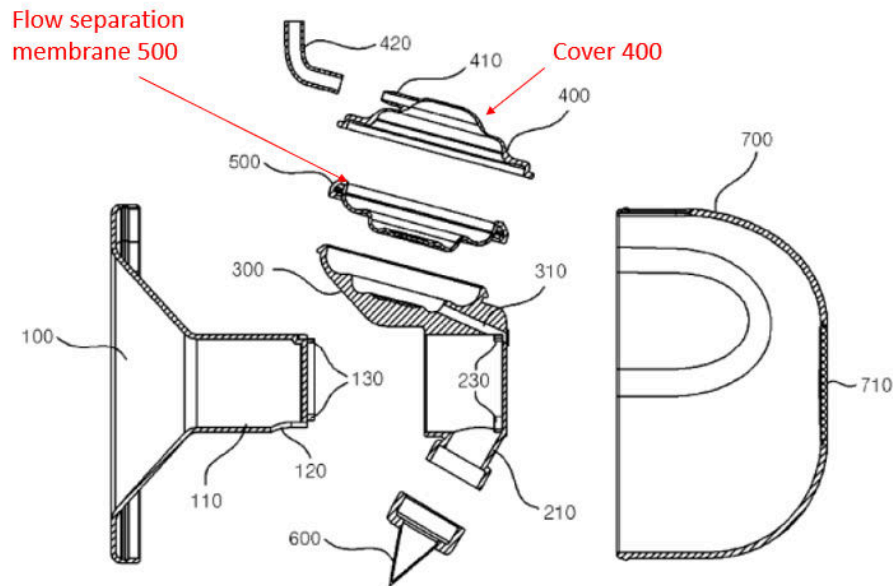
201. As I discussed above in the overview of Park, Park Park's breast pump "enables a lactating woman to freely use both hands during milking" and is "capable of preventing breast milk flowing backward," and is thereby "easily cleaned and maintained." EX1010, [8]; *see id.*, Abstract, [1].

202. Park's breast pump includes a "close-contact housing 100" and a "storing housing 700," such as illustrated in Figure 1. EX1010, [37], [42]-[44].



Id., Fig. 1 (annotated). The close-contact housing is designed to contact a mother's breast and includes a "protruding part 110, which extends forward and is formed in the portion corresponding to nipple of a lactating woman." *Id.*, [37]. The "storing housing 700" includes an "air nozzle 410" to enable the passage of air flow. *Id.*, [39]. The close-contact housing and storing housing are coupled in a "detachable" manner "so as to collect extracted breast milk even without using a separate milk bottle." *Id.*, [42].

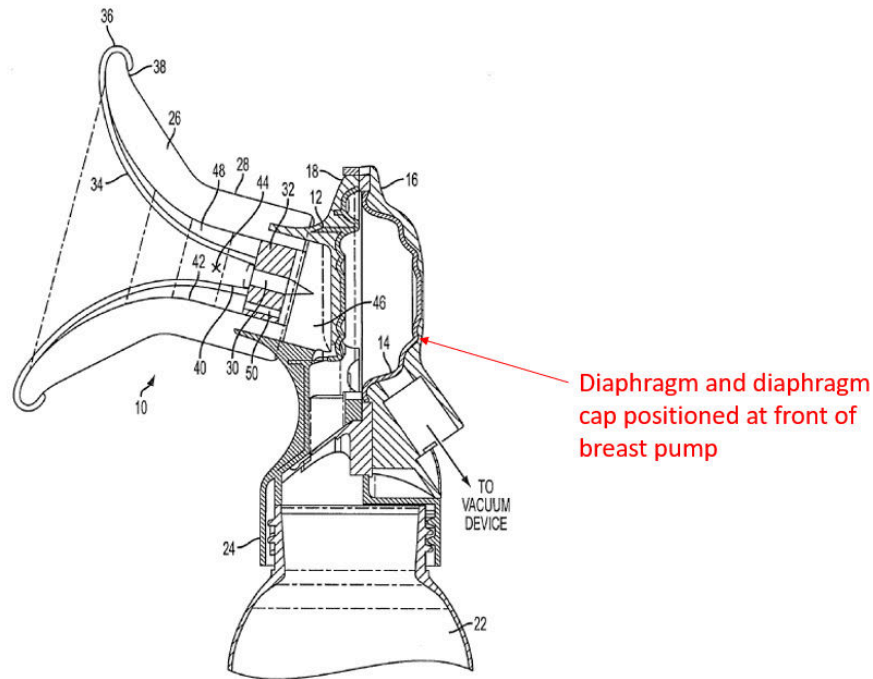
203. As shown in Figure 5 of Park, Park's device includes a "flow separation membrane 500" positioned near the top of the wearable milk collection hub along with a cover 400 that covers and seals the flow separation membrane 500. EX1010, [6], [37], [39].



EX1010, Fig. 5 (annotated), 4:59-65.

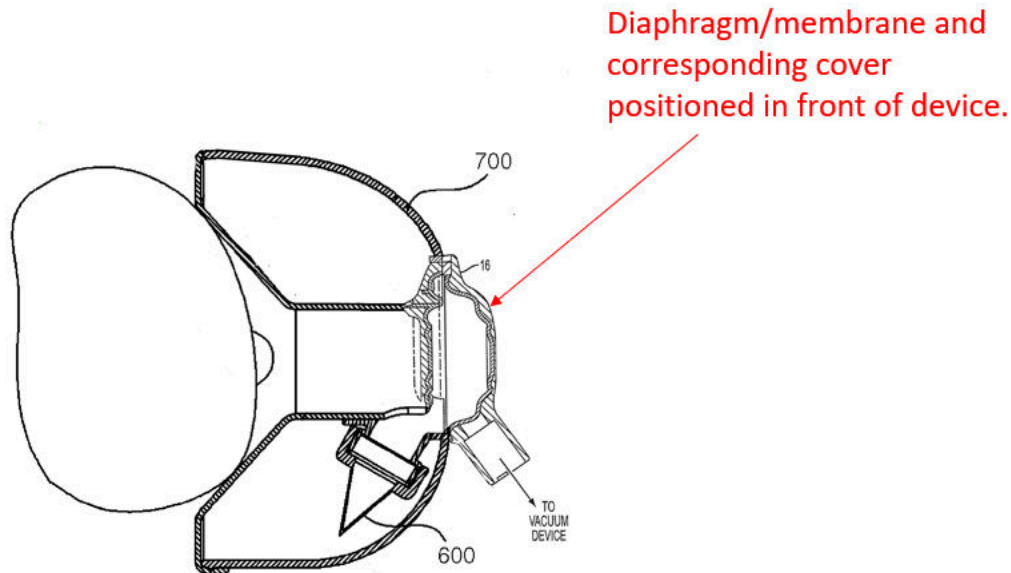
204. Silver similarly describes a breast pump system having "a barrier component (see FIG. 5) or diaphragm 14 that is enclosed in a clamshell-like chamber made of a front housing 18 and a rear housing 16." EX1011, [0059]. The diaphragm 14 "is reciprocated within the space of the housings 16, 18 by an intermittent vacuum from a vacuum source" to convey the vacuum underpressure to the area near the mother's nipple. *Id.* However, Silver differs from Park in that it advantageously positions the diaphragm and diaphragm cap at the front of the device near the

location of the nipple to minimize the dead volume near the nipple, providing numerous advantages that would have been apparent to a POSITA.



EX1011, FIG. 5 (annotated).

205. As such, multiple reasons would have motivated a POSITA to modify the breast pump system of Park to position the diaphragm and diaphragm cap at the front of the resulting device, in the area directly in front of the nipple. For example, a POSITA would have recognized that Silver's teachings could have been applied to Park's system in the following manner to achieve the benefits described below:



Combination of EX1010, FIG. 7 with EX1011, FIG. 5.² While this is one example configuration that a POSITA would have envisioned based on the teachings of Park and Silver, a POSITA would have possessed the skill to arrange and configure the components in the proposed manner to achieve the below described benefits when implementing the Park-Silver combination.

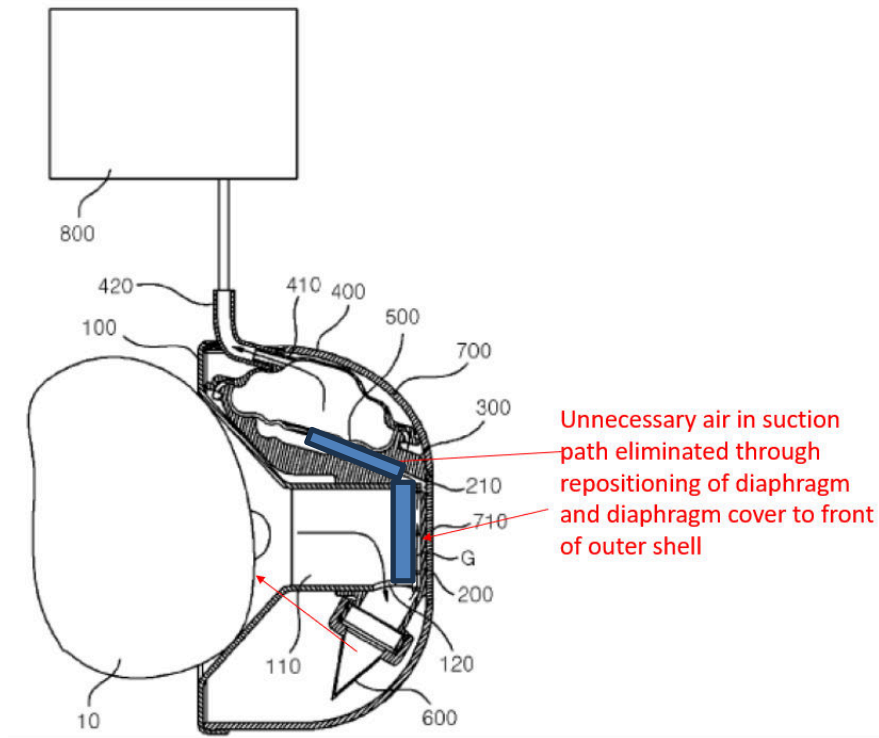
206. As a first reason, a POSITA would have been motivated to position the diaphragm and cover of the resulting device in the front of the outer shell (as suggested by Silver) and other teachings of Silver to Park's system to beneficially "substantially limit[] the amount of air between the breast/nipple and the breastshield." EX1011, [0013]-[0014], [0016], [0019]. As described by Silver, the

² Not drawn to scale.

improved assembly and positioning for the breast shield and diaphragm along with other teachings of Silver (such as the narrow shape of the inner wall of breast shield 10, front positioned diaphragm 14, and other related components (e.g., Silver's valve 30)) together act to "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"). As would have been known to a POSITA (and corroborated by Furrer), 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. Such reduction or elimination of dead volume would have produced numerous benefits of which a POSITA would have been aware. For example, "[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]. This reduction in the amount of vacuum pressure required would have beneficially led to a system in which "[l]ess energy is required for the expression of milk, and thus the size of pump used can be decreased, thereby reducing the overall cost of the device." *Id.* 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). Positioning the diaphragm in line

with the nipple tunnel enables the diaphragm to reduce dead volume in the nipple tunnel length, as would have been recognized by a POSITA.

Fig. 8



EX1010, FIG. 8 (annotated).

207. As recognized by Silver, “reduction of air...in the entire system” helps to achieve the recited “inventive objectives” and thus application of Silver’s teachings to Park to reposition the diaphragm and cover the diaphragm with a cover in the front of the device would have not only moved the diaphragm closer to the area of the nipple but also eliminated the excess air in Park’s original suction path.

EX1011, [0018], [0028].

208. As a second reason, another benefit that a POSITA would have recognized as extending from reducing or eliminating dead volume by positioning the diaphragm and diaphragm cap near the area of the nipple is that the resulting system could be designed “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.

209. As a third reason, another benefit that a POSITA would have recognized as extending from reducing or eliminating dead volume by positioning the diaphragm and diaphragm cap near the area of the nipple “because of the lower energy, the vacuum pump is quieter during use, which in turn increases the comfort and discretion.” EX1011, [0014].

210. As a fourth reason, a POSITA would have recognized that such a repositioning of the diaphragm and diaphragm cap along with other teachings of Silver, including the shape of the inner portion of the breast shield, would have allowed the vacuum pressure in the resulting device 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].

211. As a fifth reason for such a modification, a POSITA would have recognized that 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].

212. As a sixth reason, application of Silver’s suggestions to Park’s system 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].

213. As a seventh reason, a POSITA would have recognized that it would have been obvious and beneficial to position the diaphragm cap at the front of the device, and to include a removable diaphragm cap, as taught by Silver, to facilitate easy access to the internal components of the device to allow for cleaning and/or replacement of the diaphragm and other components. *See e.g.*, EX1008, [0027]. Such a positioning of the diaphragm cap would also further the goal of reducing dead volume and thereby increase the benefits incurred through reduction of dead volume in the device.

214. As an eighth reason, a POSITA would have recognized that, as described by Silver, “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]. Therefore, applying Silver’s

suggestion to locate the diaphragm and diaphragm cap at the front of the device in the area near the nipple “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), especially with the diaphragm and diaphragm cover moved to the front of the nipple tunnel, freeing up space at the top of the storing housing 700. *Id.* For example, as described by Silver, “[t]he mother may, for example, even express milk while lying down.” *Id.*, [0030].

215. As a ninth reason, a POSITA would have been motivated to apply Silver’s teachings to Park’s system to beneficially implement the resulting device such that the diaphragm and diaphragm cap are located at the front of the device because such a configuration for Park’s device applies a known technique to wearable breast pump systems. The Park-Silver combination produces predictable outcomes, as discussed earlier. Due to the similarities of the systems described by Park and Silver, including the use of media separation membranes in Park and Silver to convey vacuum pressure to the area near the nipple, a person skilled in the art would have recognized that such a modification would be relatively straight forward

and would have reasonably expected success in making these modifications. This expectation is based on the similarity between the devices, and the fact that the changes would primarily involve straightforward mechanical adjustments that would not significantly alter the overall function of the underlying device.

216. Finally, a POSITA would have recognized that the above described modifications based on the suggestions of Silver would have been beneficially applied to Park's system without detracting from the benefits of Park's original design. Specifically, such a modification to include the diaphragm and diaphragm cap at the front of the resulting device would have still retained the other remaining components of Park's system, including storing housing 700 for storing expressed milk. As would have been apparent to a POSITA, 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" thereby retaining this convenient feature of Park's device. EX1010, [6], [42]. The application of Silver's suggestions to Park would have therefore retained the advantages of Park's unmodified design by allowing "a lactating woman [to] use both hands because the lactating woman can extract breast milk even without holding a separate milk bottle." *Id.*

217. Furthermore, the resulting system would have retained Park's functionality of "preventing a phenomenon in which the breast milk filled in the storing housing 700 flows backward through the breast milk discharge tube 210" by including Park's valve 600 in the combined system. EX1010, [44]. 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].

218. In addition to the above described modification to Park based on the teachings of Silver, a POSITA would have also predictably applied Silver to Park to implement Park's electric pump 800 to be powered with a battery for multiple reasons. EX1011, [0005]. As a first reason, Park describes designs utilizing electric pumps, stating that "electric breast pumps include an air pressure generating pump having a motor and an air cylinder." EX1010, [5], [37], [49]. As would have been known to a POSITA at the time, for electric-powered breast pumps, the only two options for providing electricity to the pump was either via a wire plugged into an outlet or via a battery, as would have been well-known to a POSITA. *See e.g.*, EX1005, [0082]; EX1011, [0005]; EX1013, 7:52-58, 8:14-17; EX1015, [0003], [0020]; EX1022, [0026]-[0027] (corroborating the knowledge of a POSITA that motorized breast pumps were powered by a cord plugged into an outlet or by

battery). It would have been obvious for a POSITA to utilize a battery as the power source for Park's pump (as suggested by Silver) because it was one of the two available options and would have provided known benefits. Use of battery power for Park's pump would have provided a convenient solution that could still function even when a wall outlet is unavailable (such as during a power outage).

219. As a second reason, a POSITA would have recognized that use of a battery powered control unit, as suggested by Silver, for the pump in the resulting system would have beneficially provided a portable system that was usable during travel. Additionally, such a configuration would have allowed the user to move freely about a room, or be positioned in a location within a room without being tethered to a wall plug, allowing the user to, for example, sit or lay in the most convenient location while using the system without having to worry about being close to an outlet.

220. As a third reason, a POSITA would have been motivated to apply Silver's teachings to Park's system to beneficially implement the resulting device such that the vacuum pump controller operates off of battery power because such a configuration for Park's device applies a known technique to wearable breast pump systems. The Park-Silver combination produces predictable outcomes, as discussed earlier. Due to the similarities of the systems described by Park and Silver, including the use of motor-powered vacuum pump controllers in Park and Silver to convey

vacuum pressure to the area near the nipple, a person skilled in the art would have recognized that such a modification would be relatively straight forward and would have reasonably expected success in making these modifications. This expectation is based on the similarity between the devices, and the fact that the changes would primarily involve straightforward mechanical adjustments that would not significantly alter the overall function of the underlying device.

2. Claim 17

h. [17pre]: A breast pump system comprising:

221. Park discloses a breast pump that is “worn on a breast of a lactating woman.” EX1010, [5]. Park’s breast pump “enables a lactating woman to freely use both hands during milking” and is “capable of preventing breast milk flowing backward,” and is thereby “easily cleaned and maintained.” EX1010, [8]; *see id.*, Abstract, [1]. Silver similarly describes a breastshield for use with a breastpump for expressing milk.” EX1011, [0013].

i. [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

222. The Park-Silver combination provides a control unit comprising: a battery, and a pump configured to be powered by the battery and to generate negative air pressure. Park describes that it’s breast pump design is applicable to both manual and electric breast pump devices. EX1010, [4]-[5]. With respect to electric breast pumps, Park describes “electric breast pumps include an air pressure generating

pump having a motor and an air cylinder, a funnel-shaped suctioner connected to the air pressure generating pump and worn on a breast of a lactating woman.” *Id.* Park goes on to describe that “[w]hen such electric breast pumps are used, there are merits in that a user does not consume a great amount of force and the milk extracting efficiency is improved.” *Id.* Park then goes on to describe that its specific implementation “may further include an electric pump for suctioning air through the air tube.” *Id.*, [21]. Such electric breast pumps create suction or “negative [air] pressure.” EX1010, [4]-[6], [21], [37]. As I discussed above, in the resulting combination with Silver, the vacuum pump controller is powered by a battery. EX1011, [0005].

223. A POSITA would have also understood that Park’s vacuum pump is a controller due to the description in Park that the vacuum pump operates in “operated” and “not operated” modes. EX1010, [53]-[54]. In other words, Park’s vacuum pump contains functionality for switching between operated and not operated modes and is therefore a control unit. In the “not operated” state “a vacuum pressure is not formed inside from a communication flow passage 310 to a protruding part 110” while in the “operating” stage “a vacuum pressure is generated in the communication flow passage 310.” *Id.* A POSITA would have recognized that such motor-driven electric breast pumps that cycle between a state in which no vacuum pressure is applied and a state in which vacuum pressure is applied are, or at least plainly

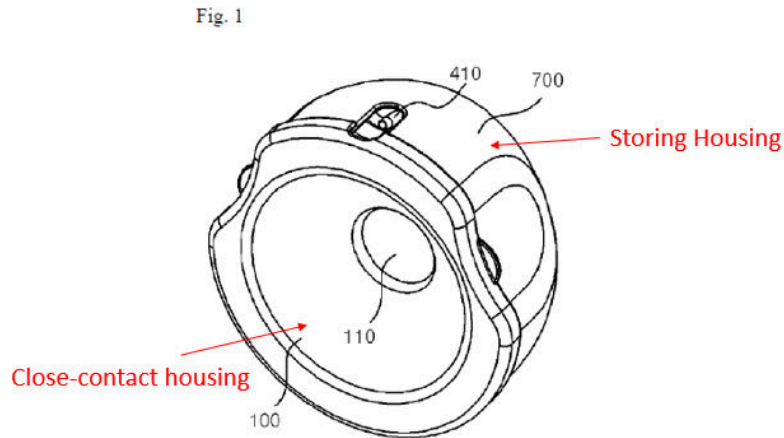
suggest, control units. Specifically, a POSITA would have recognized that such motorized-pumps would have controlled suction to safely and repeatably achieve the this cycling between vacuum pressure and non-vacuum pressure states described in Park and therefore are control units. As such, Park discloses or renders obvious the claimed control unit.

224. Alternatively, a POSITA would have found it 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, which would improve usability of the device. 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].

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

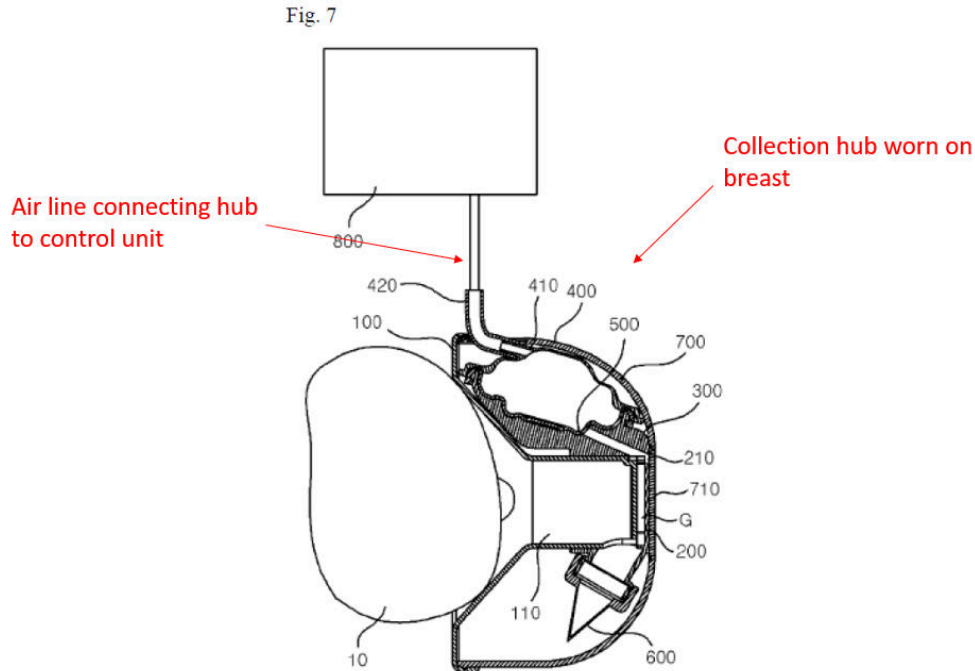
225. Park discloses that the shell of the breast pump system in the Park-Silver combination is "worn on a breast of a lactating woman" to "enable[] a lactating woman to freely use both hands during milking" and is "capable of

preventing breast milk flowing backward,” and is thereby “easily cleaned and maintained.” EX1010, [5], [8], Abstract, [1]. Park’s breast pump includes a “close-contact housing 100” and a “storing housing 700,” such as illustrated in Figure 1. EX1010, [37], [42]-[44].



Id., Fig. 1 (annotated). The “storing housing 700” includes an “air nozzle 410” to enable the passage of air flow. *Id.*, [39]. The close-contact housing and storing housing are coupled in a “detachable” manner “so as to collect extracted breast milk even without using a separate milk bottle.” *Id.*, [42].

226. As shown in Figure 7, an 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).

227. Silver provides a similar disclosure, describing that a tube 20 connects the control unit to the wearable milk collection hub:

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, thereby forming a plenum between the sheath member 34 and the inner sidewall 42 of the shield via a channel 50.

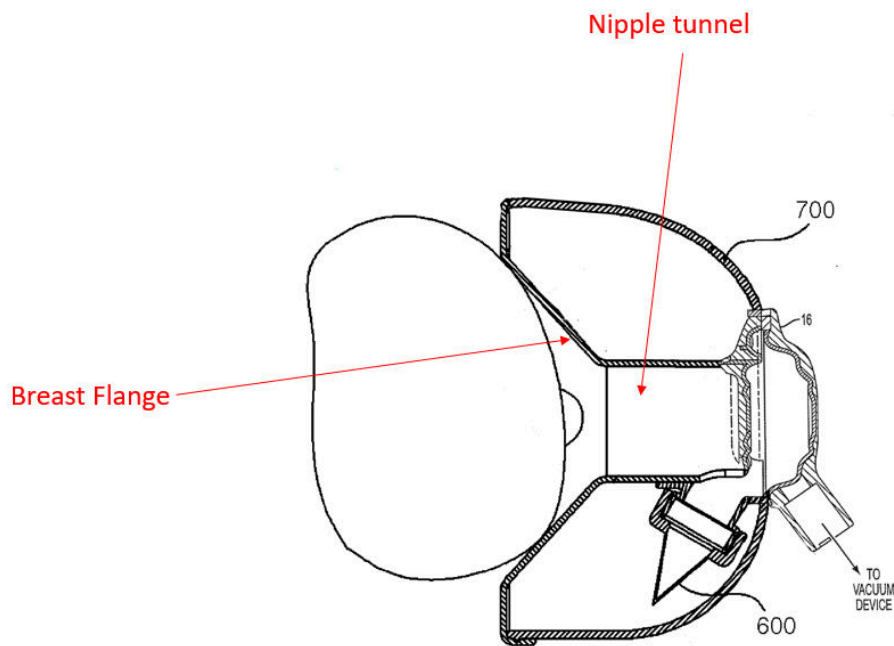
EX1011, [0067].

228. As I discussed above with respect to Elements [17a-1]-[17a-3], a POSITA would have found it 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].

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

229. As I discussed above in describing the combination of Park with Silver, a POSITA would have been motivated to apply the teachings of Silver to Park to implement Park's device with the diaphragm and diaphragm cover positioned at the front of the wearable milk collection hub, such as is depicted in the following example.

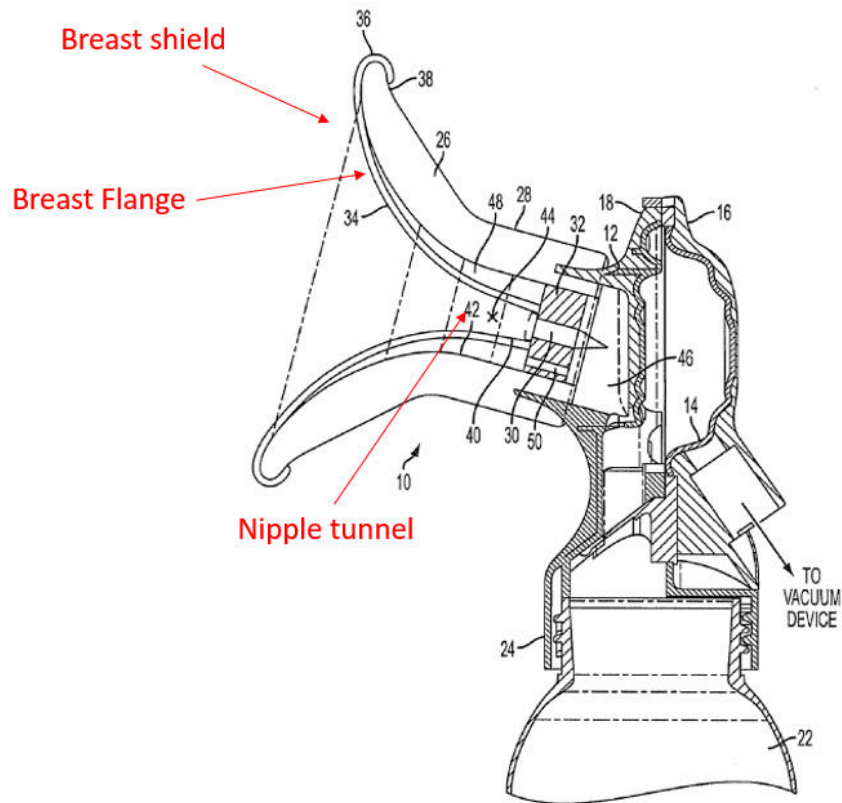


Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

230. As shown in the above mockup, the resulting combination includes a breast shield having a breast flange and a nipple tunnel extending from the breast

flange. For example, Park describes “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]. Silver includes a complimentary disclosure, describing a “breastshield” having “a sheath-like member 34” (the claimed breast flange) and a “nipple tunnel.” EX1011, [0063]-[0064].

Figure 5 of Silver shows the breast shield having a breast flange and nipple tunnel:



EX1011, FIG. 5 (annotated).

231. These components are highly similar to the breast shield, flange, and nipple tunnel of the preferred embodiment of the '454 patent. For example, the '454 patent discloses that a “breast shield” “is made up of a “breast flange” and “a nipple

tunnel” (EX1001, 5:46-49), where the breast flange “contacts the user’s breasts” (*id.*, 5:49-50) and the nipple tunnel is “shaped to receive a nipple” (*id.*, 6:23-24). The ’454 patent illustrates its breast shield 21 in Figure 3, with the flange 32 and nipple tunnel 31:

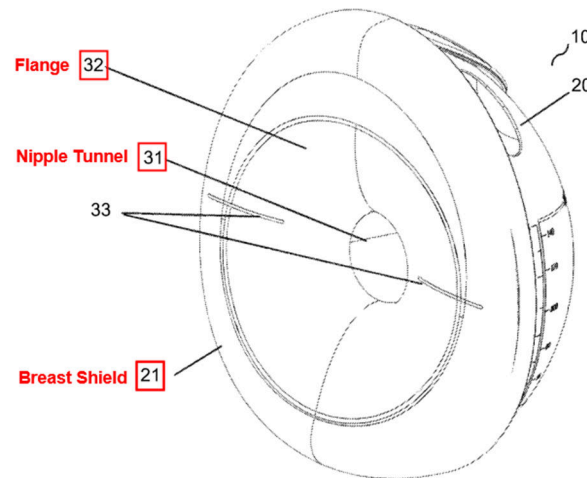


FIGURE 3

EX1001, FIG. 3 (annotated).

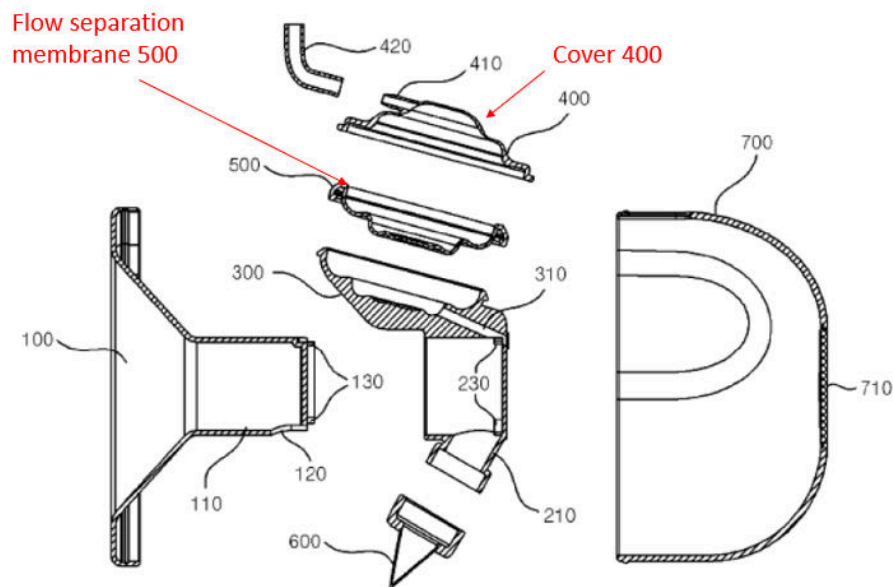
232. As can be seen, in comparing the mockup of the combination of Park with Silver to Figure 3 of the ’454 patent, each of these claimed structures is provided by the Park-Silver combination.

- I. **[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;**

233. The Park-Silver combination provides a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel. The ’454 patent interchangeably refers to a

“diaphragm” as a “membrane”: “Diaphragm cap 22 sits over the flexible diaphragm or membrane 61 and a negative pressure chamber is hence formed between diaphragm cap 22 and one side of the flexible diaphragm 61.” EX1001, 7:41-45 (referring to diaphragm and membrane by reference number 61); *see also id.*, 7:32-43, Fig. 6 (diaphragm 61).

234. Both Park and Silver disclose this claimed “membrane.” In the case of Park, Park describes applying suction to a breast by using a “flow separation membrane 500” to create negative pressure. EX1010, [6], [39]. The “flow separation membrane 500” is covered and sealed by a “cover 400,” such as illustrated in Figure 5 of Park. EX1010, [37].

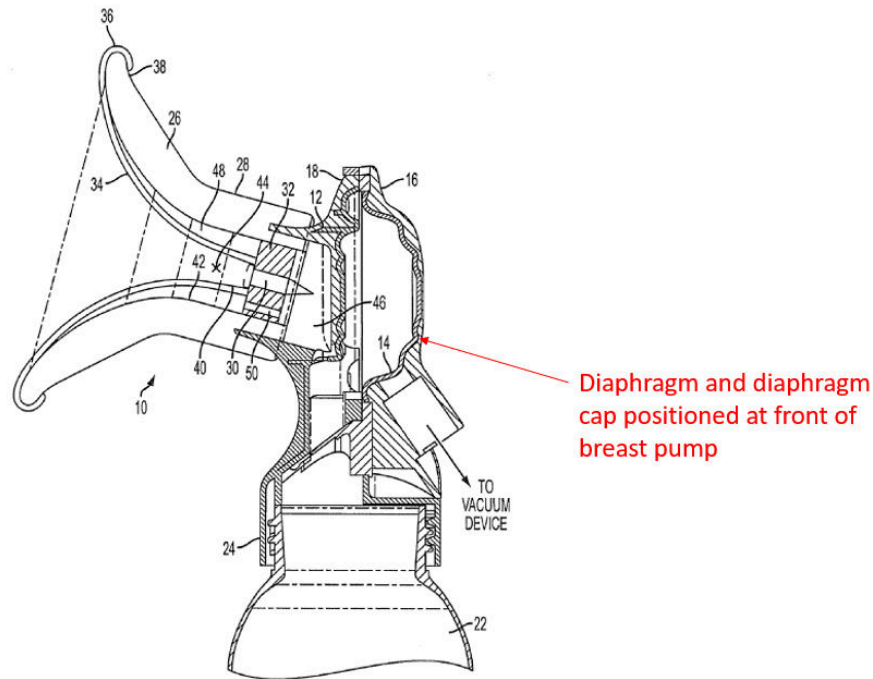


EX1010, Fig. 5 (annotated), 4:59-65. The flow separation membrane 500 “is formed of a ductile material so as to be easily bendable by external force” and generates “vacuum pressure” such that “breast milk is extracted from the breast 10 of the

lactating woman” via the “the protruding part 110” of the “close-contact housing 100.” EX1010, [39]. Specifically, “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 upward.” *Id.* Further, “when the flow separation membrane 500 is moved upward, the space between the flow separation membrane 500 and the funnel connector 300 is expanded to form a vacuum pressure.” *Id.* The vacuum pressure is then “transferred to a breast 10 of a lactating woman through the communication flow passage 310, the spacing space G, the breast milk discharge hole 210, and the inside of the protruding part 110, and thus, breast milk is extracted from the breast 10 of the lactating woman.” *Id.* The flow separation membrane further prevents milk from “flow[ing] backward up to the air nozzle 410.” *Id.*, [40].

235. Silver similarly describes a breast pump system having “a barrier component (see FIG. 5) or diaphragm 14 that is enclosed in a clamshell-like chamber made of a front housing 18 and a rear housing 16.” EX1011, [0059]. The diaphragm 14 “is reciprocated within the space of the housings 16, 18 by an intermittent vacuum from a vacuum source” to convey the vacuum underpressure to the area near the mother’s nipple. *Id.* Silver differs from Park in that it advantageously positions the diaphragm and diaphragm cap at the front of the device near the location of the

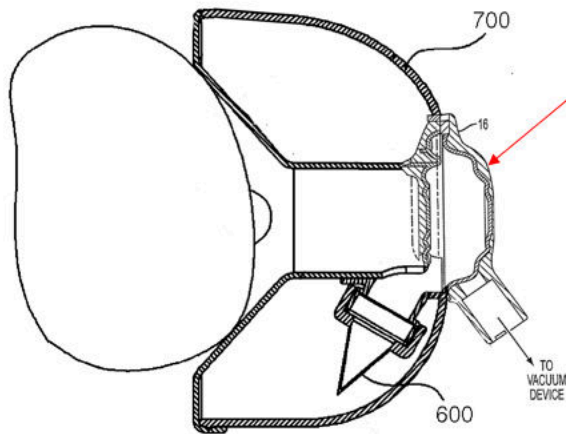
nipple to minimize the dead volume near the nipple, providing numerous advantages that would have been apparent to a POSITA.



EX1011, FIG. 5 (annotated).

236. As discussed above, A POSITA would have been motivated to apply the teachings of Silver to Park to position the diaphragm (and diaphragm cap) in the resulting device at the front of the outer shell.

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



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

- m. [17e]: 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

237. The Park-Silver combination provides 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.

238. The '454 patent describes the “outer shell” as “having a curved shape that is configured to contact the inner surface of the bra” and that it “fits or latches onto a breast shield 21 that forms the rear surface of the hub 10” (EX1004, 5:40-46), as shown below in Figure 3 of the '454 patent:

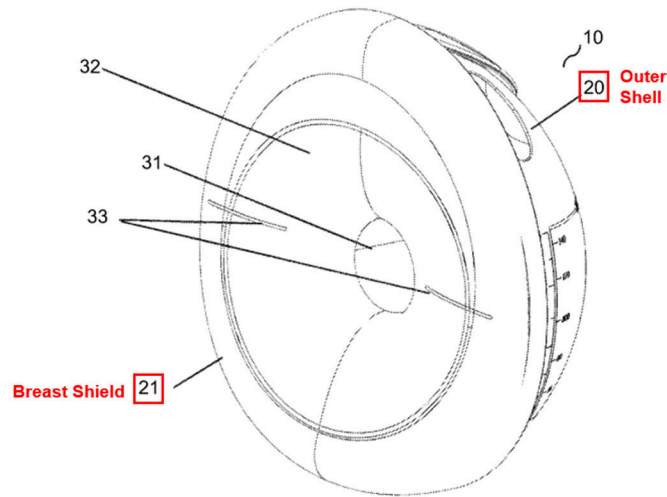
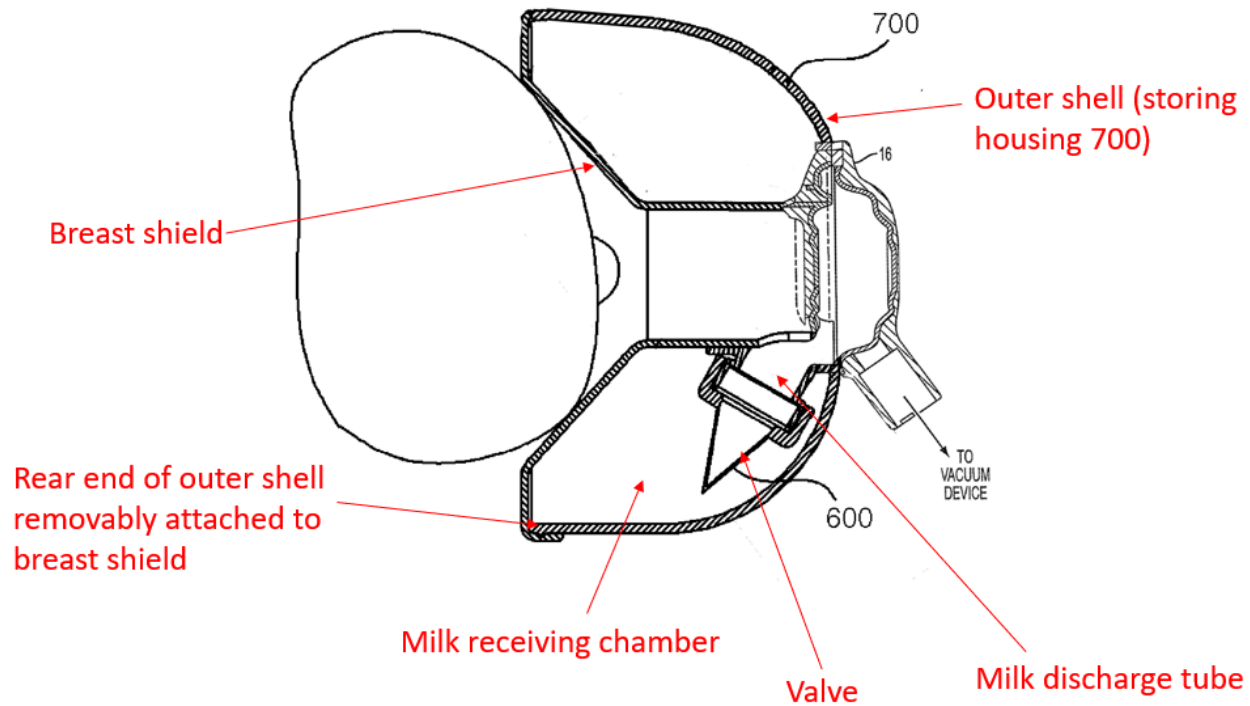


FIGURE 3

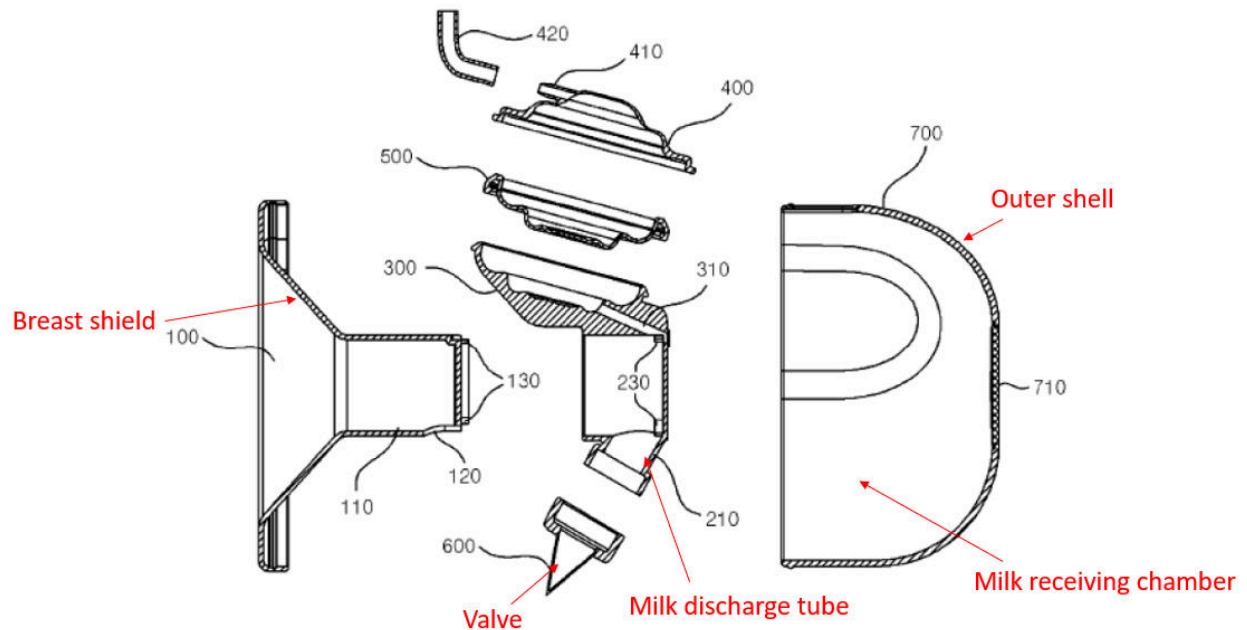
EX1004, FIG. 3 (annotated).

239. Park discloses this same configuration for the outer shell in the form of the storing housing 700. As shown in the mockup of the Park-Silver combination generated from combining figure 7 of Park and figure 5 of Silver, 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.



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

240. Park describes this detachable configuration, describing that “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]. The exploded view shown in Figure 5 of Park shows these components.



EX1010, FIG. 5 (annotated).

- n. [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.

241. The Park-Silver combination provides 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.

242. As previously discussed, according to the '454 patent, the “rear end” is the side that is directed towards the mother’s breast and the “front end” is the side that is directed away from the mother’s breast. *See, e.g.*, EX1001 at 5:56-58 (describing Figure 2 as “a perspective front view of a milk collection hub” and

Figure 3 as “a perspective rear view of a milk collection hub”); *id.*, Figs. 2, 3. The ’454 patent describes the diaphragm cap as “located at the front of the outer shell 20, and form[ing] a central region on the front surface of the outer shell 20” (*id.*, 5:56-58):

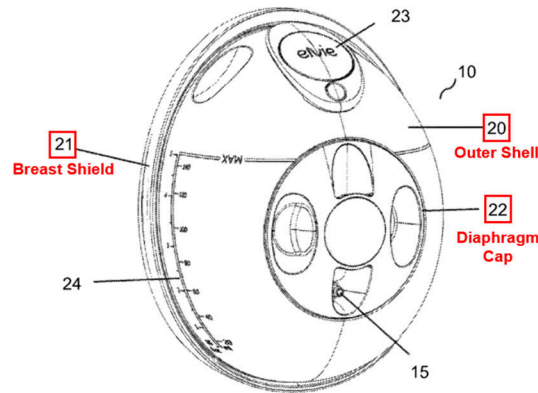


FIGURE 2

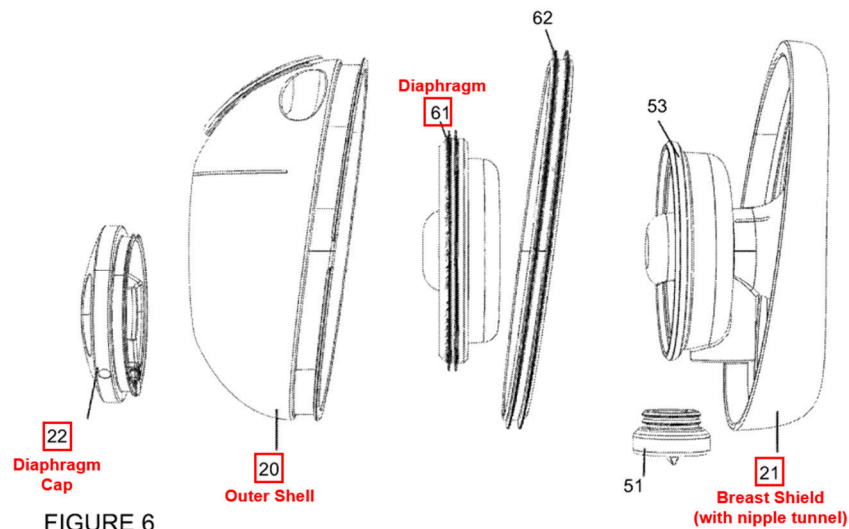
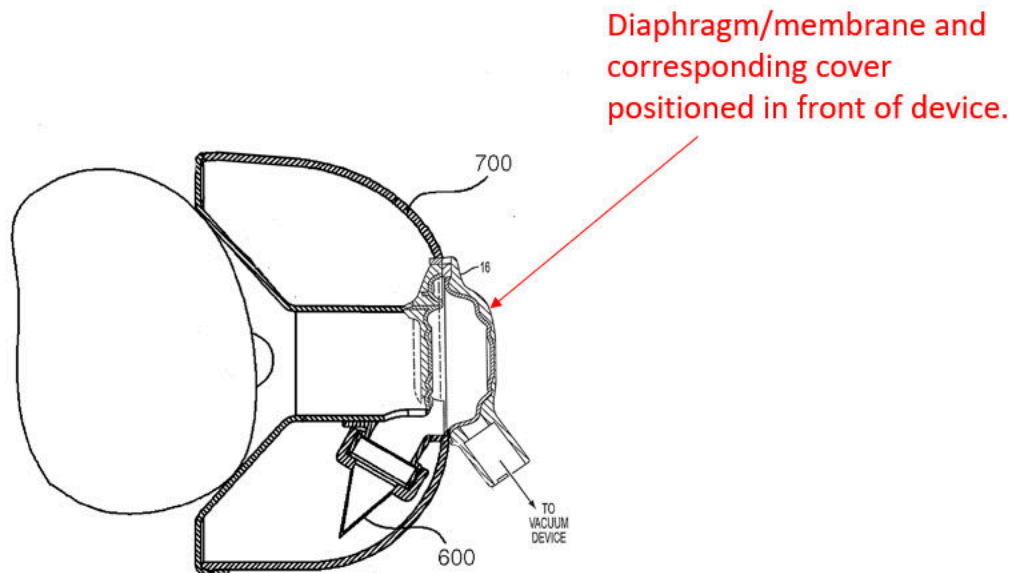


FIGURE 6

Id., Fig. 2 (annotated), Fig. 6. As can be seen, in this position, the diaphragm 61 and diaphragm cap 22 are located at the end of the nipple tunnel, away from the mother’s breast.

243. The predictable combination of Park with Silver provides this same configuration. For example, in the predictable Park-Silver combination, Park's diaphragm cover 400 would be repositioned to the front of the front surface of Park's storing housing 700 based on the suggestion of Silver to be positioned in the location of Silver's rear housing 16 (which covers Silver's diaphragm 14 and forms a front surface of Silver's housing). EX1010, [37], [39], [42], [54]-[56], FIGs 5, 7; EX1011, [0059], FIG. 5. As shown in the example mockup configuration generated from combining Figure 7 of Park with Figure 5 of Silver, the diaphragm cap of the resulting system forms a central region on a front surface of the outer shell (storing housing 700).



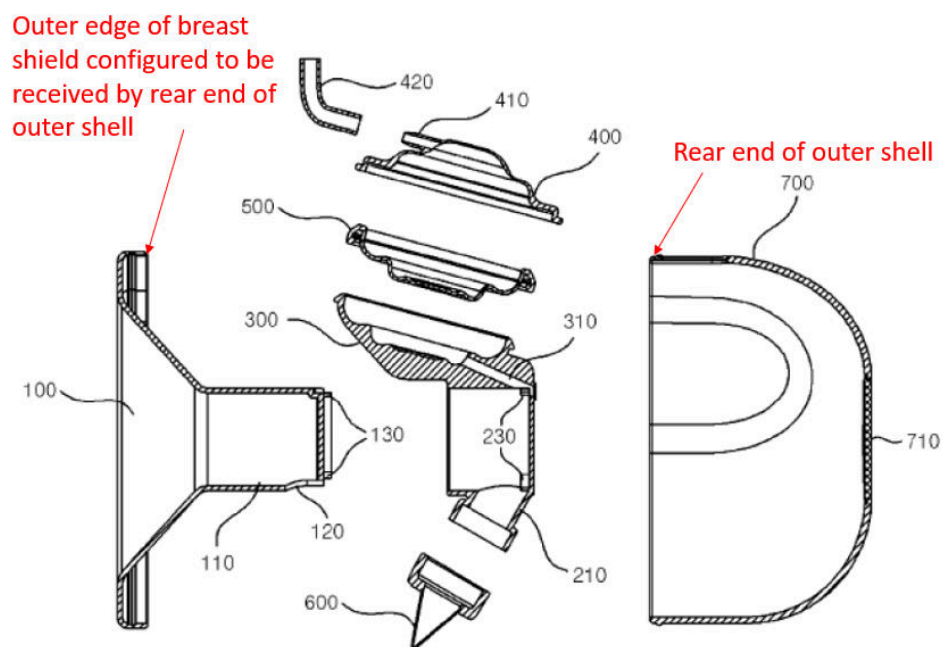
Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

244. Park describes that “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 also describes that the cover seals the diaphragm to create an air tight area for conveying vacuum pressure: “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).

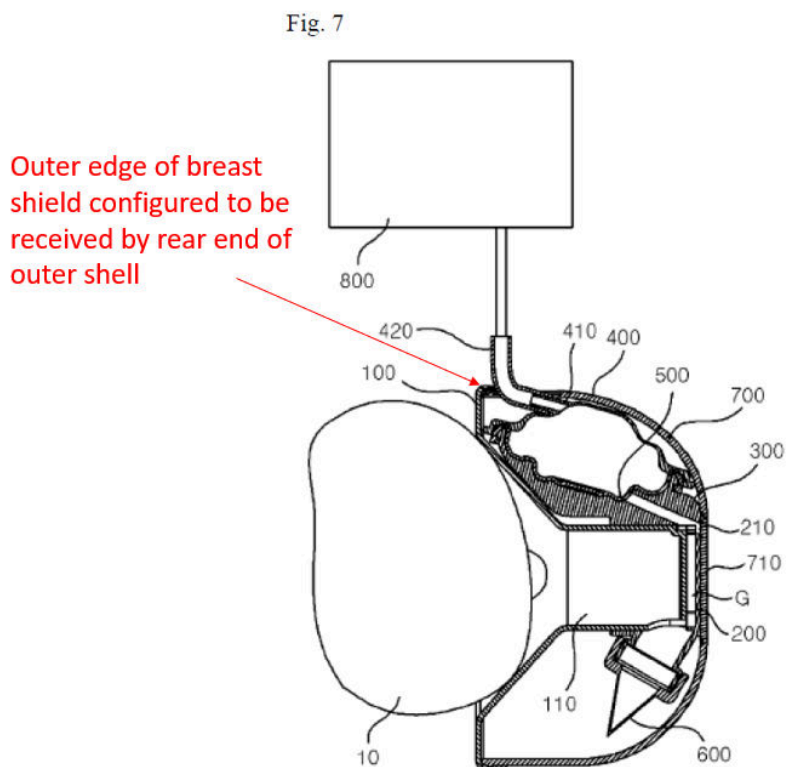
245. Silver provides a similar disclosure that compliments that of Park, describing that the “barrier component” or “diaphragm 14” is covered and sealed by rear housing 16 such that “[t]he *barrier is reciprocated* within the space of the housings 16, 18 by an intermittent *vacuum from a vacuum source*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

3. Claim [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.

246. Park’s disclosure demonstrates that the breast shield of the Park-Silver combination includes an outer edge configured to be received by the rear end of the outer shell.

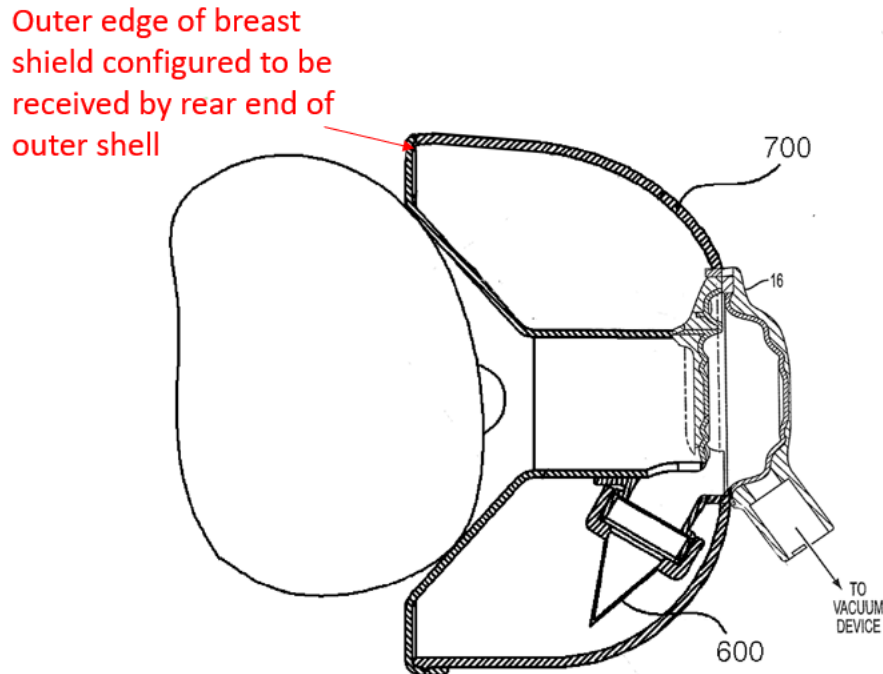


EX1010, FIG. 5 (annotated).



EX1010, FIG. 7 (annotated). The example mockup configuration generated from

combining Figure 7 of Park with Figure 5 of Silver also shows this outer edge of the breast shield configured to be received by the rear end of the outer shell:

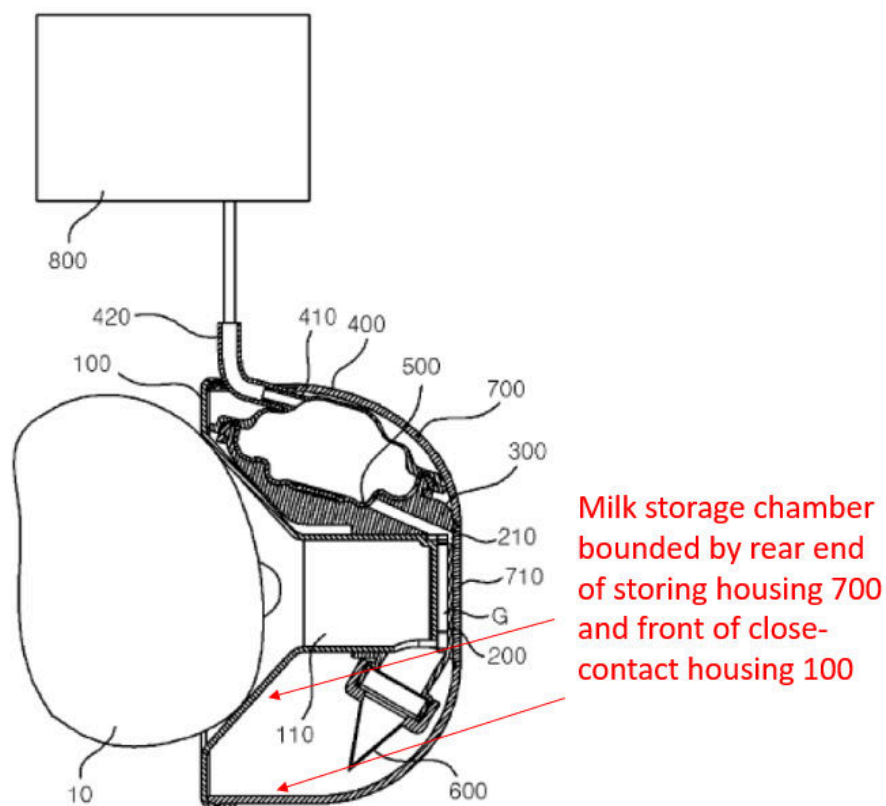


Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

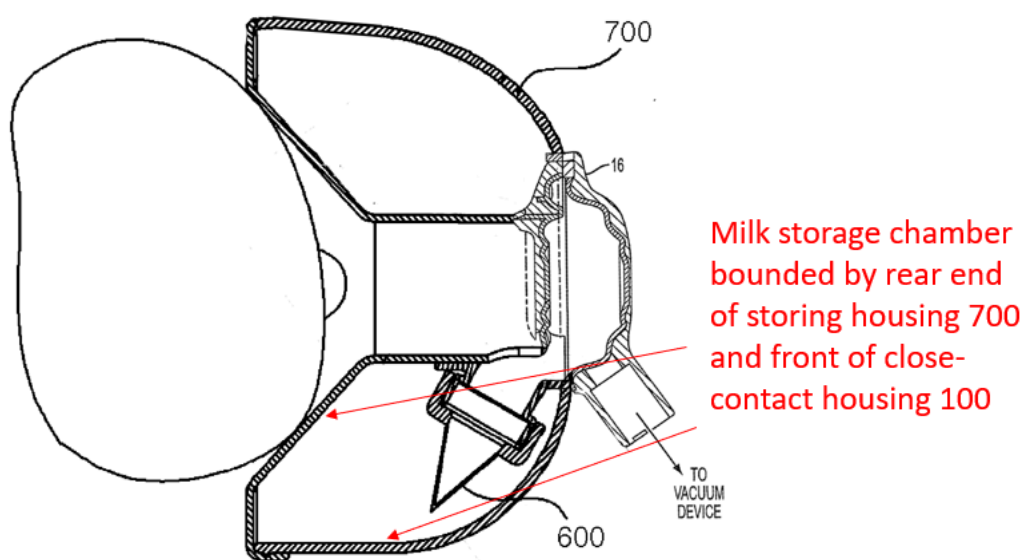
4. **Claim [19]: The breast pump system of claim 17, wherein the interior volume is bounded by the rear end of the outer shell and a front end of the breast shield.**

247. The Park-Silver combination provides that the interior volume is bounded by the rear end of the outer shell and a front end of the breast shield as demonstrated, for example, by Figure 7 of Park and the example mockup configuration generated from combining Figure 7 of Park with Figure 5 of Silver:

Fig. 7



EX1010, FIG. 7 (annotated).

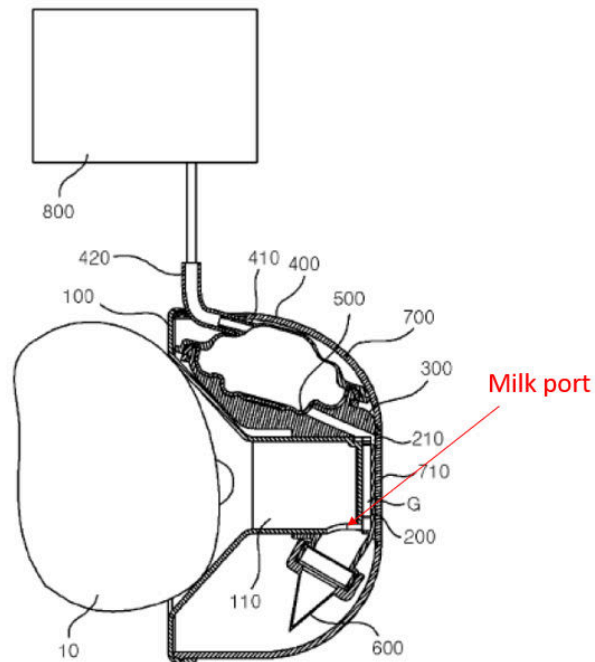


Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

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

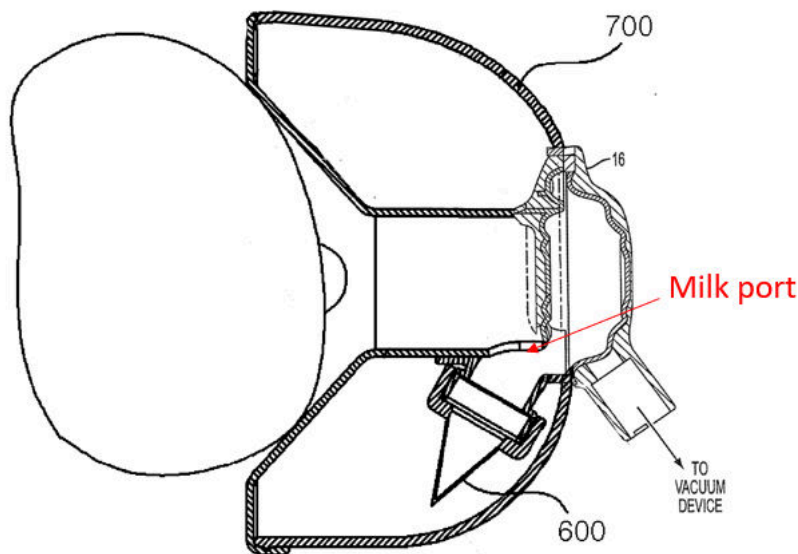
248. The Park-Silver combination provides that the breast pump system includes a milk port through which the expressed milk flows into the chamber. Specifically, Park's protruding part 110 that defines the nipple tunnel includes a milk port through which expressed milk flows through the valve 600 into the chamber defined by the storing housing 700, as shown in Figure 7. EX1010, [37], [42].

Fig. 7



EX1010, FIG. 7 (annotated).

249. Specifically, 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 discharge tube 210, and the valve 600 to the storage chamber (storing housing 700). EX1010, [37]-[38], [44]. A POSITA would have recognized that both the discharge hole 120 or a combination of the discharge hole 120 and the discharge tube 210 provides the claimed milk port. This milk port is retained in the breast pump system resulting from the predictable combination of Park with Silver:



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

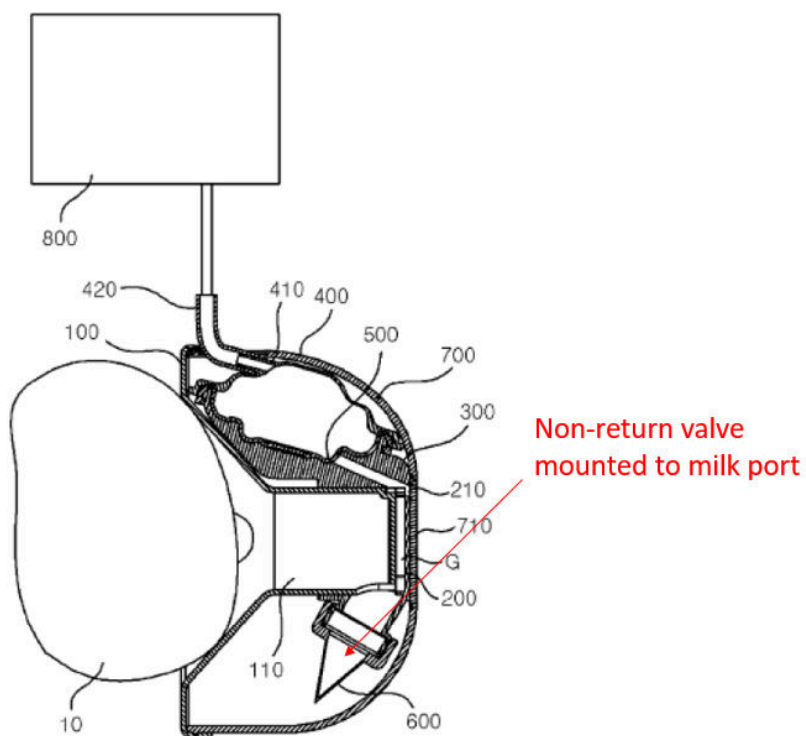
6. Claim [23]: The breast pump system of claim 21, further comprising a non-return valve configured to be mounted to the milk port.

250. The Park-Silver combination provides that the breast pump system further includes a non-return valve configured to be mounted to the milk port in the form of silicon valve 600. Specifically, Park describes:

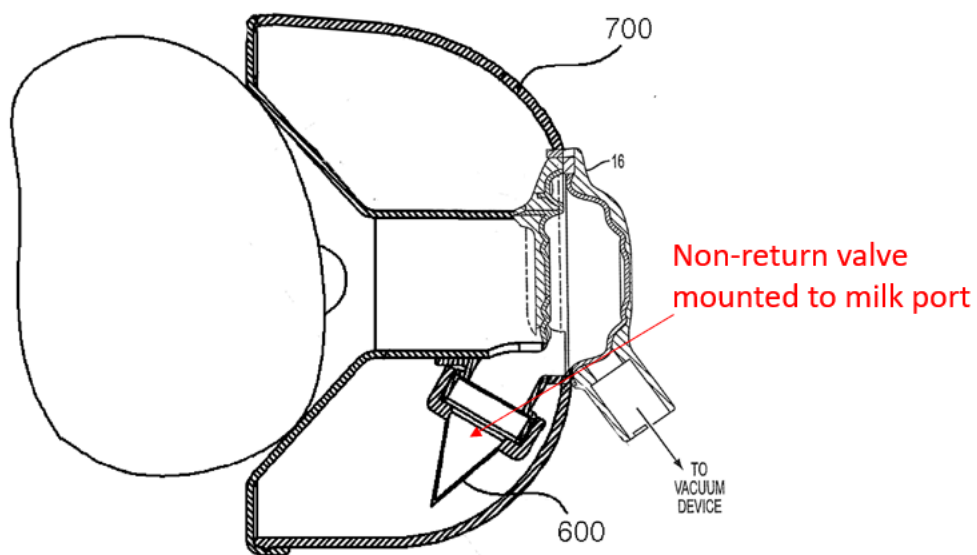
In addition, *a silicon valve 600 having a check valve function is favorably attached to the outlet side of the breast milk discharge tube 210* so as to prevent a phenomenon in which the breast milk filled in the storing housing 700 flows backward through the breast milk discharge tube 210. The silicon valve 600 has one side (in the current embodiment, an upper side) coupled to the breast milk discharge tube 210 and the other side (in the current embodiment, a lower side) formed in a sharp shape such that a cut line (Not shown) is formed on the other side. Accordingly, the breast milk discharged through the breast milk discharge tube 210 is introduced in the silicon valve 600, and is then filled in the storing housing 700 through the cut line. However, since it is difficult to introduce the breast milk in the storing housing 700 into the silicon valve 600 through the cut line, it is possible to prevent the phenomenon in which the breast milk in the storing housing 700 flow backward to the breast 10 of the lactating woman.

251. A POSITA would have recognized from the disclosure that the valve 600 prevents expressed milk from flowing backward from the housing 700 to the breast that it is a non-return valve. As shown in Figure 7 of Park, the valve 600 is mounted to the milk port:

Fig. 7



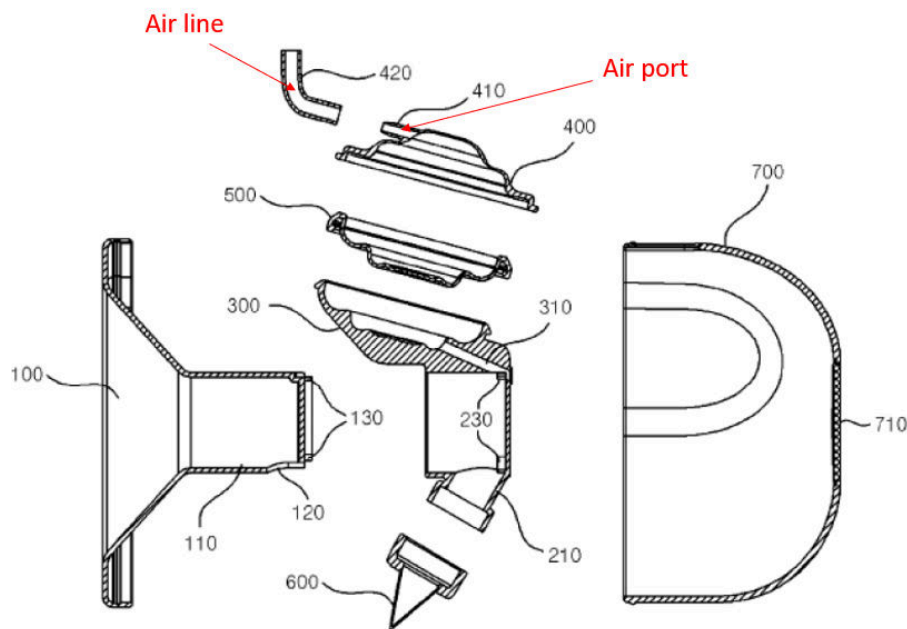
EX1010, FIG. 7 (annotated). This non-return valve 600 is retained in the breast pump system resulting from the predictable combination of Park with Silver:



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

7. Claim [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.

252. The Park-Silver combination provides that the diaphragm cap comprises an air port configured to receive an end of the air line in the form of air nozzle 410 that connects to air tube 420. Specifically, Park describes that “air between the cover 400 and the flow separation membrane 500 is suctioned to the outside through an air nozzle 410” such that “the flow separation membrane 500 is moved upward” during suction. EX1010, [39]. In another example, Park describes that “when the electric pump 800 is operated...then air between a cover 400 and the flow separation membrane 500 is discharged through an air tube 420 and an air nozzle 410.” *Id.*, [54]. The air nozzle 410 that extends from cover 400 and connects to air tube 420 is shown in Figure 5:



EX1010, FIG5 (annotated).

253. Silver includes similar disclosure confirming that the resulting Park-Silver combination includes an air port configured to receive an end of the air line, as shown, for example, in Figures 1 and 5:

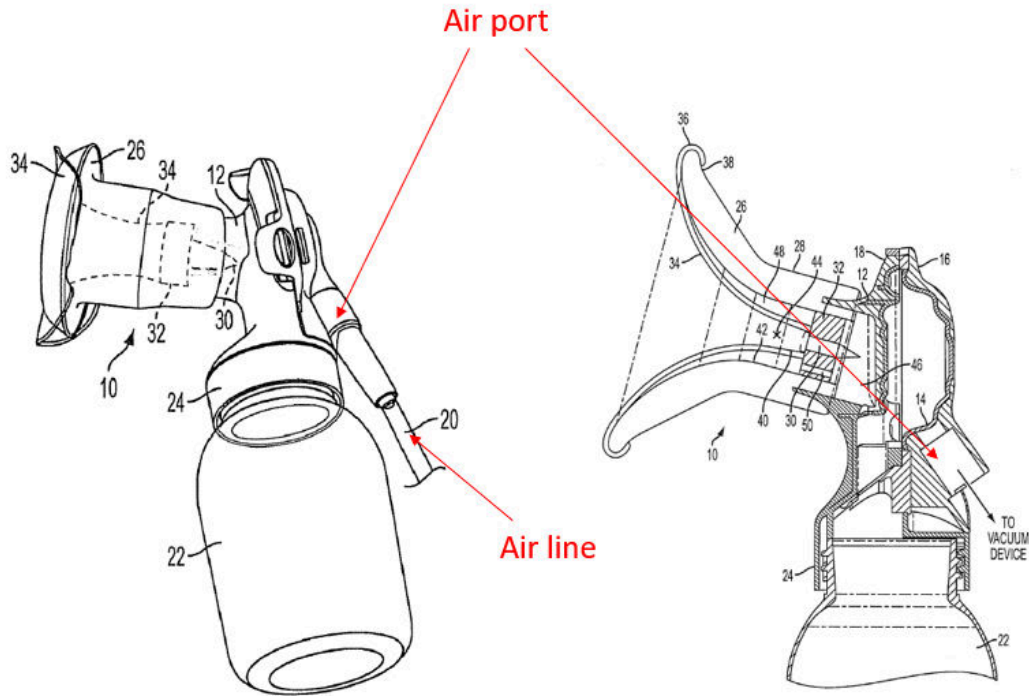
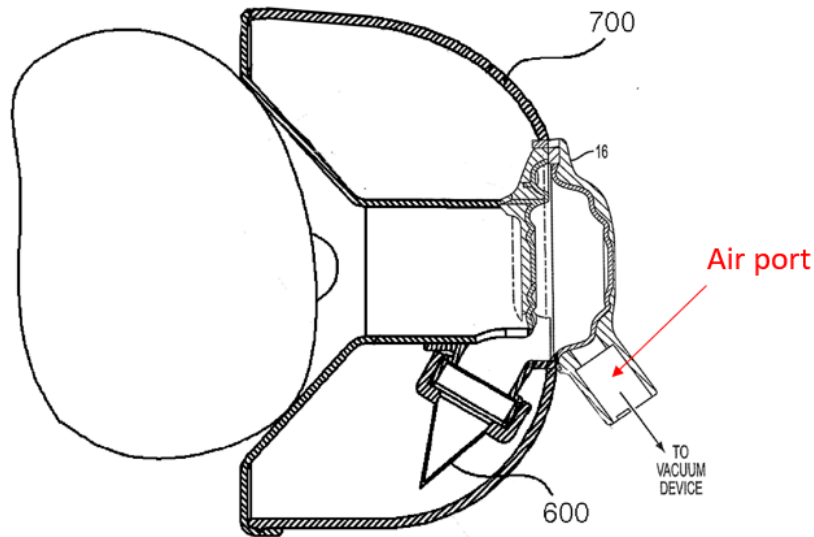


FIG. 1

EX1011, FIGs. 1, 5 (annotated), [0059], [0067]. The system resulting from the combination of Park and Silver thus includes an air port.

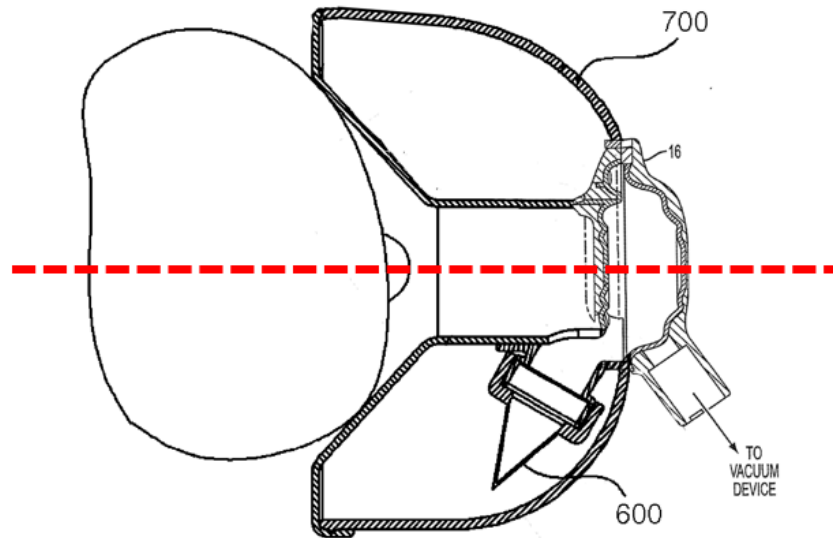


Combination of EX1010, FIG. 7 and EX1011, FIG. 5.

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

254. The diaphragm in the predictable Park-Silver combination is arranged concentric with the nipple tunnel. As I discussed in Section IX.G.1, above, multiple reasons would have prompted a POSITA to apply the teachings of Silver to the breast pump system of Park 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, in a similar manner to how Silver's diaphragm 14 and rear housing 16 (diaphragm cap) are positioned in Silver's original device. As I previously discussed, this arrangement would have led to numerous known benefits. This application of Silver to Park's device would have resulted in an arrangement in

which the diaphragm is arranged concentric with the nipple tunnel, as shown in the below mockup of the combination of Park with Silver:



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

9. Claim 28

a. [28pre]: A breast pump system comprising:

255. The Park-Silver combination provides this preamble for the reasons discussed with respect to preamble [17pre], above.

b. [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

256. The Park-Silver combination provides these claim elements for the reasons discussed with respect to elements [17a-1]-[17a-3], above.

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

257. The Park-Silver combination provides this claim element for the reasons discussed with respect to element [17b], above.

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

258. The Park-Silver combination provides these claim elements for the reasons discussed with respect to elements [17c-1]-[17c-3], above.

- e. **[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;**

259. The Park-Silver combination provides this claim element for the reasons discussed with respect to element [17d] and claim [27], above.

- f. **[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**

260. The Park-Silver combination provides this claim element for the reasons discussed with respect to element [17e], above.

- g. [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.**

261. The Park-Silver combination provides this claim element for the reasons discussed with respect to element [17f], above.

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

262. The Park-Silver combination provides claim [30] for the reasons discussed with respect to element [17f], above.

- 11. Claim [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.**

263. The Park-Silver combination provides claim [32] for the reasons discussed with respect to claim [24], above.

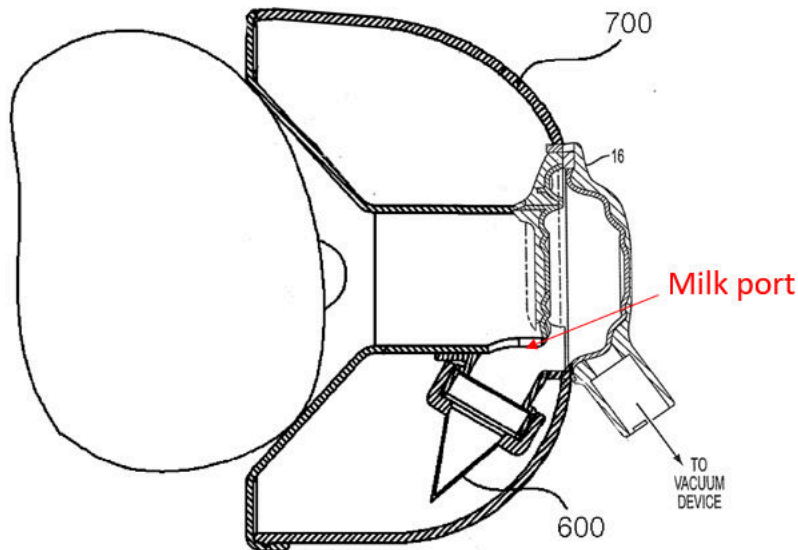
H. Ground 2B: Obviousness of Claims 22 and 31 Based on Park, Silver, and Weniger

264. Claims 22 and 31 are obvious in light of Park in view of Silver and Weniger for the reasons discussed below.

1. Motivation To Combine Park and Silver with Weniger

265. As I discussed with respect to Ground 2A, above, the breast pump system resulting from the predictable combination of Park with Silver includes a milk port through which expressed milk flows from the area around the nipple to the

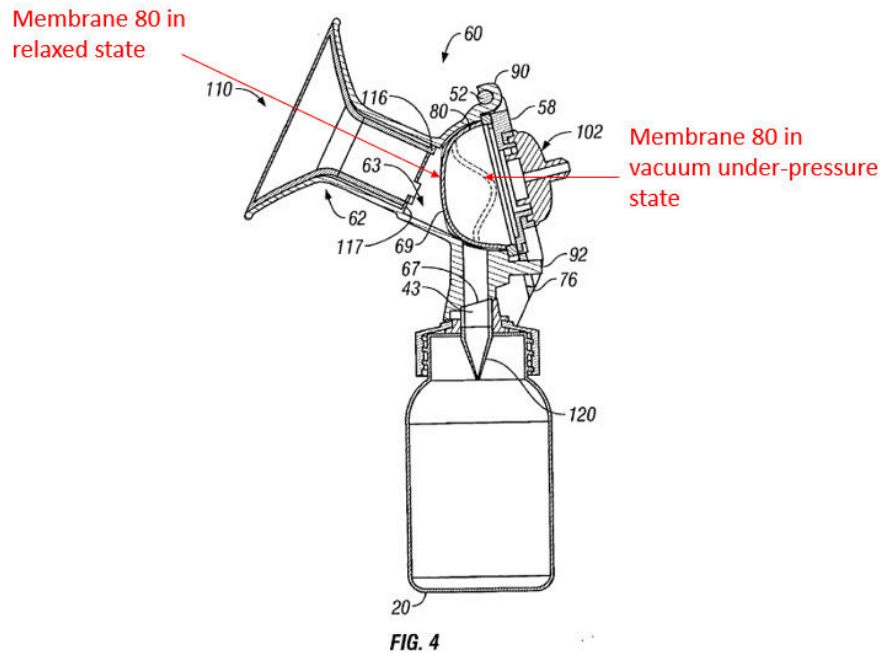
storage chamber defined by the outer shell and breast shield. EX1010, [37]-[38], [42], [44].



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

266. As I previously discussed in the overview of Weniger, above, similar to the devices of Park and Silver, Weniger's device includes 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." EX1007, [0033], [0038], [0040]. Similar to the device of Silver (and the device of the predictable Park-Silver combination), Weniger's membrane 80 is positioned at the front of the nipple tunnel in the area near the nipple. Figure

4 of Weniger shows this membrane 80 in both relaxed and vacuum under-pressure states.



EX1007, FIG. 4 (annotated).

267. 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]. Weniger goes on to describe that "[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.

268. A POSITA would have been prompted to apply the suggestion in Weniger to configure the membrane/diaphragm (e.g., Silver’s diaphragm 14) to extend over and adjacent to the milk port to make the milk passageway “discontinuous” to the Park-Silver system for similar reasons as those discussed in Ground 1D above. Specifically, as a first reason, a POSITA would have recognized that configuring the membrane/diaphragm to extend over the milk port in the predictable combination to cause the milk flow path to be discontinuous when the membrane/diaphragm is in a relaxed state while opening the passageway to make the milk flow path continuous in the underpressure state (based on the teachings of Weniger) would have prevented milk that has passed through the milk port from returning to the nipple tunnel. EX1007, [0041]. A POSITA would have recognized that it would be desirable to prevent milk from returning to the nipple tunnel as such a back flow of milk could cause discomfort for the user or potentially cause the nipple tunnel to overflow with expressed milk. Such a scenario could disrupt the seal between the breast shield and breast or could create a mess. A POSITA would have further recognized that 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.

269. As a second reason, a POSITA would have recognized that configuring the membrane/diaphragm in the resulting system to extend over the milk port in the predictable combination to cause the milk flow path to be discontinuous when the membrane/diaphragm is in a relaxed state while opening the passageway to make the milk flow path continuous in the underpressure state (based on the teachings of Weniger) would have resulted in the membrane/diaphragm creating 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., Park's valve 600) 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. As would have been recognized by a POSITA, the application of such additional pressure by extending the membrane/diaphragm over and adjacent to the milk port in the relaxed state 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.

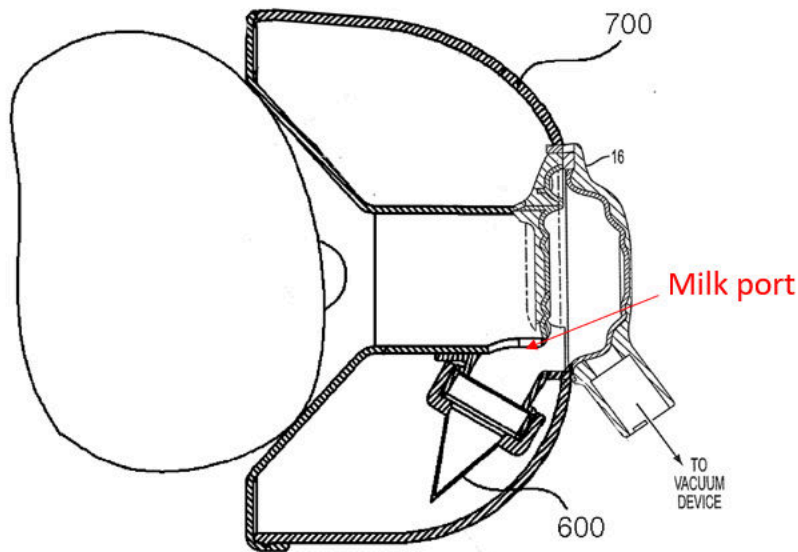
270. As a fourth reason, as would have been known to a POSITA, cyclically interrupting and re-opening the milk flow path "according to a cyclically applied underpreassure" by implementing the membrane/diaphragm to extend over and adjacent the milk port in a relaxed state would have "reduce[d] the dead volume" in

the resulting device. EX1004, 2:49-56, 6:13-17. A POSITA would have recognized that reduction in dead volume would have resulted in numerous benefits, including reducing the strain on the vacuum pump of the resulting system, which would lead to reduced energy usage requirements, reduced cost, and reduced pump noise, among other known benefits. *See e.g.*, EX1011, [0013]-[0014].

271. As a fourth reason, a POSITA would have been motivated to apply Weniger's teachings to the Park-Silver system to beneficially implement the resulting device such that the media separation membrane/diaphragm extends over and adjacent to the milk port in a relaxed state because such a configuration for Park's device (as modified by Silver) applies a known technique to wearable breast pump systems. The Park-Silver-Weniger combination produces predictable outcomes, as discussed earlier. Due to the similarities of the systems described by Park, Silver, and Weniger, including the use of very similar media separation membranes in the devices described in these references, a person skilled in the art would have recognized that such a modification would be relatively straight forward and would have reasonably expected success in making these modifications. This expectation is based on the similarity between the devices, and the fact that the changes would primarily involve straightforward adjustments that would not significantly alter the overall function of the underlying device.

2. Claims [22] and [31]

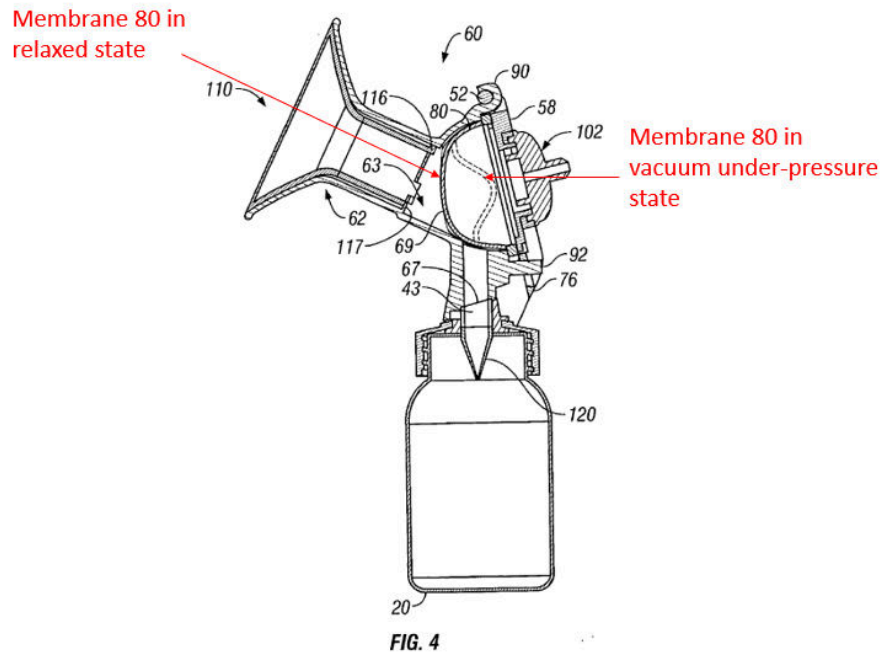
272. As I discussed above, the teachings of Park demonstrate that the resulting breast pump system includes a milk port through which expressed milk flows from the area around the nipple to the storage chamber defined by the outer shell and breast shield. EX1010, [37]-[38], [42], [44].



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

273. A POSITA would have predictably applied the teachings of Weniger to the Park-Silver system to achieve the benefits discussed above such that the media separation membrane extends over and adjacent to the milk port in a relaxed state. Similar to the disclosure of Park and Silver, Weniger describes 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.” EX1007, [0033], [0038], [0040]. Figure 4 of Weniger shows this membrane 80 in both relaxed and vacuum under-pressure states.



EX1007, FIG. 4 (annotated).

274. 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]. Weniger goes on to describe that “[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. As such, as shown above in Figure 4 of Weniger, in the predictable Park-Silver-Weniger combination, the media separation membrane (diaphragm) extends over and adjacent the milk port when in a relaxed state.

I. Ground 2C: Obviousness of Claims 25, 27-30, and 32 Based on Park, Silver, and Rigert

275. Claims 25, 27-30, and 32 are obvious in light of Park in view of Silver and Rigert for the reasons discussed below.

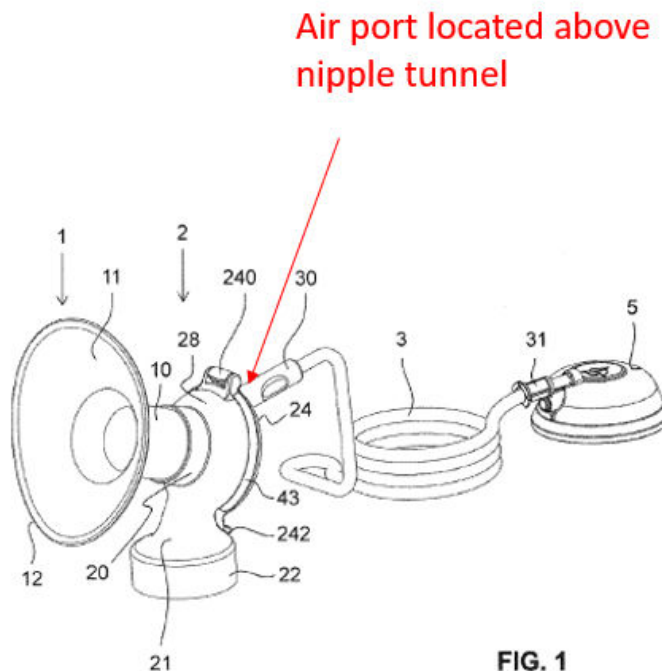
1. Motivation To Combine Park and Silver with Rigert

276. 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. EX1008, [0052]-[0058], FIGs. 1-4, 7, 13.

277. With respect to the first proposed modification based on Rigert (positioning the air port above the nipple tunnel), as I previously discussed, both Park and silver disclose that the diaphragm cap includes an air port. For example, Park describes that “air between the cover 400 and the flow separation membrane 500 is suctioned to the outside through an air nozzle 410” such that “the flow separation membrane 500 is moved upward” during suction. EX1010, [39], FIGs. 4-

5, 7. Silver similarly describes that “[v]acuum 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.” EX1011, [0067], FIGs. 1, 5.

278. Rigert describes a similar design for a breast pump that, like the breast pump system resulting from the combination of Park and Silver, includes a media separation diaphragm that receives vacuum pressure from a vacuum pump connected to the breast pump via a suction line 3 that couples to a suction connection 23. EX1008, [0052]. More specifically, the breast pump includes a “suction connection 23 [that] is integrally moulded [*sic*] in the top region of the cover 24.” *Id.*, [0058]. Furthermore, in Rigert’s design, the air port (suction connection 23) is located above the nipple tunnel:



EX1008, FIG. 1.

279. A POSITA would have been motivated to apply Rigert's suggestion to position the air port above the nipple tunnel in the resulting Park-Silver-Rigert combination for the same reasons that I discussed in Ground 1E, above. EX1008, [0052]-[0058], FIGs. 1-4, 7, 13. For example, as a first reason, a POSITA would have recognized that modifying the Park-Silver system to position the air nozzle above the nipple tunnel (based on the suggestion of Rigert) 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. EX1010, [5] (Park discussing that it's breast pump is intended to be "worn on a breast of a lactating woman.") Positioning the suction line to protrude from the bottom of the bra would have been uncomfortable for users with respect to many bra designs (such as those having an underwire).

280. As a second reason, positioning the air nozzle above the nipple tunnel (based on Rigert's suggestion) would have allowed the suction lines to exit the mother'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. As such, the resulting device could be implemented with shorter suction lines which would have reduced the strain on the vacuum pump.

281. As a third reason, positioning the air nozzle above the nipple tunnel (based on Rigert's suggestion) such that the suction tube exits through the top of the bra would have allowed the wearer to more easily visually observe the vacuum lines which would allow the wearer to identify kinks or other obstructions that could prevent or diminish suction. Additionally, 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.

282. As a fourth reason, a POSITA would have been motivated to apply Rigert's teachings to the Park-Silver system to beneficially implement the resulting device such that the air nozzle is positioned above the nipple tunnel because such a configuration for Park's system (as modified by Silver) applies a known technique to wearable breast pump systems. The Park-Silver-Rigert combination produces predictable outcomes, as discussed earlier. Due to the similarities of the systems described by Park, Silver, and Rigert, including the use of very similar media separation membranes and suction line connectors in these systems, a person skilled in the art would have recognized that such a modification would be relatively straightforward and would have reasonably expected success in making these modifications. This expectation is based on the similarity between the devices, and the fact that the changes would primarily involve straightforward adjustments that would not significantly alter the overall function of the underlying device.

283. Regarding the second proposed modification, to apply Rigert's teachings to position the diaphragm concentric with the nipple tunnel to the Park-Silver combination, multiple reasons would have prompted a POSITA to apply Rigert to the Park-Silver combination in such a manner. As a first reason, a POSITA would have recognized that such a modification would have provided for a smaller, more compact design. Such a design can lead to reduced weight and a lower profile of the resulting device, leading to an improved user experience.

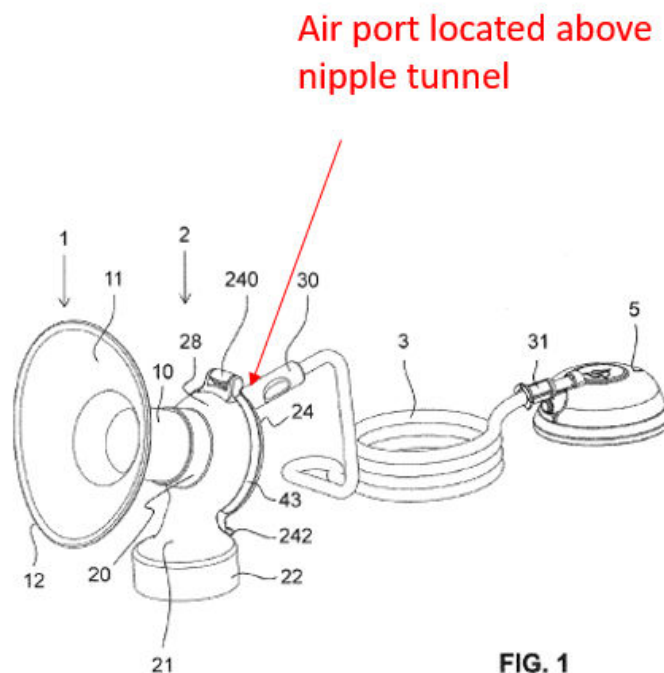
284. As a second reason, a POSITA would have recognized that positioning the diaphragm to be concentric with the nipple tunnel would have further contributed toward reducing dead volume in the resulting device by arranging the diaphragm more closely with "[t]he area of the nipple" to further reduce the amount of power needed from the pump, thereby increasing the benefits that I discussed in Section IX.G.1, above. EX1004, 2:49-56, 6:13-17; EX1011, [0013]-[0014].

285. As a third reason, a POSITA would have been motivated to apply Rigert's teachings to the Park-Silver system to beneficially implement the resulting device such that the diaphragm is concentric with the nipple tunnel because such a configuration for Park's system (as modified by Silver) applies a known technique to wearable breast pump systems. The Park-Silver-Rigert combination produces predictable outcomes, as discussed earlier. Due to the similarities of the systems described by Park, Silver, and Rigert, including the use of very similar media

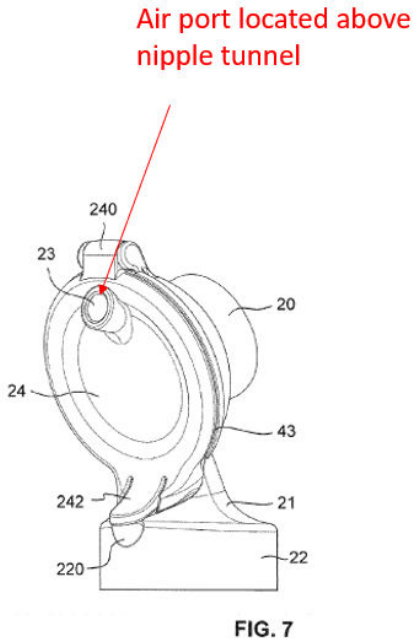
separation membranes and nipple tunnels in these systems, a person skilled in the art would have recognized that such a modification would be relatively straight forward and would have reasonably expected success in making these modifications. This expectation is based on the similarity between the devices, and the fact that the changes would primarily involve straightforward adjustments that would not significantly alter the overall function of the underlying device.

2. Claim [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.

286. The Park-Silver-Rigert combination provides that the diaphragm cap is configured such that the air port can be located above the nipple tunnel. This is demonstrated, for example, by Figures 1 and 7 of Rigert. EX1008, [0056]-[0058].



EX1008, FIG. 1.

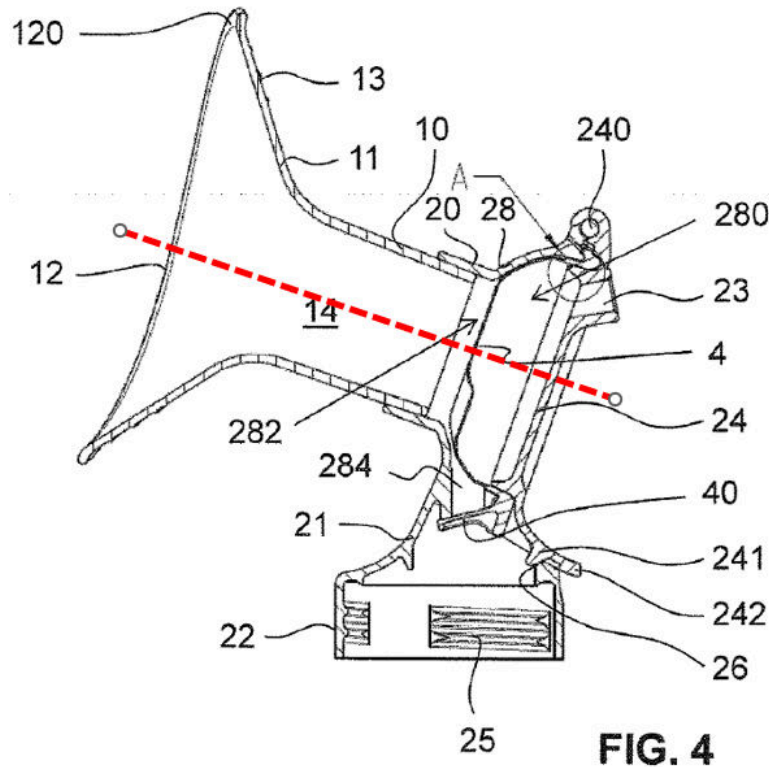


EX1008, FIG. 7, *see also*, FIGs. 2-4, 13.

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

287. As I discussed above, I believe that the Park-Silver combination fully discloses Claim [27] and Element [28d]. However, I have been asked to evaluate the Park-Silver-Rigert combination with respect to Claims [27]-[30] and [32] and it is my opinion that this combination further renders these claims obvious. 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 that I discussed above. Turning specifically to Figure 4 of Rigert, in the predictable Park-Silver-Rigert combination the diaphragm (e.g., Park's membrane 500 or Silver's diaphragm 14 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).



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

288. 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*.

J. Ground 2D: Obviousness of Claim 31 Based on Park, Silver, Rigert, and Weniger

289. Claim 31 is obvious in light of Park in view of Silver, Rigert, and Weniger for the reasons discussed with respect to Ground 2B (addressing the Park-Silver-Weniger combination). 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, above.

K. Ground 2E: Obviousness of Claims 26 and 33 Based on Park, Silver, and Kasting

290. Claims 26 and 33 are obvious in light of Park in view of Silver and Kasting for the reasons discussed below.

1. Motivation To Combine Park and Silver with Kasting

291. A POSITA would have been motivated to apply the suggestions of Kasting to the Park-Silver combination to include a pair of recessed finger grips on the diaphragm cap (e.g., Park's cover 400 or Silver's rear housing 16) in the resulting system in the same manner and for the same reasons as discussed with respect to Ground 1F, above. For example, as a first reason, applying Kasting's suggestion for including two recessed pockets to allow for the cap/cover "to be grasped in an ergonomically-convenient manner" would allow for more easy gripping and manipulation of the diaphragm cap. EX1012, 11:33-43. As such, a POSITA would have recognized that it would have been beneficial to improve the device (based on Kasting's suggestion) to make the diaphragm cap easier to grip "by the hand of user" such as by the user's fingers. EX1012, 11:24-32. This would have facilitated easy opening and closing of the diaphragm cap, such as when cleaning the inside of the device. For example, a POSITA would have recognized that easier manipulation of the diaphragm cap would have allowed for the inside of the device to be "accessible

in a simple manner” to allow for “the media separating diaphragm [to] be easily inserted and removed again.” EX1008, [0027]. For example, manipulation of the diaphragm cap to open and close the diaphragm cap would have been recognized by a POSITA as beneficial “for the purposes of replacement or cleaning.” *Id.*, [0056].

292. For example, as demonstrated in Figure 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.

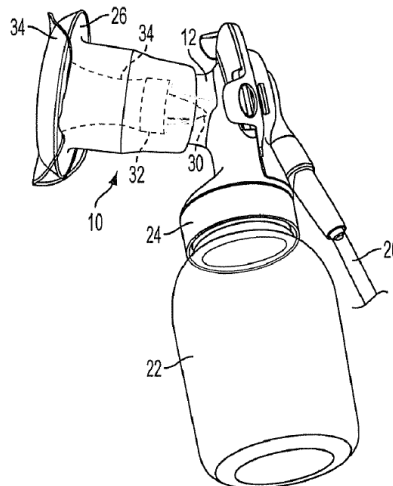


FIG. 1

EX1011, FIG. 1.

293. As a second reason, implementing Kasting’s suggestion to include recessed gripping features on the diaphragm cap of the Park-Silver device would have allowed the user to more easily manipulate the device as a whole when applying the device to the breast of the user or removing the device from the breast. A

POSITA would have recognized that dropping and potential damage to the device could be more easily prevented by providing better gripping surface through the use of recessed finger grip features as suggested by Kasting.

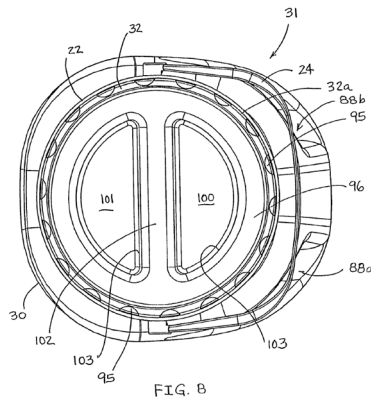
294. As a third reason, inclusion of recessed finger grips on the the diaphragm cap, as suggested by Kasting, would have allowed the user to “more easily reapply” the diaphragm cap after, for example, disassembling to clean the inside of the device.

295. As a fourth reason, a POSITA would have been motivated to apply Kasting’s teachings to the Park-Silver system to beneficially implement the resulting device such that the diaphragm cap includes recessed finger grip features because such a configuration for Park’s device (as modified by Silver) applies a known technique to a known wearable breast pump system. The Park-Silver-Kasting combination produces predictable outcomes, as discussed earlier. Due to the straightforward nature of the teachings of Kasting, for improving the ability to grip covers/caps of various devices, and the shared goal of improving sealing for various devices, a person skilled in the art would have recognized that such a modification would be relatively straight forward and would have reasonably expected success in making these modifications. This expectation is based on the simple nature of Kasting’s suggestion and the fact that the changes would primarily involve

straightforward mechanical adjustments that would not significantly alter the overall function of the underlying device.

2. Claims [26] and [33]

296. As I discussed above, the breast pump system resulting from the combination of Park with Silver and Kasting 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. A POSITA would have recognized that a user would have grasp the recessed pockets using their fingers.*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.

L. Ground 2F: Obviousness of Claim 33 Based on Park, Silver, Rigert, and Kasting

297. Claim 33 is obvious in light of Park in view of Silver, Rigert, and Kasting for the reasons discussed with respect to Ground 2E (addressing the Park-Silver-Kasting combination). 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, above.

Appendix A

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Authorized to work in the US for any employer

Work Experience

Director, Medical Device & Pharmaceutical Solutions

Siemens AG

April 2019 to Present

Global strategy and solutions role for Siemens Digital Industries Software in the definition, application, and solution development of the Siemens software portfolio to address engineering and manufacturing needs for the life sciences industry. Provide leadership for enterprise digital transformation (Industry 4.0) by using deep medical device development experience to tailor and apply software applications such as PLM, ALM, CAD, EDA, MES, Simulation, IoT, Lo-code, etc to industry needs.

- Example solutions developed include: Medical device Labeling tool integration & UDI (Unique Device Identifier) data management; QMS (Quality Management System) and RIMS (Regulatory Information Managements System) accelerators; PLM based ISO 14971 integrated risk management; Low-code apps to augment core data processing such as UDI submission or QMR; & SaaS/Cloud PLM for Medical Device industry solution for product development
- Define and provide input to product roadmaps across the business units for industry solutions.
- Partner with global sales and marketing to establish 'digital threads' to showcase digital transformation vision for customers and stakeholders and support in bridging the technical solution and industry needs.
- Assess strategic actions to partner, acquire, and/or build out solutions to resolve customer needs aligned with market opportunity.
- Partner with regulators and industry groups to provide thought leadership to mature industry practice

Vice President, R&D

Halo Innovations | Aden + Anais - Minnetonka, MN

August 2018 to March 2019

Provided R&D leadership, engineering expertise, and quality/regulatory experience for mixed medical device and CPG company. Successfully launched partnership with GE Healthcare for novel Class II bassinets. Defined product roadmap, process, and project execution for both Halo & A+A brands. Executed organizational development re-definition/implementation to support transition as a medical device company. Additionally, oversaw Quality function including overhaul and deployment of Quality Management System, 1st successful FDA inspection, and served as Management Representative.

Director of Product Development

Medela LLC

September 2013 to June 2018

Direct product development processes and innovation strategy tied to NPD and sustaining engineering within the Human Milk business unit. Business unit includes both retail and professional (hospital)

channels. Global role reporting to CTO that oversees distributed teams to achieve global strategy. Responsible for organizational development and strategic input/evaluation/execution within global R&D team. Core member with CTO for technology and product & platform roadmap development. Facilitate regular Global Product Steering Committee meetings to ensure appropriate project governance. Products successfully developed and launched for US, Europe, China, and Australian markets. Developed first platforms for next generation pumps and applications with re-use across retail and hospital channels.

R&D resource owner for all US based product development personnel including sites in California and Illinois. California site closed end 2017 (enteral feeding business acquisition) and managed R&D transition to McHenry team. Direct and indirect R&D reports approximately 24 full time employees with one digital projects lead report in Switzerland. Team consisted of Mechanical, Electrical, Software, System, Test, DevOps Engineers; Project Management, Product Care (Sustaining engineering), engineering process controls / infrastructure roles, and technicians.

Example achievements over multiple roles:

- Development of new strategic breast pump architecture, product launch, 510(k), and Bluetooth connected app launch (iOS & Android) with global rollout. Recent launch included versioned product for China with country specific app integrated with WeChat.
- Ethnographic research with paradigm shifting products for the NICU, resulting in accretive core product lines and business, including milk warming and management technologies.
- Instrumental in successful 2011 FDA Warning Letter quality system overhaul and remediation efforts. Remediated design & risk controls and significant portions of production and process Controls, supplier management, risk management, and sterilization program. Recently demonstrated MDSAP audit compliance.
- Major cost reductions and quality improvements on core products for lifecycle management
- Design enhancements and DFM to scale products and shift portfolio mix due to massive impact of the Affordable Care Act in terms of volumes, commoditization, reduced ASP
- Significant maturation and establishment of organization development and capabilities. Includes additions of in-house electrical, systems, & software engineering. Re-organization and personnel management to develop lean world-class team.
- Implementation and integration of best in class R&D engineering tools and associated processes such as requirements management, PLM/PDM, statistical techniques, FEA, CFD, etc.
- Established successful co-operative education program with Marquette University since 2013 to train, develop, and employ students from biomedical & engineering disciplines.
- Multiple patents granted and pending

Manager of Product Development

Medela LLC

June 2010 to September 2013

Manage product development department within the breastfeeding business to support new product initiatives within retail and professional channels as well as support existing product lines to maintain productivity, cost effectiveness, and sustainability. Manage & match project resources to strategic initiatives, enable individuals and teams, & provide technical guidance. Resource and prioritize projects, ensuring strategic alignment. Primary engineering member of change review board. Lead and developed R&D organizational processes including harmonization with global teams and compliance to regulations. Additional responsibilities taken on in Operations, Quality, and Regulatory to remediate products, processes, and Quality Management System to successfully address FDA warning letter.

Engineering Team Lead

Medela LLC

July 2008 to June 2010

Supervisory and execution responsibilities for new product development with particular emphasis on hospital channels. Technical lead for new market opportunity explorations, proof of concept, and product definition. Cross functional oversight including project management, ME/SE/EE internal & external resource management, systems architecture, NPD process compliance, & quality and regulatory compliance. Researched, executed, & launched multiple new products for hospital & NICU market ranging from simple parts to complex electromechanical assemblies & associated disposables.

Product Development Engineer

Medela LLC

May 2006 to July 2008

Responsible for core line product improvements, cost reductions, technical investigations, engineering analysis, & project management of breast pumps & accessories.

New Product Group Leader

Juno Lighting - Des Plaines, IL

November 2005 to May 2006

Supervise development work including problem resolutions, design of new models, mechanisms, and adaptations for a wide variety of special and unusual lighting equipment. Work usually involved the application of more than one electric, electronic, optical, or mechanical factor. Manage product engineering team to create new and innovative lighting products and streamline NPD process.

Sr. Mechanical Engineer

Motorola Inc - Deer Park, IL

June 2000 to November 2005

Mechanical program responsibilities for automotive transmission controller modules and cellular infrastructure (custom electronics design/housing/packaging). Responsibilities included customer interface and support, program team coordination, specification development and validation, quoting, sourcing, mechanical design, thermal and structural analyses, reliability, six sigma analyses, environmental testing, packaging, cost reductions, manufacturing support, acoustic testing, new technologies research, platform development, and other development engineering functions.

Mechanical Engineer, Purdue University Co-op Design Engineering Program

Dane Systems Inc - Stevensville, MI

June 1995 to December 1999

Design, Detail & Check of turnkey automation systems. Design of custom automation for various industries integrating assembly lines, vision systems, and robots. Lead designer on a variety of projects. Some designs include brake caliper assembly stations, vacuum potting chambers, robotic loaders, welding and heat stamping operations, pallet conveyance design, and various test stands.

Education

M.S. in Product Development

Northwestern University - Evanston, IL

B.S. in Mechanical Engineering

Purdue University - W Lafayette, IN

Skills

- R&D Strategy Development and Execution
- Leadership/management of technical staff
- Medical device regulatory compliance
- Manufacturing Automation & Implementation
- Stage Gate Process Development & Execution
- Cross-Discipline Aptitude & Communications
- Intellectual property management/strategy
- Risk Assessment & Management
- Statistical Processes & Tools
- Project Management
- Quality Methods (Systems & Implementation)
- Structured problem solving (8D)
- External resource management
- Electromechanical, Reusable, & Disposable Development