

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SHENZHEN ROOT TECHNOLOGY CO., LTD.,

Petitioner,

v.

CHIARO TECHNOLOGY,

Patent Owner.

IPR2024-00953

U.S. Patent No. 11,413,380

**DECLARATION OF RYAN BAUER
IN SUPPORT OF PETITION FOR INTER PARTES REVIEW
OF U.S. PATENT NO. 11,413,380**

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EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent 11,413,380
1002	File History of Application 17/203,327
1003	File History of Application 17/181,057
1004	File History of Application 16/009,547
1005	This is the instant declaration
1006	Ryan Bauer curriculum vitae
1007	Chang, U.S. Patent Application Publication 2018/0333523
1008	Weber, U.S. Patent Application Publication 2012/0277728
1009	Guthrie, U.S. Patent Application Publication 2016/0082166
1010	Khalil, U.S. Patent Application Publication 2013/0023821
1011	Pollen, U.S. Application Publication 2015/0217033
1012	Tack, U.S. Application Publication 2012/0116299
1013	Hu, U.S. Application Publication 2015/0157775
1014	Myers, PCT Publication WO 2002/102437
1015	Myers, PCT Publication WO 2008/137678

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 1-46 of U.S. Patent 11,413,380 (“the ’380 Patent,” Ex-1001).

2. A copy of my current curriculum vitae is submitted herewith as EX-1006, 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 ’380 patent. Based on my education and experience, I was at the time the

earliest priority application leading to the '380 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. MATERIALS CONSIDERED

8. 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, computer science, and communications technologies.

9. In forming my opinions expressed in this declaration, I reviewed all the materials cited within this declaration, including the documents identified in the Exhibit List (above).

10. 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 '380 patent at the time of the alleged invention, which I have been asked to initially assume is June 15, 2017.

11. 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 claims 1-46 ("Challenged Claims") of the '380 patent, as I explain in detail below.

12. 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.

13. 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.

14. 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.

III. LEVEL OF ORDINARY SKILL IN THE ART

15. 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 ’380 Patent. I understand that “the time the claimed invention was made” is often referred to as the priority or critical date.

16. I have been asked to assume that the priority date for the ’380 patent is June 15, 2017. As such, in this declaration, I adopt June 15, 2017, to be the relevant date to ascertain the perspective of one of ordinary skill in the art.

17. 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.

18. Based on my background and experience, a POSITA as of June 15, 2017, would have 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.

IV. TECHNOLOGY BACKGROUND

19. 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.

20. 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.

21. 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”).

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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. Another typical embodiment includes a membrane or 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 separation since it keeps milk away from the pump mechanism for cleaning and sanitary purposes.

29. Many diverse types of pumps have been used to generate the negative pressure in breast pumps, such as bellows, diaphragms, piston-cylinder, peristaltic motion, or any kind of mechanical deformation or air removal of the target volume. *See, e.g.*, Pollen (EX-1011) ¶45 (“The term, “vacuum pump,” refers to any device that provides subatmospheric pressure continuously, cyclically, or at least momentarily. Vacuum pump 16 is schematically illustrated to represent all types of vacuum pumps, examples of which include, but are not limited to, a diaphragm pump, a bellows pump, a piston pump, a reciprocating pump, a peristaltic pump, a positive displacement pump, a gear pump, a lobed rotor pump, a screw compressor, a scroll compressor, and a rotary vane pump.”). Similarly, these technologies or others can be deployed in a multi-cycle (high frequency) capacity during each breast pump cycle such as multi-stroke pistons, diaphragms, and piezo actuators. This is a common approach to miniaturize the pumping mechanism and remove air or liquid directly from the target volume to generate negative pressure.

30. A diaphragm pump was a well-known type of pump used in breast pumps at the time of the '380 patent. *See, e.g.*, Weber (EX-1008) ¶19 (“The vacuum pump is preferably a diaphragm pump, wherein the chamber is the vacuum-generating pump chamber of the vacuum pump, and the diaphragm is the diaphragm of the pump chamber used for generating the vacuum.”); Khalil (EX-1010) ¶67 (“The vacuum pump 81 is preferably a diaphragm vacuum pump of a known type,

which is operated by means of an electric motor.”); Tack (EX-1012) ¶6 (“To address this concern, in a first aspect of the present invention, a drive mechanism for a breast pump is provided comprising a housing, a motor coupled to a rotatable drive element within the housing, a resilient membrane coupled to the housing, and a flexible strap coupled between the drive element and the membrane, wherein rotation of the drive element causes the flexible strap to pull and resiliently deform the resilient membrane to create the negative pressure in a vacuum chamber of a breast pump.”) and Hu (EX-1013) ¶9 (“[T]he host unit comprises a miniature diaphragm vacuum pump, a miniature magnetic valve, and an air loop comprising an air inlet and an air outlet; an air inlet of the miniature diaphragm vacuum pump and an air outlet of the miniature magnetic valve communicate with each other and both are connected to the air inlet of the air loop; an air inlet of the magnetic valve and an air outlet of the miniature diaphragm vacuum pump are both connected to the air outlet of the air loop.”).

31. By the time of the ’380 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. Some common configurations that were known to a POSITA include:

- Separate breast cups, pump, milk container. *See, e.g.*, Weber (EX-1008) at Fig. 1, ¶67; . U.S. Patent No. 6,379,327 (“Lundy”) at Figs. 1, 3, 3:42-46.
- Handheld breast pumps. *See, e.g.*, Tack (EX-1012) at Fig. 1, ¶24.
- Wearable integrated breast pumps that fit entirely in a bra. *See, e.g.*, Chang at Fig. 1, ¶19 (“[T]he 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.”); Khalil ¶32 (“The breastshield unit according to the invention can be designed as a hands-free unit and worn under a bra. In a preferred embodiment, a milk collection container is integrated in the housing of the unit or can be coupled directly thereto.”).

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.*, WO 2002/102437 (EX-1014) at Figs. 20A and 20B, ¶44; WO 2008/137678 (EX-1015) at Fig. 1, pp. 12-13; and Guthrie at Fig. 1, ¶26.

32. As can be seen from the above, 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 '380 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.

33. 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 is a breast pump that is fully supported by the bra at the breast:

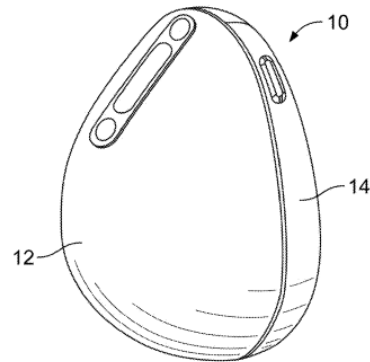


FIG. 1A

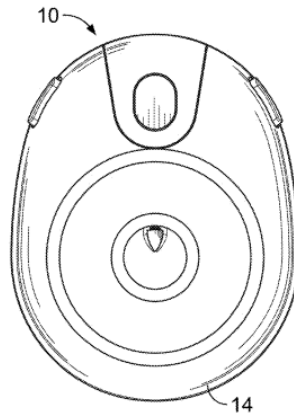


FIG. 1B

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. Also, the bulk of the pump system would protrude even further in the bra, which some women would object to because it alters their appearance and/or is not discrete.

34. Chang clearly 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.

Chang ¶19. 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), which separated the components of the pump so they could be supported by different parts of the body:

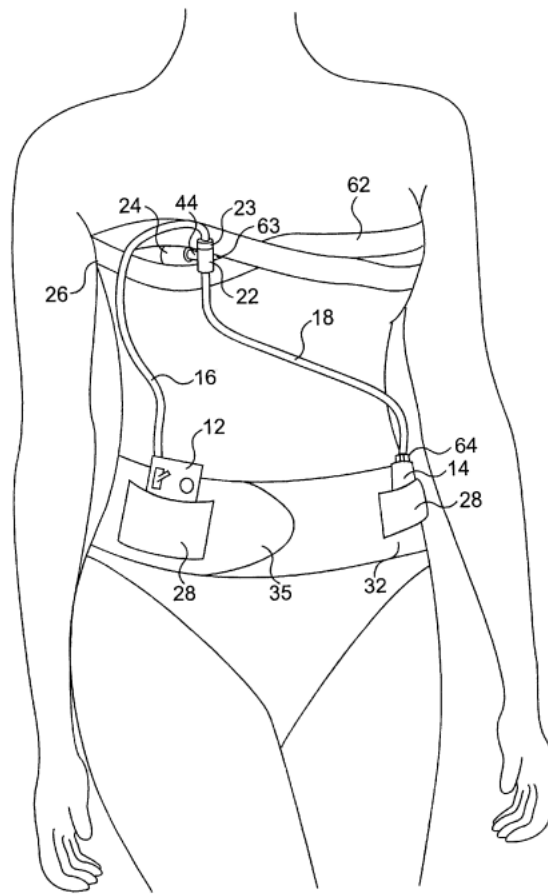


FIG. 3

Fig. 3, 3:42-46.

35. All the claims of the '380 patent are directed to a “self-contained, in-bra wearable device.” *See* '380 Patent, claims 1, 29. Such devices, which are worn and held entirely in a bra, were well-known in the prior art, as acknowledged by the '380 patent. *See, e.g., id.* at 2:5-10 (“Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or

connections.”); *id.* at 2:43-44 (“A further integrated wearable breast pump system is shown in [Khalil]”).

V. THE ’380 PATENT

A. Specification

36. The ’380 patent is entitled “Breast Pump System.” It generally discloses a breast pump that is wearable inside a bra. EX-1001, 3:57-62. The specification of the ’380 patent begins by acknowledging that fully integrated in-bra breast pumps existed in the prior art, including as disclosed by U.S. Application Publication 2016/0206794 (“Makower”):

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

Id. 2:5-15.

37. The ’380 patent contends that Makower’s prior art device had disadvantages, such as a collapsible bag as the milk container, a noisy and complex pump mechanism, and limited milk capacity. *Id.* at 2:16-42. The ’380 patent also discusses the prior art breast pump of U.S. Application Publication 2013/0023821

(“Khalil”), which it contends had disadvantages such as an annular diaphragm which resulted in a large, bulky device. The ’380 patent purports to overcome such disadvantages. *Id.*, 2:5-57.

38. The ’380 patent claims are generally directed to “a self-contained, in-bra wearable” breast pump device with a pump housing, a pump powered by a rechargeable battery, a breast shield, a milk container, and a diaphragm (or membrane) that deforms in response to changes in air pressure caused by a pump. *Id.*, claims 1 (“a self-contained, in-bra wearable device comprising:”), 29 (same).

39. The specification discloses that the breast shield engages with the user’s breast. *Id.*, 5:40-47. The shield is also connected to the milk container for collecting milk expressed by the user. *Id.* The housing includes one or more pumps, control electronics, and a rechargeable battery. *Id.*, 5:47-49, 5:58-59. The breast shield and milk container are “directly removable or attachable from the housing.” *E.g., id.*, 5:58-6:3.

40. Figures 1 and 2 below show the front and rear view of a breast pump system, with housing 1, milk container 3 and breast shield 7 indicated:

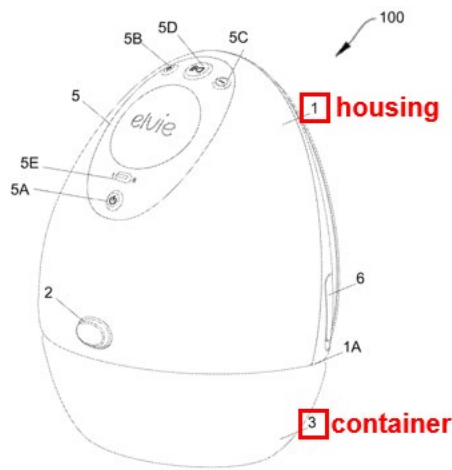


FIGURE 1

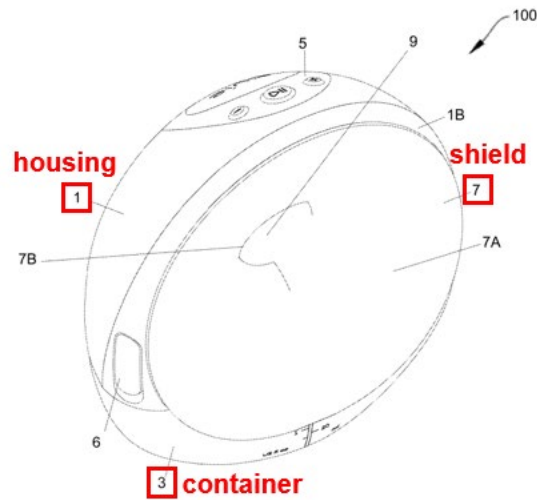


FIGURE 2

Id., Figs. 1 2 (annotated), 5:56-6:3, 6:14-21.

41. Breast shield 7 has concave inner flange 7A which contacts the breast, and elongate nipple tunnel 9 aligned with an opening on breast shield 7 and extending from curved section 7B in breast shield 7. *Id.*, 8:62-64 (“The breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast.”), 9:27-31 (“The breast shield 7 comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel 9) aligned with the opening and extending away from the user's breast. Breast shield nipple tunnel 9 extends from a curved section 7B in the breast shield 7.”). The nipple tunnel “defines a milk-flow path from the inner surface of breast shield 7A, through nipple tunnel 9, and into milk container 3.” *Id.*, 9:39-42.

42. The '380 patent also discloses that the breast pump system has a “diaphragm,” which is variously referred to as a “membrane” or “barrier,” that transfers negative air pressure from the pump to the milk-collection side, i.e., breast side, of the system. *Id.*, 10:25-29; 11:18. Front and rear exploded views of the '380 patent's breast pump system are illustrated in Figures 5 and 6, with housing 1, milk container 3, breast shield 7, and diaphragm 13 indicated:

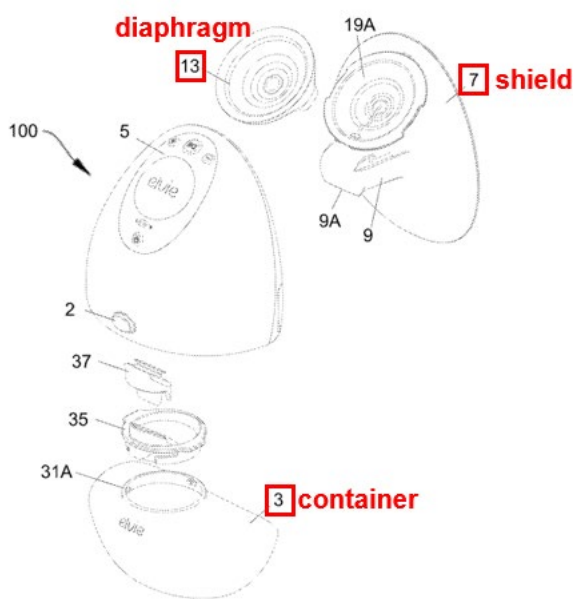


FIGURE 5

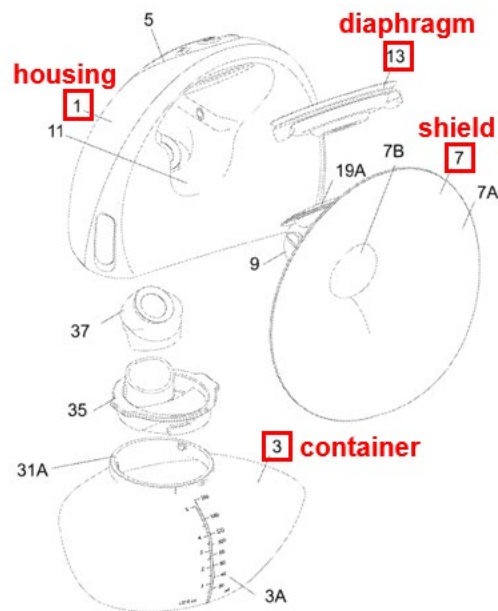


FIGURE 6

Id., Figs. 5, 6 (annotated).

43. The diaphragm 13 is held in a diaphragm housing and transfers negative pressure generated by the pump into nipple tunnel 9, which imposes a sucking action on the user's nipple. *Id.*, 10:25-35, 11:19-20. The diaphragm housing has a first

half (19A) integral with breast shield 7 and a second half (19B) in a recessed portion of housing 1, as shown in Figure 4 below:

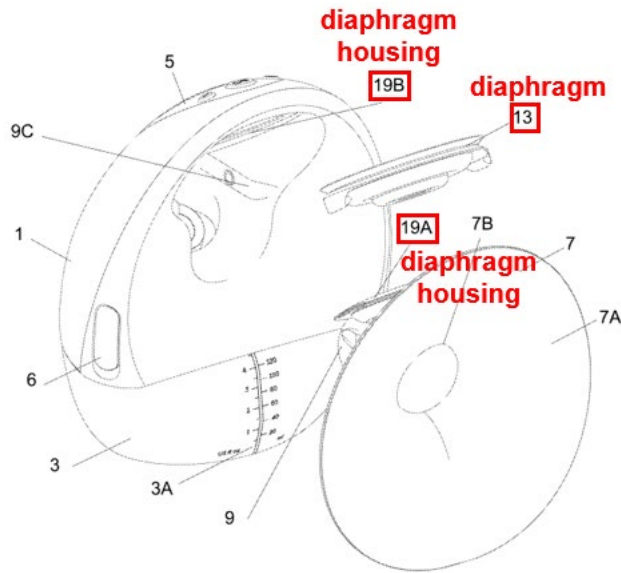


FIGURE 4

Id., Fig. 4 (annotated), 11:23-27.

B. Claims

44. The '380 patent has 46 claims, with claims 1 and 29 being independent claims. For convenience, I have reproduced the claims below:

Element	Claim Limitations
Claim 1	
1[pre]	A breast pump device comprising:
1[a]	a self-contained, in-bra wearable device comprising:
1[b]	a pump housing that includes:
1[b][i]	a rechargeable battery,

1[b][ii]	a power charging circuit for controlling charging of the rechargeable battery,
1[b][iii]	control electronics powered by the rechargeable battery,
1[b][iv]	a pump powered by the rechargeable battery and configured to generate negative air pressure,
1[b][v]	a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery, and
1[b][vi]	a recess or cavity that defines a pumping chamber;
1[c]	a breast shield made up of a breast flange and a nipple tunnel;
1[d]	a milk container that is configured to be attached to and removed from the pump housing; and
1[e]	a diaphragm that is configured to prevent milk from reaching the pump, the diaphragm being seated against a diaphragm housing that is fixed to a recessed surface of the pump housing, and the diaphragm being a membrane that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.
Claim 2	
2	The breast pump device of claim 1, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.
Claim 3	
3	The breast pump device of claim 1, wherein the breast shield is a one piece item that in use presents a single continuous surface to a nipple and a breast.

Claim 4	
4[a]	The breast pump device of claim 1, wherein the breast shield has a top and bottom when positioned upright for normal use, and
4[b]	wherein the breast shield is generally symmetrical about a center-line running from the top to the bottom of the breast shield when positioned upright for normal use.
Claim 5	
5	The breast pump device of claim 1, wherein the breast shield is configured to slide in and out from the pump housing, together with the diaphragm that prevents milk from reaching the pump.
Claim 6	
6	The breast pump device of claim 1, wherein the breast pump device includes only the breast shield and the milk container that are directly removable from the pump housing in normal use or normal dis-assembly.
Claim 7	
7	The breast pump device of claim 1, wherein the diaphragm is substantially circular and the diaphragm housing is substantially circular.
Claim 8	
8	The breast pump device of claim 1, wherein the milk container is substantially rigid.
Claim 9	
9	The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the pump housing and to form a flat bottomed base for the breast pump device.

Claim 10	
10	The breast pump device of claim 1, wherein the milk container has a surface shaped to continue a curved shape of the pump housing so that the breast pump device can be held comfortably inside a bra.
Claim 11	
11	The breast pump device of claim 1, wherein the milk container is attachable to the pump housing with a mechanical or magnetic mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the pump housing with a single push action.
Claim 12	
12	The breast pump device of claim 1, wherein the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows under gravity into the milk container.
Claim 13	
13	The breast pump device of claim 1, wherein the diaphragm defines a milk-flow side chamber on one side of the diaphragm and an air-side chamber on the other side of the diaphragm.
Claim 14	
14	The breast pump device of claim 1, wherein the diaphragm is configured to self-seal under negative pressure around its outer edge, to form a watertight and airtight seal around the recess or cavity in the pump housing.
Claim 15	
15[a]	The breast pump device of claim 1, wherein the diaphragm housing is a first diaphragm housing, and

15[b]	wherein the breast pump device further comprises a second diaphragm housing attached to the nipple tunnel and configured to define a milk-flow side chamber, the diaphragm being configured to be positioned between the first diaphragm housing and the second diaphragm housing.
Claim 16	
16	The breast pump device of claim 15, wherein the diaphragm is configured to be releasably secured around an edge of the second diaphragm housing.
Claim 17	
17	The breast pump device of claim 15, wherein the second diaphragm housing is positioned, when the breast pump device is upright, over a top surface of the nipple tunnel.
Claim 18	
18	The breast pump device of claim 15, wherein the second diaphragm housing includes an air hole to transfer negative air pressure to the nipple tunnel.
Claim 19	
19	The breast pump device of claim 15, wherein the diaphragm is a flexible and generally circular diaphragm and the second diaphragm housing has a corresponding generally circular shape.
Claim 20	
20	The breast pump device of claim 15, wherein the second diaphragm housing is an integral part of the breast shield.
Claim 21	
21	The breast pump device of claim 15, wherein the diaphragm is configured to be attached around an edge of the second diaphragm housing.

Claim 22	
22	The breast pump device of claim 15, wherein the diaphragm is configured to seal, self-seal, self energizing seal or interference fit seal against the first diaphragm housing.
Claim 23	
23	The breast pump device of claim 1, wherein the diaphragm is a flexible and generally circular diaphragm.
Claim 24	
24	The breast pump device of claim 1, wherein the diaphragm is a flexible and generally circular diaphragm that, in a relaxed state, includes an inner raised area and a concentric outer raised area.
Claim 25	
25	The breast pump device of claim 1, wherein the milk container is configured to be pressed or pushed into engagement with the pump housing.
Claim 26	
26	The breast pump device of claim 1, wherein the self-contained, in-bra wearable device is configured so that expressed milk flows under gravity through an opening in the nipple tunnel and into the milk container through a duck-bill valve that stays sealed when there is negative air pressure being applied by the pump to ensure that negative air pressure is not applied to the milk container.
Claim 27	
27	The breast pump device of claim 1, wherein the milk container comprises a curved surface that includes a flat area that serves as a base for the milk container.

Claim 28	
28	The breast pump device of claim 1, wherein the milk container has a curved surface configured to enable the breast pump device to be held comfortably in a bra.
Claim 29	
29[pre]	A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:
29[a]	a self-contained, in-bra wearable device comprising:
29[b]	a housing that includes:
29[b][i]	a rechargeable battery,
29[b][ii]	a power charging circuit for controlling charging of the rechargeable battery,
29[b][iii]	control electronics powered by the rechargeable battery,
29[b][iv]	a pump powered by the rechargeable battery and configured to generate negative air pressure, and
29[b][v]	a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;
29[c]	a breast shield made up of a breast flange and a nipple tunnel;
29[d]	a milk container that is configured to be attached to and removed from the housing; and
29[e]	a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing, the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

Claim 30	
30	The breast pump device of claim 29, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.
Claim 31	
31	The breast pump device of claim 29, wherein the breast shield is a one piece item that in use presents a single continuous surface to a nipple and a breast.
Claim 32	
32[a]	The breast pump device of claim 29, wherein the breast shield has a top and bottom when positioned upright for normal use, and
32[b]	wherein the breast shield is generally symmetrical about a center-line running from the top to the bottom of the breast shield when positioned upright for normal use.
Claim 33	
33	The breast pump device of claim 29, wherein the breast pump device includes only the breast shield and the milk container that are directly removable from the housing in normal use or normal dis-assembly.
Claim 34	
34	The breast pump device of claim 29, wherein the membrane is substantially circular.
Claim 35	
35	The breast pump device of claim 29, wherein the milk container is substantially rigid.

Claim 36	
36	The breast pump device of claim 29, wherein the milk container has a surface shaped to continue a curved shape of the housing so that the breast pump device can be held comfortably inside a bra.
Claim 37	
37	The breast pump device of claim 29, wherein the milk container is attachable to the housing with a mechanical or magnetic mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action
Claim 38	
38	The breast pump device of claim 29, wherein the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows under gravity into the milk container.
Claim 39	
39	The breast pump device of claim 29, wherein the membrane defines a milk-flow side chamber on one side of the membrane and an air-side chamber on the other side of the membrane.
Claim 40	
40	The breast pump device of claim 29, wherein the membrane is configured to self-seal under negative pressure around its outer edge, to form a watertight and airtight seal around the recess or cavity in the housing.
Claim 41	
41	The breast pump device of claim 29, the membrane is a flexible membrane.

Claim 42	
42	The breast pump device of claim 29, wherein the membrane is a flexible and generally circular membrane that, in a relaxed state, includes an inner raised area and a concentric outer raised area.
Claim 43	
43	The breast pump device of claim 29, wherein the milk container is configured to be pressed or pushed into engagement with the housing.
Claim 44	
44	The breast pump device of claim 29, wherein the self-contained, in-bra wearable device is configured so that expressed milk flows under gravity through an opening in the nipple tunnel and into the milk container through a duck-bill valve that stays sealed when there is negative air pressure being applied by the pump to ensure that negative air pressure is not applied to the milk container.
Claim 45	
45	The breast pump device of claim 29, wherein the milk container comprises a curved surface that includes a flat area that serves as a base for the milk container.
Claim 46	
46	The breast pump device of claim 29, wherein the milk container has a curved surface configured to enable the breast pump device to be held comfortably in a bra.

VI. RELEVANT LEGAL STANDARDS

45. 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.

46. In expressing my opinions and considering the subject matter of the claims of the '380 Patent, I am relying upon certain basic legal principles that have been explained to me.

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

48. 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.

49. 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.

50. 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.

51. 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.

52. 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.

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

54. 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.

55. 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.

56. 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.

57. 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.

58. 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.

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

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. During prosecution of the '380 patent's parent application, U.S. Patent Application No. 17/181,057 ("057 application"; EX-1003), the Examiner construed the term "self-contained, in-bra wearable device" to mean "complete, or having all that is needed, in itself" and is capable of being worn in a bra." EX-1003 at 2167. The applicant did not dispute the examiner's construction. I apply this understanding in this declaration.

61. For all other terms, I apply their plain and ordinary meaning.

VIII. PRIOR ART

A. Chang (EX-1005)

62. Chang is a U.S. patent application publication. It was published on November 22, 2018. Chang is a continuation of PCT Application PCT/US17/17112 filed on February 9, 2017. It is entitled "Breast Pump Assembly and Methods." Chang was the patent behind the Willow breast pump which had viral media coverage at the 2017 Consumer Electronics Show.

63. Chang is generally related to a "portable breast pump system." Chang, ¶1. Chang discloses an integrated breast pump where all its components fit entirely within in a user's bra. *See, e.g., id.* Fig. 6A, ¶72, ¶80; ¶101.

64. Chang discloses a breast pump that is “wearable” (*id.*, ¶4) and “fit[s] comfortably and conveniently into a bra of a user” (*id.*, ¶11). *Id.*, ¶19 (the components of the system “are all contained within a cup of a brassiere”). The breast pump includes a “housing or outer shell 12” (in blue) and “flange 14” (in purple):

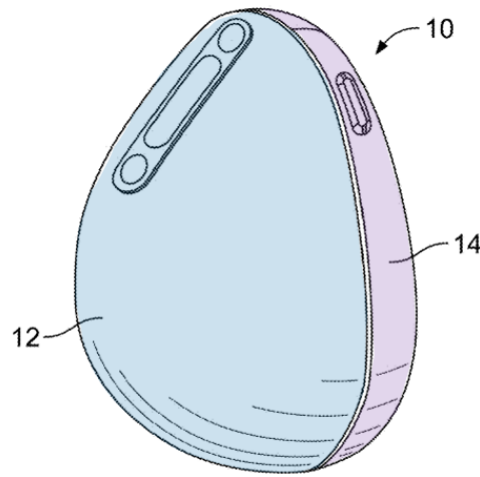
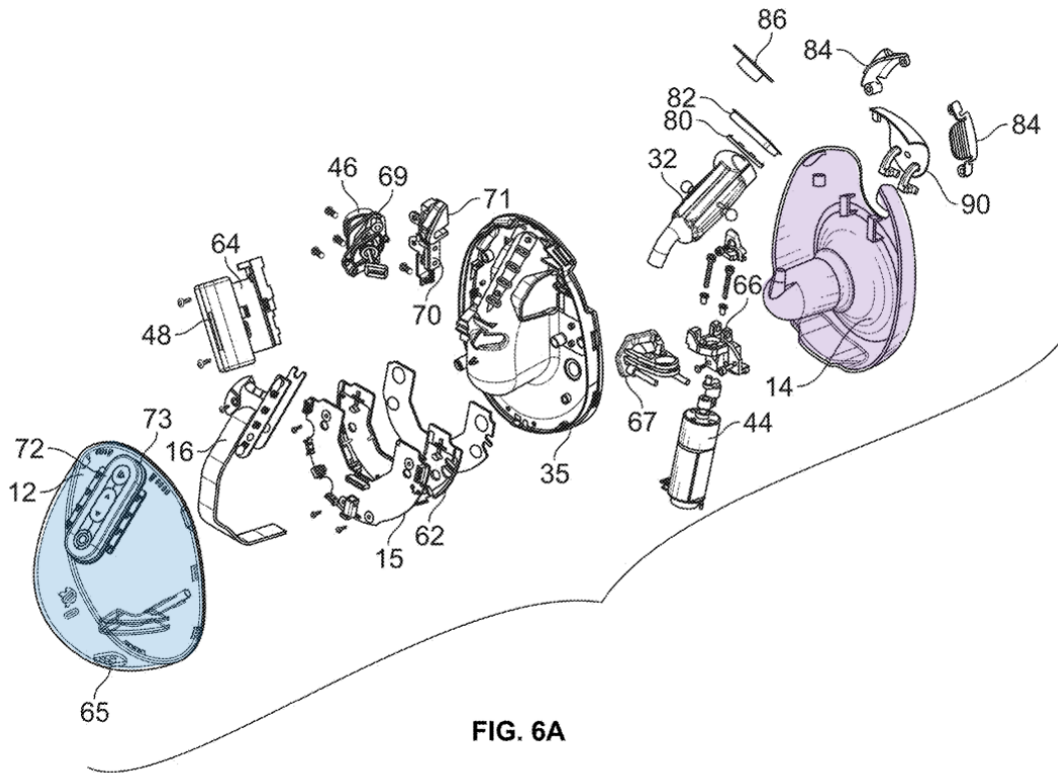


FIG. 1A

Id. Fig. 1A (annotated), ¶71. The flange, which is “sized and shaped to engage a breast of a user” (*id.*, ¶71), includes “a nipple receiving portion...contoured to more closely match the natural shape of the nipple.” *Id.* ¶90. The shape of the flange 14 is apparent in Chang’s Figure 6A”



Id., Fig. 6A (annotated); *see also, e.g., id.* Figs. 1, 2, 4; *id.* ¶¶71-72, 80.

65. The breast pump includes a “milk collection container.” *Id.* Figs. 8, 11B, ¶¶81, 86, 99-101, 105-106.

In at least one embodiment, the milk collection container comprises a one-way valve that permits milk inflow into the milk collection container but prevents milk backflow from the milk collection container to the conduit. In one embodiment, the collection container or container assembly includes an extra part, valve or fitment that is attached thereto and facilitates creating a seal with the container to establish a closed system. In one embodiment, the milk container can include a one-way valve that cannot be removed without destroying milk container or valve function. The valve can assume a myriad of shapes and kinds including an umbrella valve, a duckbill valve, a ball valve or other valve. Moreover, in

one or more embodiments, the container can be flexible or rigid, or disposable or reusable.

Id. ¶21.

66. Chang discloses that its breast pump also includes a “rechargeable battery” that power powers its system, including a “system controller” circuit board and a pump (e.g., “motors 44, 46 are further provided and controlled electronically by the system to effect manipulation of actuators (described below) operating on a conduit or flex-tube 32”). *Id.* ¶72. Chang discloses that its “pump” can be “one or more pumps and equivalents thereof known to those skilled in the art.” *Id.* ¶68. Chang also discloses that its breast pump may include sensors to control “the pumping cycles.” *Id.* ¶96.

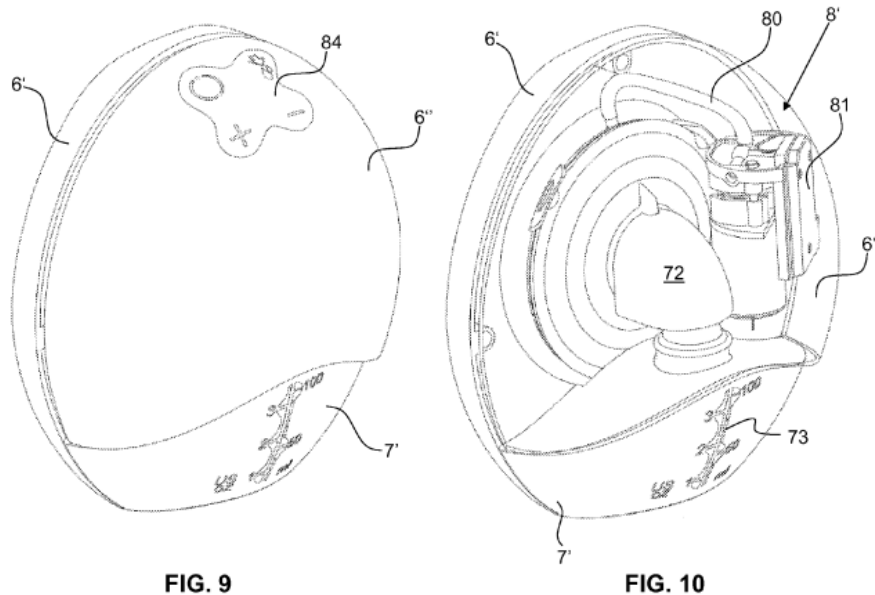
B. Khalil (EX-1006)

67. Khalil is a U.S. patent application publication, entitled “Breastshield Unit.” It was published on January 24, 2013.

68. Khalil is generally related to an integrated breast pump, referred to as a “breastshield unit.” Khalil, Abstract. Like, Chang, Khalil also discloses an integrated breast pump where all its components fit entirely within in a user’s bra:

The breastshield unit according to the invention can be designed as a hands-free unit and worn under a bra. In a preferred embodiment, a milk collection container is integrated in the housing of the unit or can be coupled directly thereto.

Id. ¶32; *see also* ¶70 (“The breastshield unit is small and easy to clean and is particularly suitable for use as a hands-free breastpump unit that can be worn in the bra.”). An embodiment of Khalil’s breastshield unit is illustrated below:



Id. Figs. 9-10; *see also id.* Fig. 11, Abstract, ¶66.

69. As can be seen from above, Khalil discloses that its breastshield unit has a shell, which include cover 6'' and shell ring 6', a milk container 7' and an integrated pump unit 8' with vacuum pump 81. *Id.* ¶66-67.

70. Khalil discloses that its pump can include any “known” type of electric “diaphragm pump.” *Id.* ¶67 (“The vacuum pump 81 is preferably a diaphragm vacuum pump of a known type, which is operated by means of an electric motor.”). The power source for the pump may also be integrated into the housing. *Id.* ¶67 (“A

pump seat 82, in which a vacuum pump 81 is held, is formed integrally in this cover 6". A power source is preferably integrated in this vacuum pump 81.").

71. Khalil discloses that its milk collection container 7' is "arranged in the lower area adjoining the cover (6")" and uses a locking lug 71, "integrally formed" on it, to "engage in a corresponding recess...of the shell ring (6')":

A milk collection container 7' is arranged in the lower area adjoining the cover 6". It is preferably made of plastic like the cover 6". A locking lug 71 is integrally formed on this milk collection container 7' and can engage in a corresponding recess (not shown in the Figures) of the shell ring 6'. In this way, the milk collection container 7' is connected releasably to the shell ring 6'. The milk collection container 7' additionally has a coupling part 72 with an integrated valve (not shown here) which can be plugged onto the milk port 45 of the membrane housing part 4 facing away from the breast, such that the expressed milk can flow from the underpressure chamber 40 into the interior of the milk collection container 7'. The valve corresponds to the non-return valve 5 in the embodiments described above.

Id. ¶69; *see also id.* Figs. 4, 9, 10.

72. Khalils also discloses a funnel-shaped flange, referred to as a "breast interface," "for placing on a human mother's breast." *Id.* ¶¶48 ("The breastshield unit 9 has a breast interface 1 for placing on a human mother's breast and a shell 6 on which the breast interface 1 is secured releasably."); *id.* at 60 ("As can be seen here, the breast interface 1 preferably has a base part 12 with a slightly funnel-shaped

configuration and the stub 10 formed integrally thereon.”). The breast interface has a stub 10 which is where the user’s “nipple B protrudes into”:

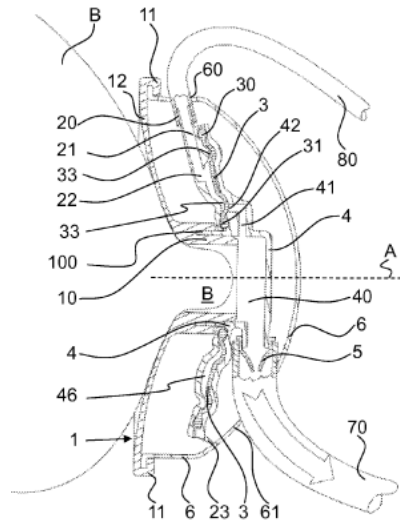


FIG. 4

Id. ¶60, Fig. 4.

C. Weber (EX-1007)

73. Weber is a U.S. patent application publication that was published on November 1, 2012. Weber is entitled “Device and Method for Expressing Human Breast Milk.”

74. Weber is generally directed to a “device for expressing human breast milk” using a battery-operated “vacuum pump.” Weber, Abstract; *see also id.* ¶3 (“In the devices of the second type, the vacuum pump is operated electrically, it being possible for the vacuum pump to be connected to the power supply network and/or to be operated via a battery or another energy accumulator.”), 70 (“The

electric motor can be operated from the electric supply network and/or the motor can be battery operated.”).

75. Weber discloses that a “diaphragm” (14’) (annotated below in purple) may be driven by and connected to the “vacuum pump” (9) via a vacuum line (12), such as illustrated in the Figure 12:

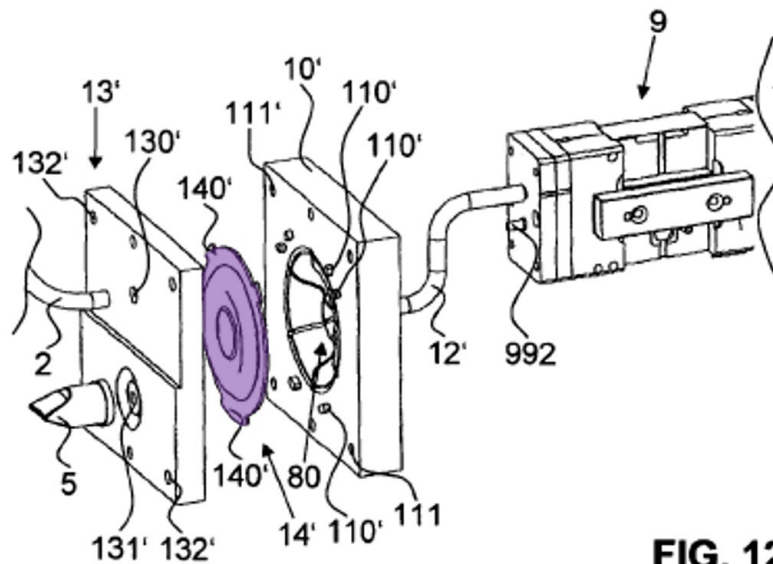
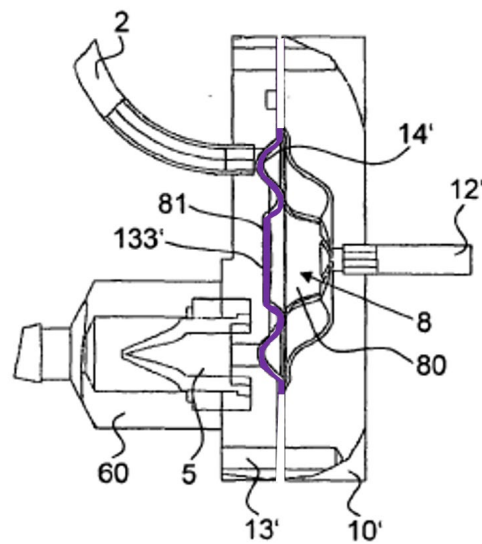


FIG. 12

Id. Fig. 12 (annotated); ¶98. As can be seen in Figure 13 below (and Fig. 12 above), the diaphragm rests in a recessed part of base plate 10 which “may be part of a vacuum pump housing” and is held “unambiguously in chamber 8” (*id.* ¶97):



Id. Fig. 13 (annotated); 95-97.

76. The diaphragm “serves as a partition wall between the breast-shield-side part 81, which is filled with milk during use, and the...pump-side part 80, which has a negative pressure and is filled with air”:

[T]he diaphragm 14' has the function of separating media and serves as a partition wall between the breast-shield-side part 81, which is filled with milk during use, and the unit- or pump-side part 80, which has a negative pressure and is filled with air. Furthermore, as before, the diaphragm 14' is moved cyclically, as is described below. As a result, the diaphragm 14' transports the milk from the breast shield 4 through the breast-shield-side part 81 into the milk collecting container 7, irrespective of the relative position of the breast shield 4, the vacuum pump 9, and the milk collecting container 7 with respect to one another.

Id. ¶96; *see also id.* ¶76.

77. Weber further discloses that its components of its device “can be combined with one another individually or in groups in order to form further embodiments.” *Id.* ¶111 (“The elements of the above-described embodiments can be combined with one another individually or in groups in order to form further embodiments”). As examples, Weber discloses in Figures 12 and 13 (above) a “vacuum-transmitting line” 2 connects the breast shield to the vacuum pump. Weber also discloses that its breast shield can be connected directly to a pump housing. *Id.* ¶21 (“The vacuum pump may have, but does not have to have, the above-mentioned vacuum-transmitting and milk-conducting line. In another embodiment, the vacuum pump for the breast shield is connected directly to the first port of the chamber”); *see also id.* ¶99. Weber also discloses embodiments where the milk collecting container 7 “may...be fastened directly to the vacuum pump”:

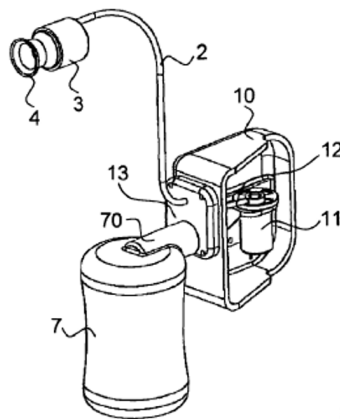


FIG. 6

Id. Fig. 6, ¶69 (“As illustrated in FIG. 6, the milk collecting container 7 may alternatively be fastened directly to the vacuum pump 1. For this purpose, there is

preferably a suitably shaped adapter 70 on the milk collecting container 7, the adapter being detachably connectable to a housing 10 of the vacuum pump.”).

78. Weber discloses that its embodiments “can also be used in known breast pumps.” *Id.* ¶110 (“The two vacuum pumps described with reference to FIGS. 12 to 15 can also be used in known breast pumps. That is to say, for example, in systems in which the suction line between the vacuum pump and breast shield is separate from the flow of milk.”). Weber further explains that its breast shield is “small and can be fixed in a bra” (*id.* ¶13), and states, “[t]he combination of the three elements a vacuum-transmitting and milk-conducting line, a pump chamber diaphragm with its triple function, and the breast shield that is of small design and avoids dead volumes results in a device that can be designed to be small and quiet, and furthermore is optimally suitable for any type of use, in particular ‘hands-free’ use.” *Id.* ¶47.

D. Guthrie (EX-1008)

79. Guthrie is a U.S. patent application publication, entitled “Smart Breast Pump System.” It was published on March 24, 2016.

80. Guthrie discloses a breast pump that includes “milk capture and collection elements” and an internal vacuum pump. Guthrie ¶35 (“smart sensor and internal pump 207 includes a vacuum pump portion that is integral to milk capture and collection element 206”); *see also id.* Fig. 2C. Guthrie also discloses that

rechargeable batteries may be used to power its pump and that such batteries may be charged via a USB cable. *Id.* ¶40 (“However, in a preferable embodiment, charging cable 404 includes a USB-A style adapter 405 that may be connected to a power source for charging batteries associated with any of the electrical components of the milk capture and collection element 101, shown in FIG. 1”).

81. Guthrie also discloses the use of milk containers with flat bottoms that allows them to “stably stand whether or not it contains milk, ensuring that [it] does not tip or spill milk that has been collected.” *Id.* ¶37 (“Bottle 304 further includes a flat base 307 to allow bottle 304 to stably stand whether or not it contains milk, ensuring that bottle 304 does not tip or spill milk that has been collected”).

IX. THE CLAIMS OF THE '380 PATENT ARE OBVIOUS

82. It is my opinion that all the claims of the '380 patent are obvious in view of Chang combined with other prior art references as discussed below. In particular, claims 1-4, 6-9, 11-16, 18-26, 29-35, 37-44 are obvious in light of Chang, Weber and Guthrie. Claims 5, 10-12, 17, 25-28, 36-38, 43-46 are obvious in light of Chang, Weber, Guthrie and Khalil.

A. Obviousness of Claims 1-4, 6-9, 11-16, 18-26, 29-35, 37-44 Based on Chang, Weber, and Guthrie

83. Claims 1-4, 6-9, 11-16, 18-26, 29-35, 37-44 are obvious in light of Chang, Weber and Guthrie.

1. Motivation To Combine Chang, Weber, Guthrie

84. A POSITA would have been motivated to combine the Chang, Weber, and Guthrie references for the reasons discussed below.

85. A POSITA would have been motivated to use Weber's diaphragm pump in Chang's breast pump device. As discussed above, Chang discloses an integrated breast pump device where all its components fit entirely within in a user's bra. Chang expressly suggests that that its breast pump device can be used with pumps that were "known" to a POSITA. Chang, ¶68 ("reference to 'the pump' includes reference to one or more pumps and equivalents thereof known to those skilled in the art"). For example, Chang describes an embodiment with a pump that generates suction by cyclical compression and decompression of a conduit or flex-tube. *See e.g., Id.* ¶22 ("According to another aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a flange or skin contact member configured to form a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit by cyclically compressing and allowing decompression of a portion of the conduit; and an external shell containing the conduit and the driving mechanism and supporting the skin contact member."); *see also id.* ¶¶25, 28, 84-86. Chang also indicates that its embodiments are not limited to that design and suggests the use of other pump

designs, such as ones that generate suction using a flexible member having a non-tubular shape:

Although both portions 32S and 32L [of the flex-tube] are shown as tubular portions, the present disclosure is not limited to such, as one or both portions could be shaped otherwise.”

Id. ¶79.

86. When considering other types of pumps that could be used with Chang, a POSITA would have been familiar with the use of diaphragm pumps in breast pumping applications. In diaphragm pumps, a diaphragm (or membrane) deforms in response to changes in air pressure caused by the pump to generate suction. A POSITA would have been motivated to consider such pumps, because as I discussed above in the in the Technology Background, a POSITA would have been quite familiar with diaphragm pumps and their use in breast pump applications at the time of the '380 patent.

87. Weber discloses a diaphragm pump that it expressly suggests could be used in other known breast pumps:

The two vacuum pumps described with reference to FIGS. 12 to 15 can also be used in known breast pumps. That is to say, for example, in systems in which the suction line between the vacuum pump and breast shield is separate from the flow of milk

Weber ¶110; *see also id.* ¶22 (“In a preferred embodiment, the vacuum pump is an electric diaphragm pump”).

88. Weber describes individual components of its disclosed embodiments, which include a breast shield, pump, and milk container, “can be combined with one another individually or in groups in order to form further embodiments.” *Id.*, ¶111. For example, Weber discloses that a breast shield and pump may be directly connected:

The vacuum pump may have, but does not have to have, the above-mentioned vacuum-transmitting and milk-conducting line. In another embodiment, the vacuum pump for the breast shield is connected directly to the first port of the chamber

Id., ¶21. Weber also discloses a milk collection container and vacuum pump may be directly connected:

As illustrated in FIG. 6, the milk collecting container 7 may alternatively be fastened directly to the vacuum pump 1. For this purpose, there is preferably a suitably shaped adapter 70 on the milk collecting container 7, the adapter being detachably connectable to a housing 10 of the vacuum pump.

Id., ¶69, Fig. 6. A POSITA also would have been motivated to combine the breast pump of Chang with the milk container of Weber. Chang discloses a flexible milk collection container that is located within the housing and is configured to be attached to and removed from the flex-tube so that milk that is pumped by the flex tube flows into the container. *Chang*, ¶¶102-107. But Chang also teaches, “[i]t is to be recognized that the collection or container assembly can be placed in alternative locations as well.” *Id.*, ¶105. And Chang also discloses that its invention can be

used with a milk container that “can be flexible or rigid, or disposable or reusable.” *Id.*, ¶21. These teachings would have motivated a POSITA to use a rigid container in an alternative location such as below the pump housing. Weber is an example of a prior art breast pump having a rigid container located below the pump housing.

89. As discussed in the Technology Background section above, Chang similarly teaches that having integrated components or separate components are alternatives that are a matter of choice for the designer, which is a concept that was well-understood by the POSITA.

90. When Weber suggests that its pump “can also be used in known breast pumps” (Weber ¶110), a POSITA would have known that such designs would have included integrated in-bra breast pumps. For example, Weber indicated that the prior art included “hands-free” breast pumps where “the breast shield is in each case integrated into a pump housing” and worn in a bra. *Id.*, ¶6 (discussing WO 02/102437 and WO 2008/137678). Weber further states that its design “results in a device that can be designed to be small and quiet, and furthermore is optimally suitable for any type of use, in particular ‘hands-free’ use.” *Id.*, ¶47. Chang is an example of a breast pump that would have been known to a POSITA that integrates the breast shield into a pump housing (*see, e.g.*, Chang, Fig. 6A, ¶72, 80; 101), and thus would have been recognized as a breast pump with which Weber’s pump design could have been used.

91. Thus, for these reasons, Chang and Weber would have motivated a POSITA to use the known diaphragm pump of Weber in the known breast pump of Chang. As discussed in the Technology Background, known technologies in the breast pump industry were often combined in a myriad of ways to achieve different designs to meet consumer preferences and needs. It would have been well within the ordinary skill of a POSITA to combine these disclosed components of Chang and Weber.

92. In addition, A POSITA also would have been motivated to combine the breast pump device of Chang with the power charging circuit of Guthrie. Chang discloses that the power supply for its breast pump was a rechargeable battery “configured to be plugged into a power source for charging.” *Chang*, ¶72. Although Chang does not expressly refer to it, a POSITA would have known that a device with a rechargeable battery necessarily would have power charging circuit for controlling the charging of the battery.

93. Rechargeable batteries were at the time of the '380 patent (and still are) typically charged using household electricity, which in the U.S. is alternating current and 120 volts. Rechargeable batteries for electronic devices such as breast pumps operate using direct current and low voltages (e.g., 3 volts). Household electricity must be converted using electrical components such as a rectifier (to convert AC to DC) and a transformer (to step down voltage) to work with the rechargeable battery.

Such electrical components were often contained in a “transformer brick” or block-shaped plug that have been ubiquitous for electrically-powered consumer devices for decades, but such components can be located in the devices themselves instead.

94. Additional modifications would also need to be made to account for additional battery-related factors such as the battery’s chemistry (e.g., Nickel-Cadmium, Nickel Metal-Hydride, and Lithium-Ion) and desired parameters such as charging time, temperature, and safety. Such modifications were typically carried out by a power charging circuit that is embodied by electrical components on one or more printed circuit boards inside the device. Without such a power charging circuit, the battery would not charge, could be damaged, and could catch fire or explode.

95. As I noted above, Chang does not expressly describe the power charging circuitry that would be needed for controlling charging of its rechargeable battery, so a POSITA would have looked elsewhere for information about a power charging circuit. Guthrie discloses a power charging circuit for controlling charging of a rechargeable battery in a breast pump application.

96. Guthrie discloses an external charging cable that connects to the breast pump device to “charge batteries associated with any of the electrical components of the milk capture and collection element....” Guthrie, ¶40. Guthrie further discloses using a charging cable that has a USB-A style adapter that can be plugged into a home electrical outlet:

[C]harging cable 404 includes a USB-A style adapter 405 that may be connected to a power source for charging batteries associated with any of the electrical components of the milk capture and collection element 101, shown in FIG. 1. Accordingly, adapter 405 may connect directly or indirectly to a source of power, such as a standard home electrical outlet, in order to charge the electrical components of the milk capture and collection element 101 shown in FIG. 1. Examples of indirect connections between adapter 405 and a source of power include connections to power adapters, transformers, or other devices meant to output power at a level appropriate for the electrical components of the milk capture and collection element 101 and the smart breast pump system disclosed herein.

Id. As discussed above, a POSITA would have known that such electrical components include a power charging control circuit so that the electricity provided by the charging cable is modified to account for battery-related factors such as the battery's chemistry and desired parameters such as charging time, temperature, and safety.

97. Thus, for these reasons, Chang and Guthrie motivated a POSITA to use the power charging circuit of Guthrie to control charging of the rechargeable battery in the breast pump of Chang.

98. A POSITA would have also been motivated to combine Chang's breast pump of Chang with Guthrie's milk container. Chang discloses a specific embodiment where its milk container is a flexible and located within the housing of the breast pump. It is configured to be attached to and removed from the pump's

flex-tube so that milk that is pumped by the flex tube flows into the container. Chang ¶¶102-107. Chang, however, also instructs that other configurations for the container are possible: “[i]t is to be recognized that the collection or container assembly can be placed in alternative locations as well” (*id.* ¶105), and the milk container “can be flexible or rigid, or disposable or reusable” (*id.* ¶21). These teachings would have motivated a POSITA to use a rigid container in an alternative location such as below the pump housing, and Guthrie would have provided a known example of a breast pump that has a rigid container located below the pump housing.

2. Claim 1

a. 1[pre]: A breast pump device comprising:

99. To the extent the preamble is considered a limitation, Chang discloses a “breast pump device.” For example, Chang is directed to and discloses “portable breast pump systems and methods for collecting milk from a breast of a nursing mother.” *Chang*, ¶1 (“The present disclosure generally relates to portable breast pump systems and methods for collecting milk from a breast of a nursing mother”); *see also id.*, Abstract (“Systems and methods for pumping milk from a breast, wherein the milk is expressed from the breast under suction and milk is expelled from the pumping mechanism to a collection container under positive pressure”).

b. 1[a]: a self-contained, in-bra wearable device comprising:

100. Chang discloses a “a self-contained, in-bra wearable device.” As previously noted in the Claim Construction section above, during the prosecution of the parent ’057 application the examiner considered this term to mean ““complete, or having all that is needed, in itself” and is capable of being worn in a bra.” *See* EX-1003 at 2167.

101. Chang discloses a breast pump that is complete, has all that is needed in itself and is capable of being worn in a bra. For example, Chang discloses a breast pump where all the components of the pump can be worn in a bra:

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.

Chang ¶19; *see also id.* ¶4 (“There is a continuing need for a small, portable, self-powered, energy efficient, wearable breast pump system that is easy to use, that mimics natural nursing, and is discrete by not exposing the breast of the user and nearly unnoticeable when worn.”), ¶11 (“The natural breast profile is contemplated to fit comfortably and conveniently into a bra of a user and to present a natural look.”).

c. 1[b]: a pump housing that includes:

102. Chang discloses this “a pump housing”. Chang discloses that its device has a “housing or outer shell.” *Id.*, ¶71 (“The housing or outer shell 12 of system 10 can be shaped and configured to be contoured to the breast of a user and to thus provide a more natural appearance when under the clothing of the user.”). Housing 12 is annotated in blue in Chang’s Figures 1A and 6A, below:

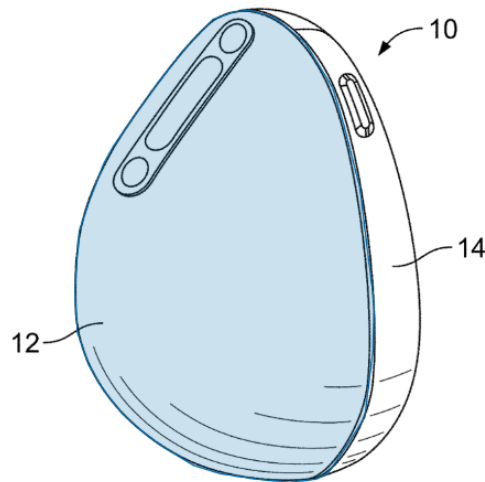
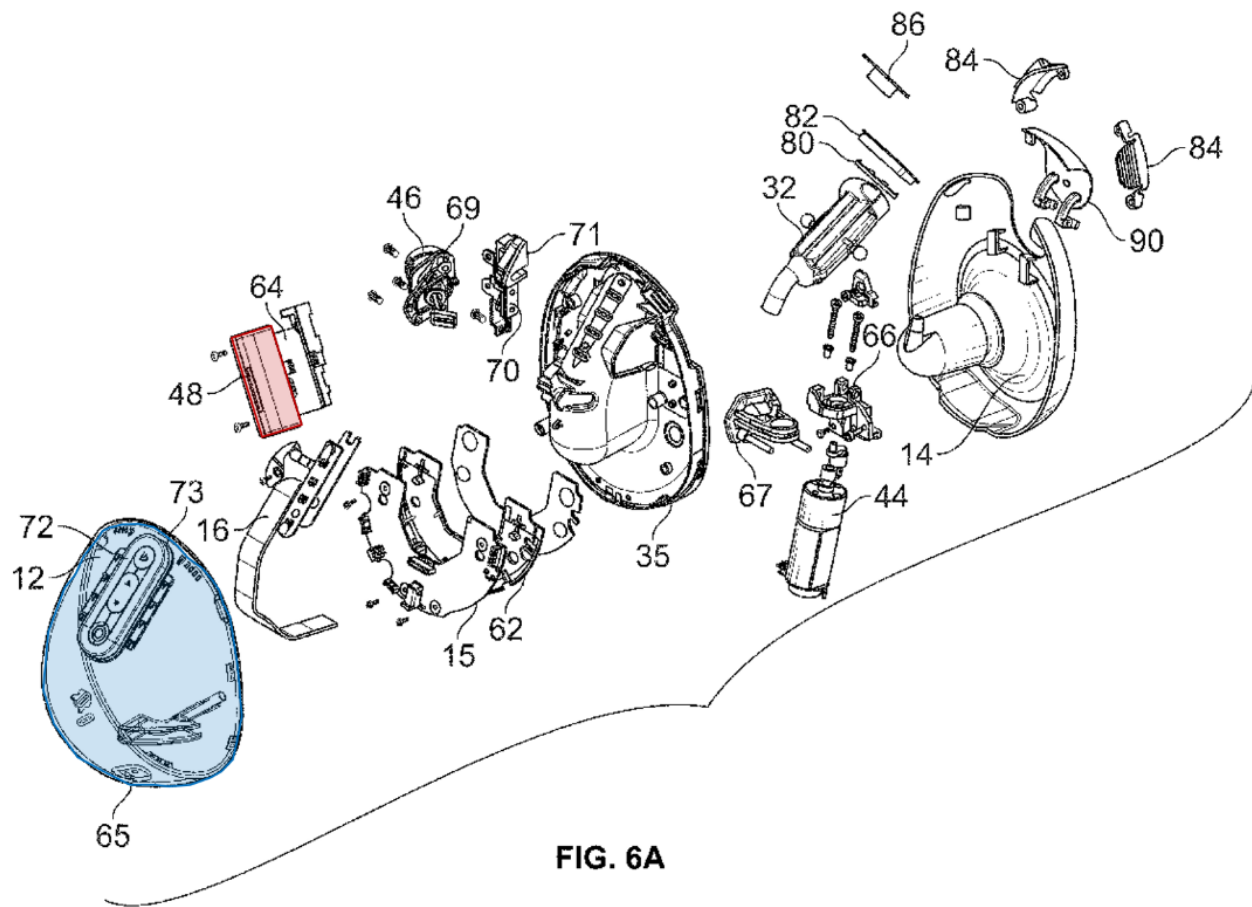


FIG. 1A



Id. Figs. 1, 6A; *see also id.* ¶¶71, ¶80.

d. 1[b][i]: a rechargeable battery,

103. Chang discloses “a rechargeable battery” in its housing. Chang discloses that it’s breast pump device “is battery powered” and that “the battery is received in the compartment of the external shell.” *Id.*, ¶20. The battery is rechargeable: “A battery 48 is included to provide a rechargeable power source and is configured to be plugged into a power source for charging.” *Id.*, ¶72; *see also id.* ¶80 (“A battery bracket 64 is also supported by the chassis 35 and is sized and shaped

to receive a rechargeable battery 48 assembly that powers the system 10.”), Fig. 6A, above (item 48 annotated in red).

104. Guthrie also discloses the use of a “rechargeable battery” under its pump housing. For example, Guthrie discloses:

In another embodiment, a vacuum pump similar to external vacuum pump 103 may be disposed within the pump portion of milk capture and collection element 101. Accordingly, 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 vacuum pump disposed within the pump portion of milk capture and collection element 101 may be disposed in such a manner as to allow the vacuum pump to apply vacuum pressure to a woman's breast, while simultaneously allowing milk to flow into the milk collection portion of milk capture and collection element 101. Regardless, a vacuum pump used in conjunction with the smart breast pump system disclosed herein are relatively small and substantially silent.

Guthrie, ¶27; *see also id.* ¶35 (“in this embodiment, milk capture and collection element 206 includes an integral smart sensor and internal pump 207”), Fig. 2C.

105. Guthrie also discloses that its battery may be charged using a charging cable: “a charging cable 404 that may charge batteries associated with any of the electrical components of the milk capture and collection element 101.” *Id.*, ¶40.

106. For the reasons discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Guthrie.

e. 1[b][ii]: a power charging circuit for controlling charging of the rechargeable battery,

107. Chang alone or in combination with Guthrie teaches “a power charging circuit for controlling charging of the rechargeable battery.” As discussed above for the previous claim element, Chang discloses a breast pump device with a rechargeable battery.

108. A POSITA would have known and found it obvious that a device with a rechargeable battery has a power charging circuit for controlling charging of the battery. As I have discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, rechargeable batteries are typically charged using household electricity, which in the U.S. is alternating current and 120 volts. Rechargeable batteries for devices such as breast pumps operate using direct current and low voltages (e.g., 3 volts). As such, a POSITA would have known that household electricity must be converted using electrical components such as a rectifier (to convert AC to DC) and a transformer (to step down voltage) to work with the rechargeable battery. Such electrical components are often contained in a “transformer brick” or block-shaped plug that have been ubiquitous for electrically-powered consumer devices for decades, but such components can be located in the devices themselves instead.

109. After such conversion of electricity, it must be further modified to account for additional battery-related factors such as the battery's chemistry (e.g., Nickel-Cadmium, Nickel Metal-Hydride, and Lithium-Ion) and desired parameters such as charging time, temperature, and safety. Such modifications are carried out by a power charging circuit comprising electrical components on one or more printed circuit boards, typically inside the device. Without such a power charging circuit, a POSITA would have understood the battery would not charge, could be damaged, and could catch fire or explode.

110. Alternatively, the combination of Chang and Guthrie teaches it. Although a POSITA would have known that Chang's device would include "power charging circuitry" for its rechargeable battery, Chang does not expressly discuss it. As such, a POSITA would have looked elsewhere for information about a power charging circuit.

111. As discussed above for the previous claim element Guthrie also discloses the use of a rechargeable battery in a breast pump system. Guthrie further discloses power charging circuit for controlling charging of its rechargeable battery. For example, Guthrie discloses an external cable connects to the breast pump device to "charge batteries associated with any of the electrical components of the milk capture and collection element 101...." Guthrie, ¶40. As I discussed in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would

have understood that such electrical components include power charging control circuit so that the electricity provided by the charging cable is modified to account for battery-related factors such as the battery's chemistry and desired parameters such as charging time, temperature, and safety.

112. Guthrie discloses that its breast pump device can have a USB-A style adapter for its charging cable. A USB-A style adapter is a type of industry standard connector for transmitting power and data. Because it is a standard interface, it was foreseeable that users of the Guthrie breast pump would use power supplies of varying characteristics to charge the device. Accordingly, a POSITA would have known that the power charging circuit to modify the electricity to account for battery-related factors such as the battery's chemistry and desired parameters such as charging time, temperature, and safety would be located inside the breast pump, on the device-side of the USB-A adapter.

113. For the reasons discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Guthrie.

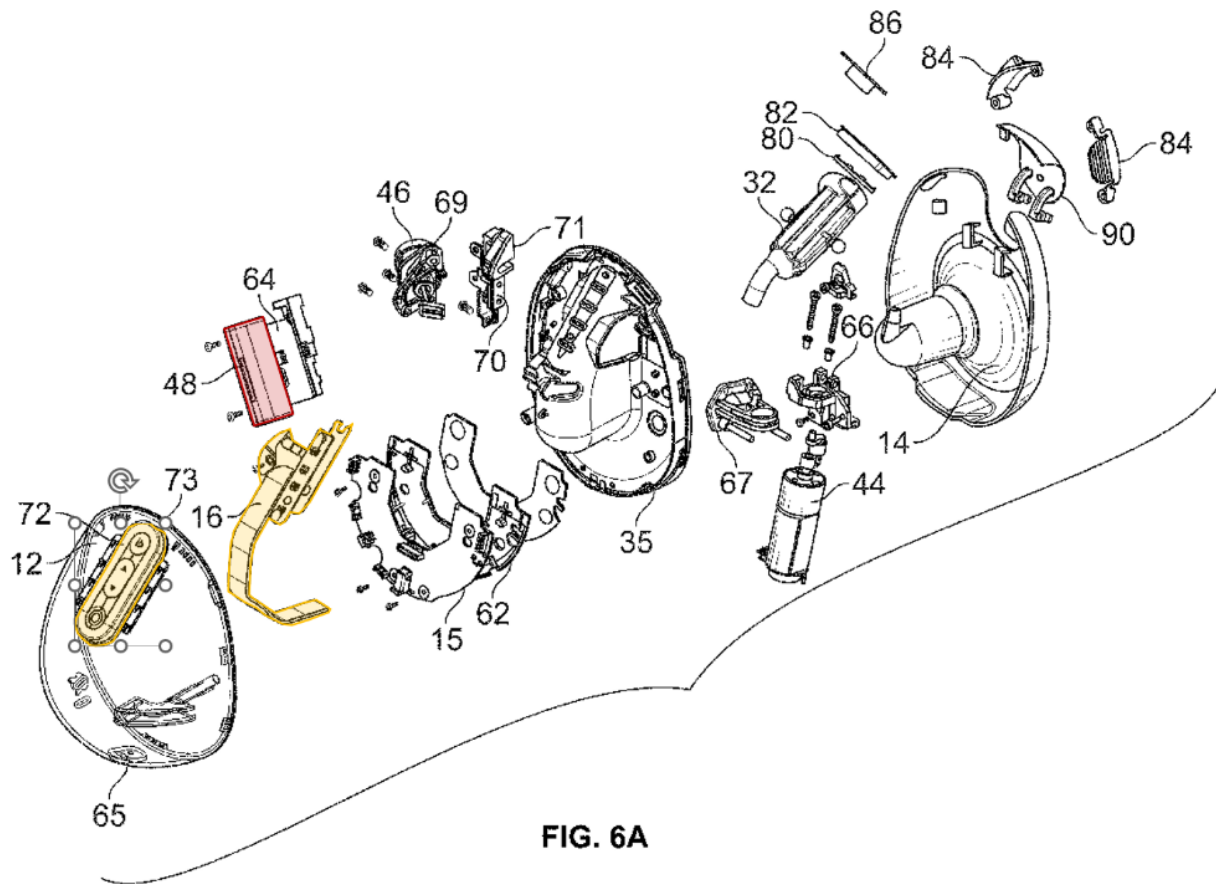
f. 1[b][iii]: control electronics powered by the rechargeable battery,

114. Chang discloses “control electronics powered by the rechargeable battery.” Chang discloses control electronics powered by rechargeable battery 48 that are within its housing:

The system controller is embodied in a circuit board 15 that is in communication with a flex-circuit 16, each cooperating to connect to and control various electro-mechanical components of the system 10. A control panel 17 is in electronic communication with the controller via the flex-circuit 16 and provides the user with the ability to power the system on and off as well as to alter functioning. One or more motors 44, 46 are further provided and controlled electronically by the system to effect manipulation of actuators (described below) operating on a conduit or flex-tube 32 (See FIGS. 4 and 5). A battery 48 is included to provide a rechargeable power source and is configured to be plugged into a power source for charging.

Chang ¶72.

115. Chang further discloses a “user interface panel can include a button membrane 72 and a button membrane housing 73 each supported on the housing 12 and placed in engagement with the flex-circuit 16 that provides the user with system control.” *Id.*, ¶80. Below, in Figure 6A, the battery 48 is annotated in red, and the button membrane and flex-circuit 16 are annotated in yellow:



Id. Fig. 6A (annotated).

g. 1[b][iv]: a pump powered by the rechargeable battery and configured to generate negative air pressure,

116. The combination of Chang and Weber teaches “a pump powered by the rechargeable battery and configured to generate negative air pressure.”

117. In an embodiment, Chang discloses a pump that generates a vacuum with a compressible “conduit or flex-tube.” Chang, ¶¶72-75. Chang, however, indicates that it is not limited to just this pump design: “reference to ‘the pump’ includes reference to one or more pumps and equivalents thereof known to those skilled in the art.” *Id.* ¶68. Chang further provides that the pump need not rely on a

tubular structure. *Id.* ¶79 (“Although both portions 32S and 32L are shown as tubular portions, the present disclosure is not limited to such, as one or both portions could be shaped otherwise.”).

118. Weber discloses use of a specific kind of vacuum pump with a diaphragm. Weber ¶19 (“The vacuum pump is preferably a diaphragm pump, wherein the chamber is the vacuum-generating pump chamber of the vacuum pump, and the diaphragm is the diaphragm of the pump chamber used for generating the vacuum.”). As I discussed above in the Technical Background, the diaphragm pump was a common type of pump that was well-known to be used in breast pumps. These types of pumps generate negative pressure, e.g., vacuum or suction. Weber teaches that its pump design can be used in other known breast pumps:

The two vacuum pumps described with reference to FIGS. 12 to 15 can also be used in known breast pumps. That is to say, for example, in systems in which the suction line between the vacuum pump and breast shield is separate from the flow of milk.

Weber, ¶110. Weber also discloses that its pump is battery operated. *Id.* ¶22 (“In a preferred embodiment, the vacuum pump is an electric diaphragm pump”), ¶70 (“The electric motor can be operated from the electric supply network and/or the motor can be battery operated.”).

119. For the reasons discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Weber.

h. 1[b][v]: a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery, and

120. The combination of Chang and Guthrie teaches a “a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery.”

121. Chang discloses that the housing of its breast pump has a “cover jack...included to provide access to the battery assembly and for accepting a power cord connector.” Chang, ¶80. Chang does not specify describe a specific interface to charge its battery, so a POSITA would have been motivated to look elsewhere. As I discussed above with respect to claim element 1[b][ii], Guthrie discloses the use of a USB-A type charging socket for transferring power to the power charging circuit and the rechargeable battery. *See, e.g.*, Guthrie ¶40 (“However, in a preferable embodiment, charging cable 404 includes a USB-A style adapter 405 that may be connected to a power source for charging batteries associated with any of the electrical components of the milk capture and collection element 101, shown in FIG. 1.”).

122. For the reasons discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Guthrie.

i. 1[b][vi]: a recess or cavity that defines a pumping chamber;

123. Weber discloses “a recess or cavity that defines a pumping chamber.” As discussed, Weber discloses a “vacuum-generating pump chamber of [a] vacuum pump.” Weber, ¶19. As shown in Figure 13 below, Weber discloses a pumping chamber 8 that is defined by a recess or cavity between cover 13' and base plate 10': .

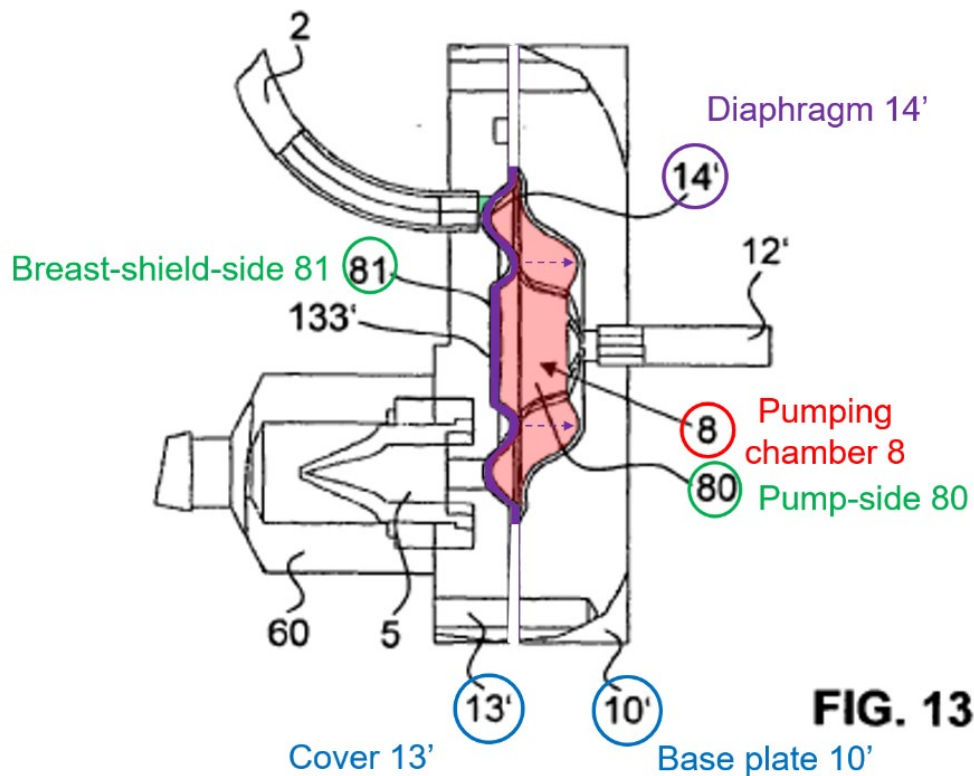


FIG. 13

Id. Fig. 13 (annotated). The diaphragm 14 is shown in a relaxed position in annotated Figure 13, above, and divides pumping chamber 8 into a breast-shield-side 81 and a pump-side 80. *Id.*, ¶95 (“The expressed milk is transported on the breast side from the breast shield 4 via the first line to a chamber 8 and from there is transported further into the milk collecting container 7. Furthermore, a diaphragm 14’ is also arranged here in the chamber 8, the diaphragm dividing the chamber 8 into a breast-shield-side region and a drive-side or unit-side region.”); *see also id.* 96 (“[T]he diaphragm 14’ has the function of separating media and serves as a partition wall between the breast-shield-side part 81, which is filled with milk during use, and the unit- or pump-side part 80, which has a negative pressure and is filled with air. Furthermore, as before, the diaphragm 14’ is moved cyclically, as is described below. As a result, the diaphragm 14’ transports the milk from the breast shield 4 through the breast-shield-side part 81 into the milk collecting container 7, irrespective of the relative position of the breast shield 4, the vacuum pump 9, and the milk collecting container 7 with respect to one another.”).

124. For the reasons discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Weber.

j. 1[c]: a breast shield made up of a breast flange and a nipple tunnel;

125. Chang discloses “a breast shield made up of a breast flange and a nipple tunnel.” Chang’s breast pump device includes a breast shield with a flange:

An opposite side of the pump system 10 is configured with a flange 14 which is sized and shaped to engage a breast of a user. The flange 14 is contoured to comfortably fit against a wide range of user's bodies and to provide structure for sealingly engaging with breast tissue. In one particular embodiment, the flange 14 can form generally rigid structure, and alternatively or additionally unlike a standard flange can lack sharp edges or a lip portion against which breast tissue might be engaged during use.

Chang ¶71.

126. Chang’s flange has a “nipple tunnel,” which is described as “a nipple receiving portion”:

The nipple receiving portion of the skin contact member 14 is contoured to more closely match the natural shape of the nipple, thereby eliminating or significantly reducing dead space that exists around the nipple in prior art systems. The nipple receiving portion can be cylindrical in the portion adjoining the breast contact portion, and then can taper conically.

Id., ¶90). The shape of Chang’s flange can be readily ascertained from Figure 4 below, with the nipple receiving portion (i.e., nipple tunnel) shown in green and the portion that engages the user’s breast in purple.

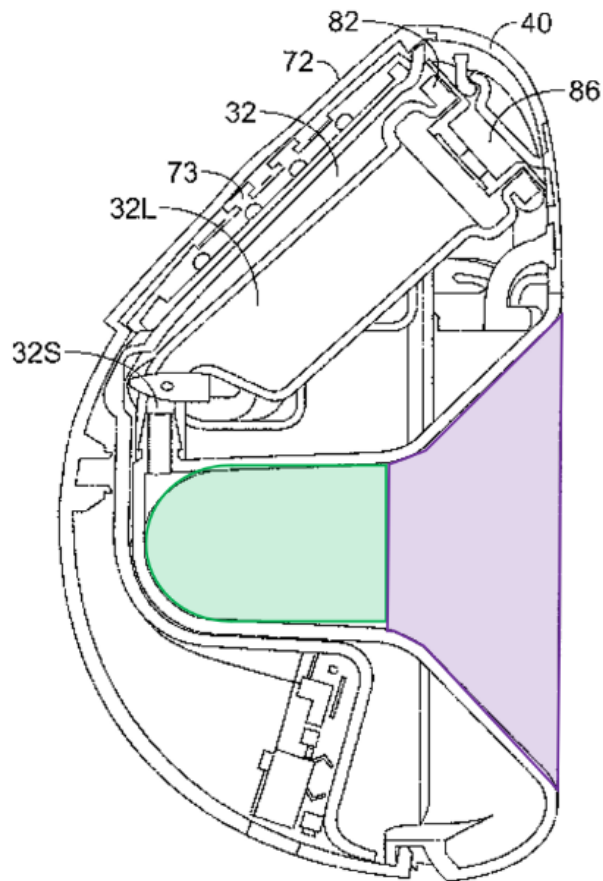


FIG. 4

Id. Fig. 4 (annotated).

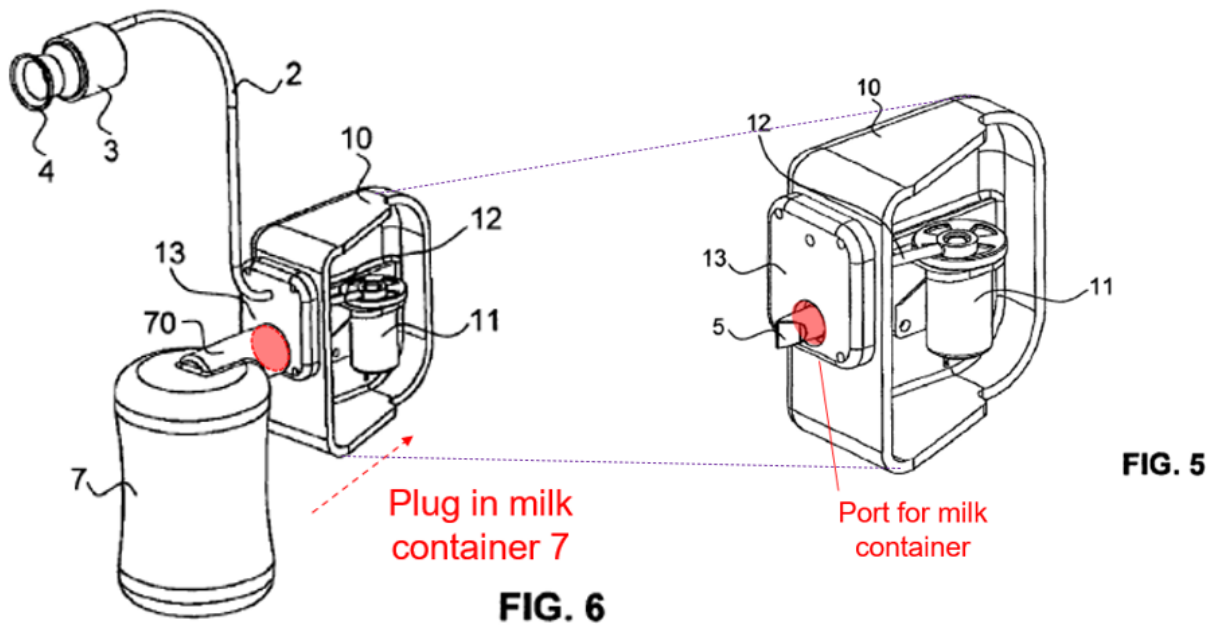
127. A POSITA would have understood that Chang's flange 14 and extended portion for receiving the nipple disclose this breast shield element. For example, the '380 patent discloses that "[t]he breast shield 7 is designed to engage with the user's breast, and comprises a concave inner flange 7A which contacts the breast." EX-1001 at 8:62-64; *see also id.* 9:13-15("the breast shield is the only component which contact's the wearer's breast.").

k. 1[d]: a milk container that is configured to be attached to and removed from the pump housing; and

128. The combination of Chang and Weber teaches “a milk container that is configured to be attached to and removed from the pump housing.”

129. Chang discloses a milk container, which it refers to as a “container.” *See* Chang, ¶¶102-107. Chang discloses a specific embodiment where its milk container is a flexible and located within the housing of the breast pump. It is configured to be attached to and removed from the pump’s flex-tube so that milk that is pumped by the flex tube flows into the container. *Id.* ¶¶102-107. Chang, however, also instructs that other configurations for the container are possible: “[i]t is to be recognized that the collection or container assembly can be placed in alternative locations as well” (*id.* ¶105), and the milk container “can be flexible or rigid, or disposable or reusable” (*id.* ¶21).

130. Weber discloses a milk container (e.g., “milk collecting container 7”) that can be attached to and removed directly from a pump housing (e.g., “housing 10”). For example, this is illustrated in Figures 5 and 6 below:

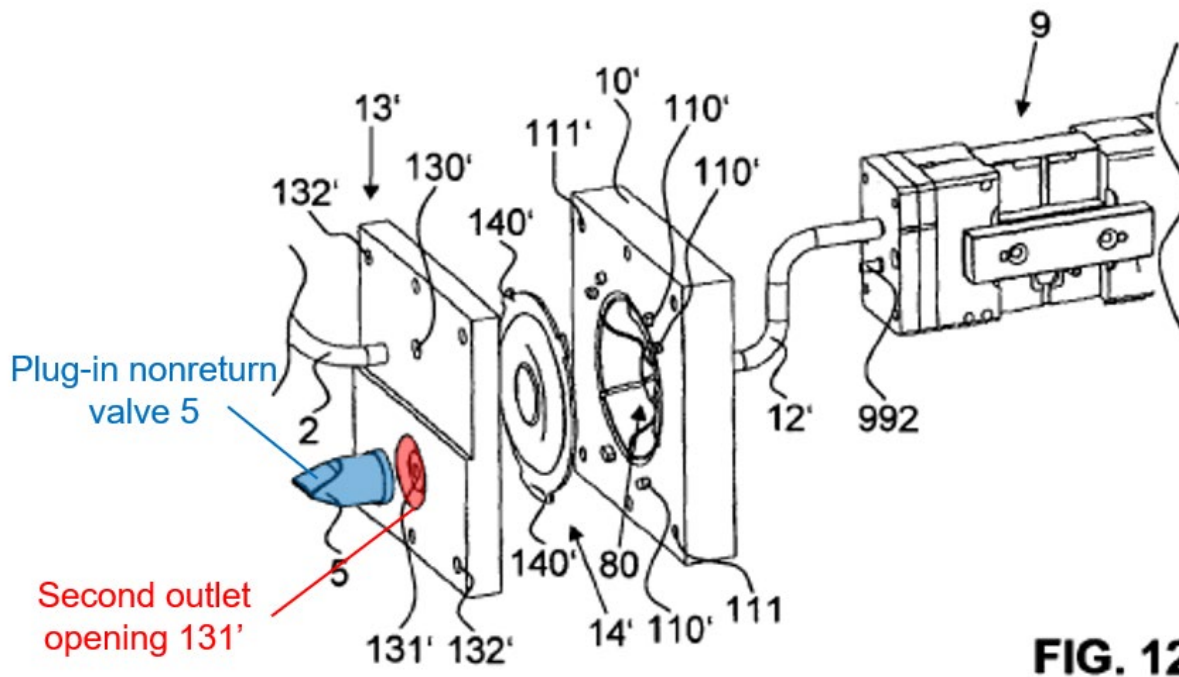


Id. Figs. 5 (annotated), 6 (annotated).

As illustrated in FIG. 6, the milk collecting container 7 may alternatively be fastened directly to the vacuum pump 1. For this purpose, there is preferably a suitably shaped adapter 70 on the milk collecting container 7, the adapter being detachably connectable to a housing 10 of the vacuum pump.

Id., ¶69.

131. Weber discloses that this “detachably connectable” milk container configuration may be used in Weber’s other embodiments, such as shown in Figure 12 below:



Id. Fig. 12 (annotated); *see also id.* at ¶75 (“In the cover 13, i.e. in the valve plate, there is a first outlet opening 130, which connects the environment to the cover-side part of the pump chamber. The outlet opening 130 serves as a first port for the first line 2. A second outlet opening 131, which likewise connects the cover- and the breast-side part of the pump chamber to the surroundings, respectively, is designed as a second port. The second port is provided with the nonreturn valve 5. A duckbill valve may be plugged onto a connector. However, other types of valve are also usable.”).

132. For the reasons discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Weber. For example, as I discuss in that section, Chang would have

motivated a POSITA to use a rigid container in an alternative location, and Guthrie would have provided a known example of a breast pump that has a rigid container located below the pump housing.

- I. **1[e]: a diaphragm that is configured to prevent milk from reaching the pump, the diaphragm being seated against a diaphragm housing that is fixed to a recessed surface of the pump housing, and the diaphragm being a membrane that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.**

133. Weber discloses “a diaphragm that is configured to prevent milk from reaching the pump, the diaphragm being seated against a diaphragm housing that is fixed to a recessed surface of the pump housing, and the diaphragm being a membrane that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.”

134. For example, Weber discloses a “diaphragm”:

The milk line can be realized in various ways. In a preferred embodiment, there is a partition wall, which separates a vacuum pump drive and the line from each other. As a result, the chamber is divided by the partition wall into a breast-shield-side region and a drive-side region. The two regions are completely separated from each other and are connected to each other only via the diaphragm. Thus, milk does not pass into the drive-side region of the vacuum pump, nor does dirt or air pass from the drive-side region pass into the milk-conducting line and therefore into the breast shield and the milk

collecting container. The partition wall is preferably a diaphragm.

In a preferred embodiment, the diaphragm is driven and serves to convey the expressed milk. As a result, the milk can be expressed independently of the relative position of the breast shield, the milk collecting container, and the vacuum pump with respect to one another. The mother may, for example, even express milk while lying down. This is optimum in particular in a “hands-free” embodiment since the mother may bend down and in general move very freely.

Weber, ¶¶16-17; *see also id.* ¶23 (“The diaphragm preferably has a substantially circular outline. The diaphragm is preferably driven in the central region thereof, preferably in the center thereof.”), ¶71 (“The diaphragm 14 is arranged in a recess 112 of the housing 10, which forms part of a pump chamber.”), ¶95 (“Furthermore, a diaphragm 14’ is also arranged here in the chamber 8, the diaphragm dividing the chamber 8 into a breast-shield-side region and a drive-side or unit-side region.”), ¶96 (“the diaphragm 14’ has the function of separating media and serves as a partition wall between the breast-shield-side part 81, which is filled with milk during use, and the unit- or pump-side part 80, which has a negative pressure and is filled with air. Furthermore, as before, the diaphragm 14’ is moved cyclically, as is described below. As a result, the diaphragm 14’ transports the milk from the breast shield 4 through the breast-shield-side part 81 into the milk collecting container 7,

irrespective of the relative position of the breast shield 4, the vacuum pump 9, and the milk collecting container 7 with respect to one another.”).

135. Referring to Figures 12 and 13 below, Weber discloses that the diaphragm is configured to prevent milk from reaching the pump:

[T]he diaphragm 14' has the function of separating media and serves as a partition wall between the breast-shield-side part 81, which is filled with milk during use, and the unit- or pump-side part 80, which has a negative pressure and is filled with air.

Id., ¶96; *see also id.* ¶16 (“The two regions are completely separated from each other and are connected to each other only via the diaphragm. Thus, milk does not pass into the drive-side region of the vacuum pump, nor does dirt or air pass from the drive-side region pass into the milk-conducting line and therefore into the breast shield and the milk collecting container”).

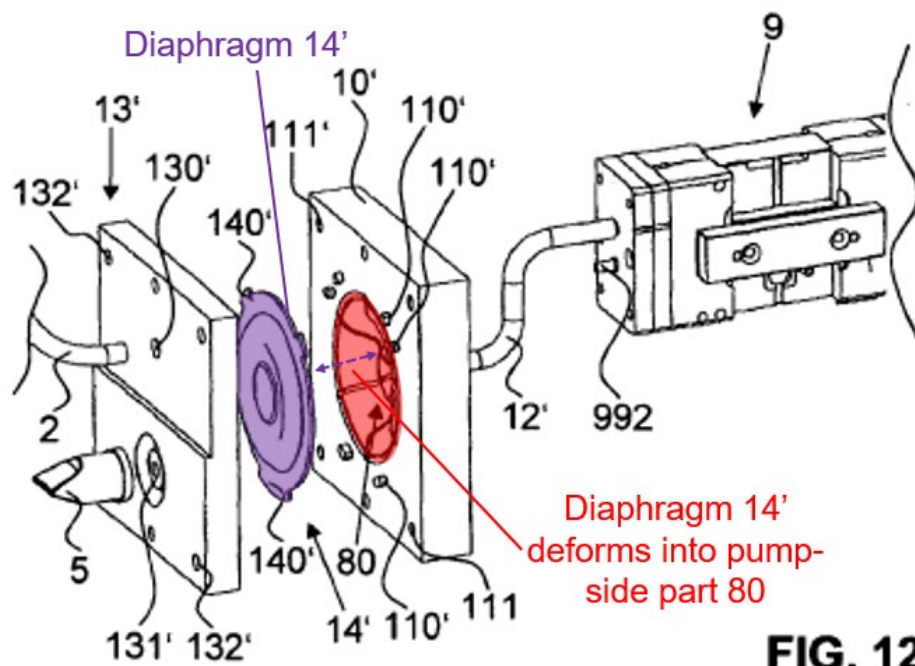


FIG. 12

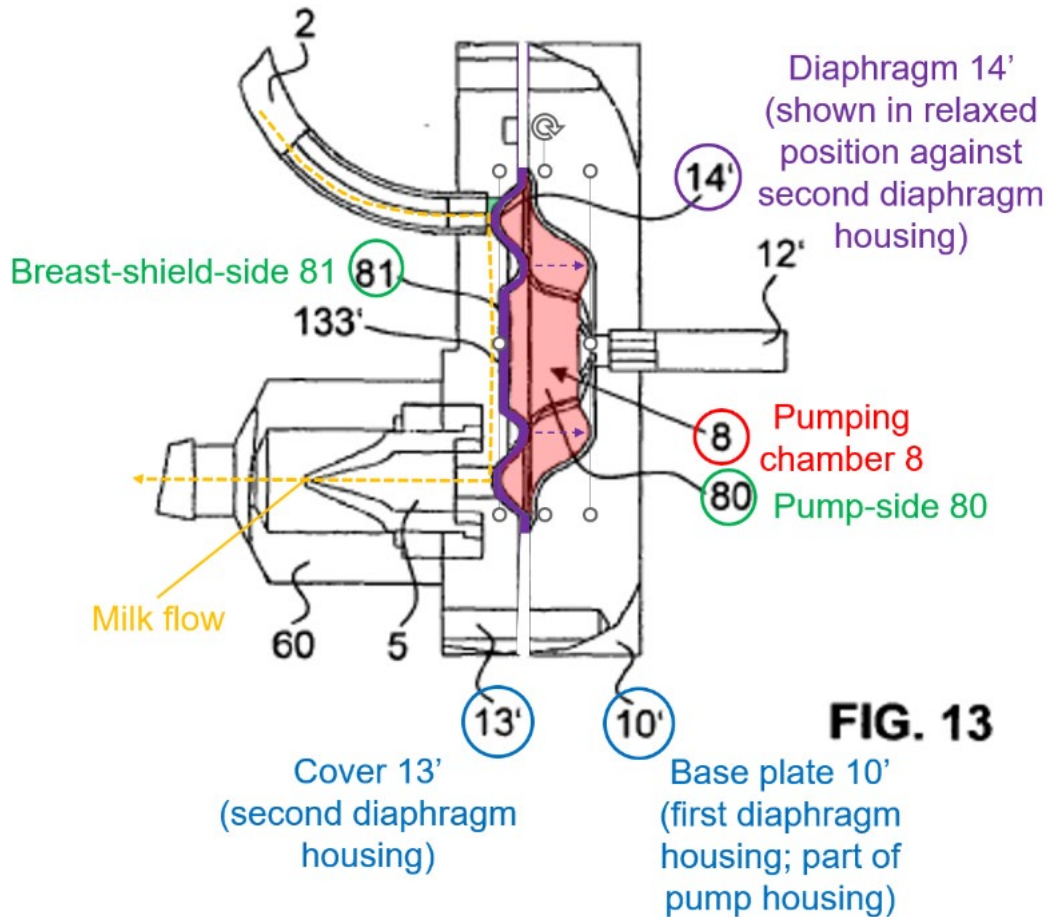


FIG. 13

Id., Figs. 12-13 (annotated).

136. Weber further discloses that its diaphragm is seated against the diaphragm housing that is fixed to a surface of the housing and arranged in a recess of the housing:

The diaphragm 14 is arranged in a recess 112 of the housing 10, which forms part of a pump chamber.

Id., ¶71.

The diaphragm 14' illustrated here has a circular outline, the diaphragm having laterally protruding wings 140'. There are three wings 140'. The base plate 10', which in turn may be part of a vacuum pump housing has lateral

stops 110' between which the wings 140' are held. As a result, the diaphragm 14' can be held in an unambiguous position in the chamber 8, which facilitates assembly.

Id., ¶97.

137. Weber discloses that its diaphragm is a membrane (a POSITA would understand that the term “diaphragm” means “membrane”) that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel:

Furthermore, as before, the diaphragm 14' is moved cyclically, as is described below. As a result, the diaphragm 14' transports the milk from the breast shield 4 through the breast-shield-side part 81 into the milk collecting container 7, irrespective of the relative position of the breast shield 4, the vacuum pump 9, and the milk collecting container 7 with respect to one another.

Id., ¶96.

The embodiment described here is a separate diaphragm pump, referred to here as a pump unit 9. The diaphragm 14' is connected to the pump unit 9 via a vacuum line 12' and is driven by the pump unit 9 on the basis of the cyclically changing pressure in the vacuum line 12'.

Id., ¶98.

138. For the reasons discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Weber.

3. Claim 29

139. Claim 29 is very similar to claim 1. The combination of Chang, Weber, and Guthrie as set forth above also discloses and teaches all the elements of claim 29.

a. 29[pre]: A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:

140. Element 29[pre] corresponds to elements 1[pre] and 1[a]. The prior art discloses this element of claim 29 for the same reasons discussed above for element 1[pre] and 1[a].

b. 29[a]: a self-contained, in-bra wearable device comprising:

141. Element 29[a] is the same as element 1[a]. The prior art discloses this element of claim 29 for the same reasons discussed above for element 1[a].

c. 29[b]: a housing that includes:

142. Element 29[b] is the same as element 1[b] except it uses the term “housing” rather than “pump housing.” The prior art discloses this element of claim 29 for the same reasons discussed above for 1[b]. For example, as discussed above, Chang discloses that its device has a “housing or outer shell.”

d. 29 [b][i]: a rechargeable battery,

143. Element 29[b][i] is the same as element 1[b][i]. The prior art discloses this element of claim 29 for the same reasons discussed above for element 1[b][i].

- e. **29 [b][ii]: a power charging circuit for controlling charging of the rechargeable battery,**

144. Element 29[b][ii] is the same as element 1[b][ii]. The prior art discloses this element of claim 29 for the same reasons discussed above for element 1[b][ii].

- f. **29 [b][iii]: control electronics powered by the rechargeable battery,**

145. Element 29[b][iii] is the same as element 1[b][iii]. The prior art discloses this element of claim 29 for the same reasons discussed above for element 1[b][iii].

- g. **29 [b][iv]: a pump powered by the rechargeable battery and configured to generate negative air pressure, and**

146. Element 29[b][iv] is the same as element 1[b][iv]. The prior art discloses this element of claim 29 for the same reasons discussed above for element 1[b][iv].

- h. **29 [b][v]: a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;**

147. Element 29[b][v] is the same as element 1[b][v]. The prior art discloses this element of claim 29 for the same reasons discussed above for element 1[b][v].

- i. **29 [c]: a breast shield made up of a breast flange and a nipple tunnel;**

148. Element 29[c] is the same as element 1[c]. The prior art discloses this element of claim 29 for the same reasons discussed above for element 1[c].

- j. 29 [d]: a milk container that is configured to be attached to and removed from the housing; and**

149. Element 29[d] is the same as element 1[d]. The prior art discloses this element of claim 29 for the same reasons discussed above for element 1[d].

- k. 29 [e]: a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing, the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.**

150. Element 29[e] corresponds to elements 1[b][vi] and 1[e]. Element 1[e] recites “a diaphragm housing that is fixed to a recessed surface of the pump housing,” whereas element 29[e] recites “a pumping chamber at least in part with an external surface of the housing.” The prior art discloses this element of claim 29 for the same reasons discussed above for elements 1[b][vi] and 1[e]. For example, Weber’s diaphragm is configured to define a pumping chamber at least in part with an external surface of the housing. *See, e.g.,* Weber ¶71 (“The diaphragm 14 is arranged in a recess 112 of the housing 10, which forms part of a pump chamber.”), ¶95 (“Furthermore, a diaphragm 14’ is also arranged here in the chamber 8, the diaphragm dividing the chamber 8 into a breast-shield-side region and a drive-side or unit-side region.”), ¶96 (“the diaphragm 14’ has the function of separating media and serves as a partition wall between the breast-shield-side part 81, which is filled with milk during use, and the unit- or pump-side part 80, which has a negative

pressure and is filled with air. Furthermore, as before, the diaphragm 14' is moved cyclically, as is described below. As a result, the diaphragm 14' transports the milk from the breast shield 4 through the breast-shield-side part 81 into the milk collecting container 7, irrespective of the relative position of the breast shield 4, the vacuum pump 9, and the milk collecting container 7 with respect to one another.”). A POSITA would understand that the term “diaphragm” means “membrane.”

4. **Claims 2, 30: The breast pump device of claim [1/29], wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.**

151. In my opinion, Chang discloses claims 2 and 30. Chang’s breast shield is “symmetrical about the nipple receiving portion” which is “cylindrical.” Chang, ¶¶80, 90. Additionally, the breast pump device “is disabled when the flange [“breast shield”] is not placed in an operating position.” *Id.*, ¶17. A POSITA would have understood that if the flange (“breast shield”) is symmetrical about the cylindrical nipple receiving portion and has an operating position, the flange is thus configured to rotate smoothly around a nipple inserted into the nipple receiving portion (“nipple tunnel”). This ensures the flange is positioned into a correct operating position onto a breast.

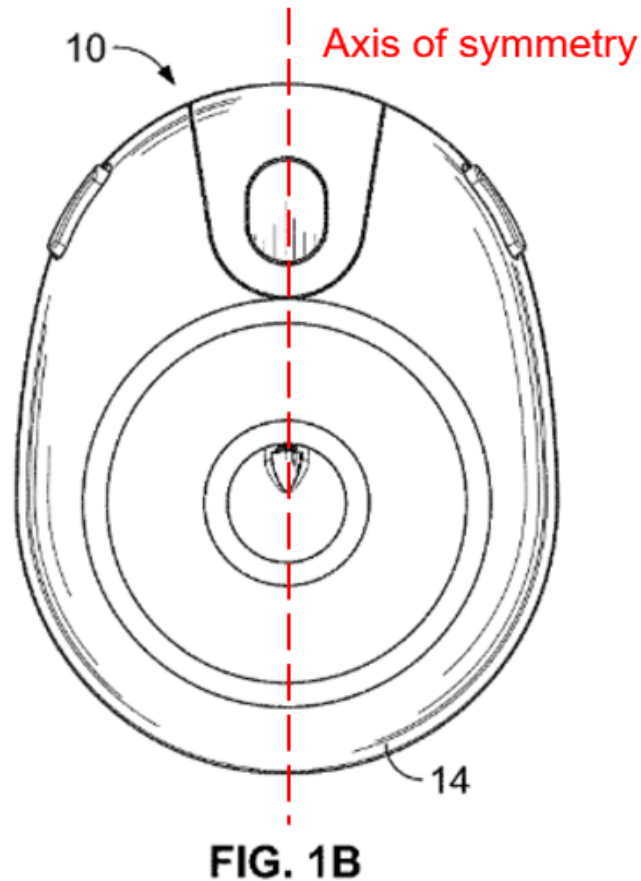
- 5. Claims 3, 31: The breast pump device of claim [1/29], wherein the breast shield is a one piece item that in use presents a single continuous surface to a nipple and a breast.**

152. In my opinion, Chang discloses claims 3 and 31. Chang discloses that the breast shield is a “skin contact member or flange configured to form a seal with the breast.” Chang, ¶22. The breast shield has “a nipple receiving portion . . . contoured to more closely match the natural shape of the nipple” and “surfaces that extend outwardly from a nipple receiving portion of the flange to engage breast tissue.” *Id.*, ¶¶71, 90. A POSITA would have understood that Chang’s breast shield is a one-piece, single item with a single continuous surface that is applied to a nipple and breast to “form a seal with the breast.” *Id.*, ¶22.

- 6. Claims 4, 32: The breast pump device of claim [1/29], wherein the breast shield has a top and bottom when positioned upright for normal use, and wherein the breast shield is generally symmetrical about a center-line running from the top to the bottom of the breast shield when positioned upright for normal use.**

153. In my opinion, Chang discloses claims 4 and 32. Figure 1B shows a back view of Chang’s breast pump, the side facing the user’s breast and includes the breast shield. Chang, ¶71. Figure 1B shows Chang’s breast pump in an upright orientation when it engages the breast for normal use. *Id.* My annotated version of Figure 1B (below) shows the breast shield has a top and bottom and is symmetrical

about a center-line running vertically from the top to the bottom of the breast shield when positioned upright for normal pumping use.

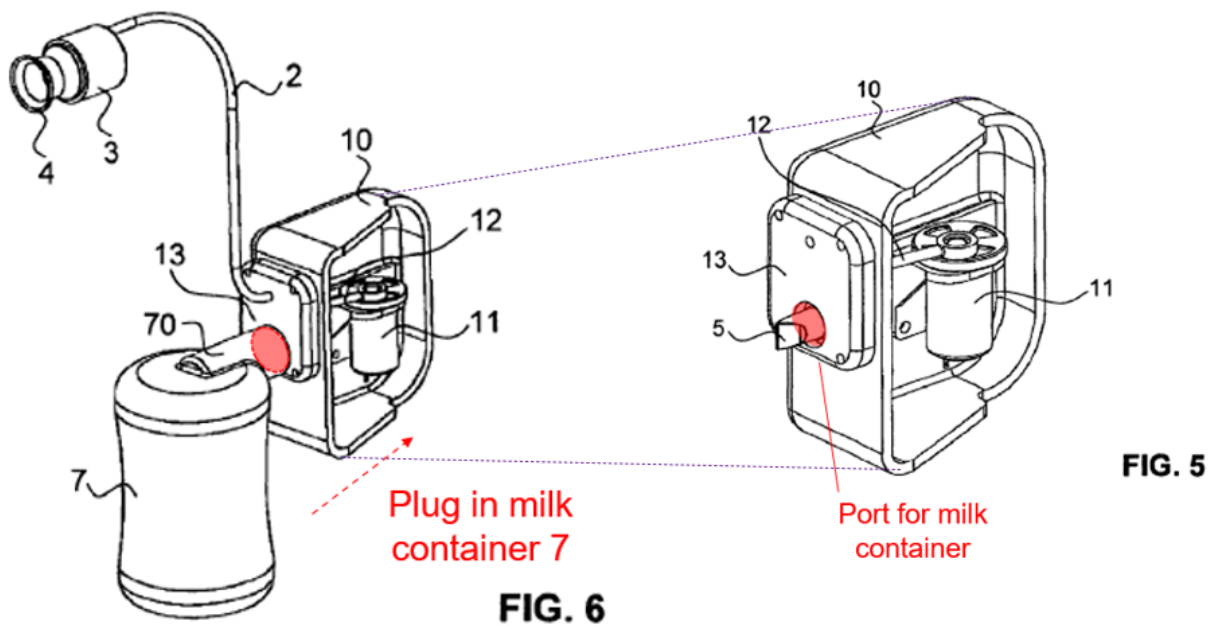


Id., Fig. 1B.

7. **Claims 6, 33: The breast pump device of claim [1/29], wherein the breast pump device includes only the breast shield and the milk container that are directly removable from the [pump housing/housing] in normal use or normal dis-assembly.**

154. In my opinion, the combination of Chang and Weber teaches claims 6 and 33. Chang's breast shield can be "removed from engagement with the remainder

of the” breast pump device. Chang, ¶105. As I explained for claim limitation 1[d], Weber discloses an embodiment in which the milk collecting container is configured to be attached to and removed from the pump housing, as shown in my annotated version of Figures 5 and 6 (below):



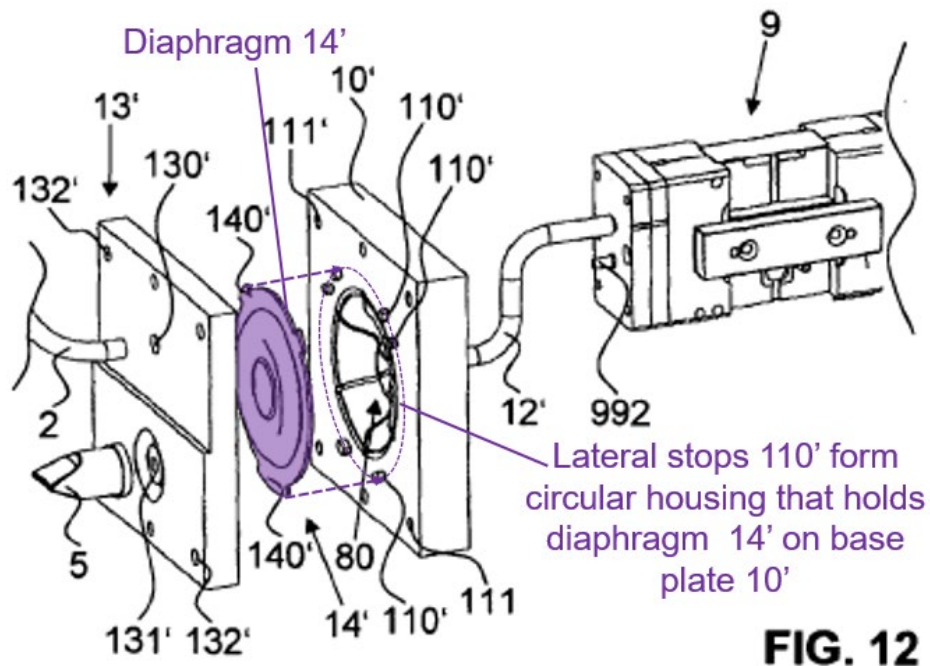
Weber Figs. 5-6.

155. As I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Weber. For example, as I discuss in that section, Chang would have motivated a POSITA to use a rigid container in an alternative location, and Guthrie would have provided a known example of a breast pump that has a rigid container located below the pump housing. Thus, it is my opinion that the Chang-Weber combination

discloses breast shield and milk container that are directly removable from the pump housing in normal use or normal disassembly.

8. **Claim 7, 34: The breast pump device of claim 1, wherein the diaphragm is substantially circular and the diaphragm housing is substantially circular (Claim 7) / The breast pump device of claim 29, wherein the membrane is substantially circular (Claim 34).**

156. In my opinion, Weber discloses claims 7 and 34. For example, my annotated version of Weber's Figure 12 (below) highlights circular diaphragm 14':



Weber, Fig. 12, ¶97. The diaphragm is held in a diaphragm housing comprising the cover 13' and base plate 10', which is part of the pump housing 9. *Id.*, ¶¶97, 99. Cover 13' and base plate 10' include circular-outlined recesses in which the diaphragm sits. When the cover and base plate are mated together, the recesses form

a pumping chamber 8 with a circular outline in which the diaphragm sits. *Id.*, ¶¶95, 97, Figs. 12-13.

157. Thus, as I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, it is my opinion that a POSITA would have been motivated to combine Chang and Weber.

9. Claims 8, 35: The breast pump device of claim [1/29], wherein the milk container is substantially rigid.

158. In my opinion, each of Chang, Guthrie, and Weber discloses claims 8 and 35. First, Chang discloses these claims. Chang states, “the container can be flexible or rigid, or disposable or reusable.” Chang ¶21.

159. Second, Guthrie discloses these claims. As shown in my annotated version of Figures 3A-B (below), Guthrie teaches a bottle 304 (red) and a valve 301 (green) that may be replaced with a rubber nipple for feeding an infant. Guthrie, ¶¶37-38.

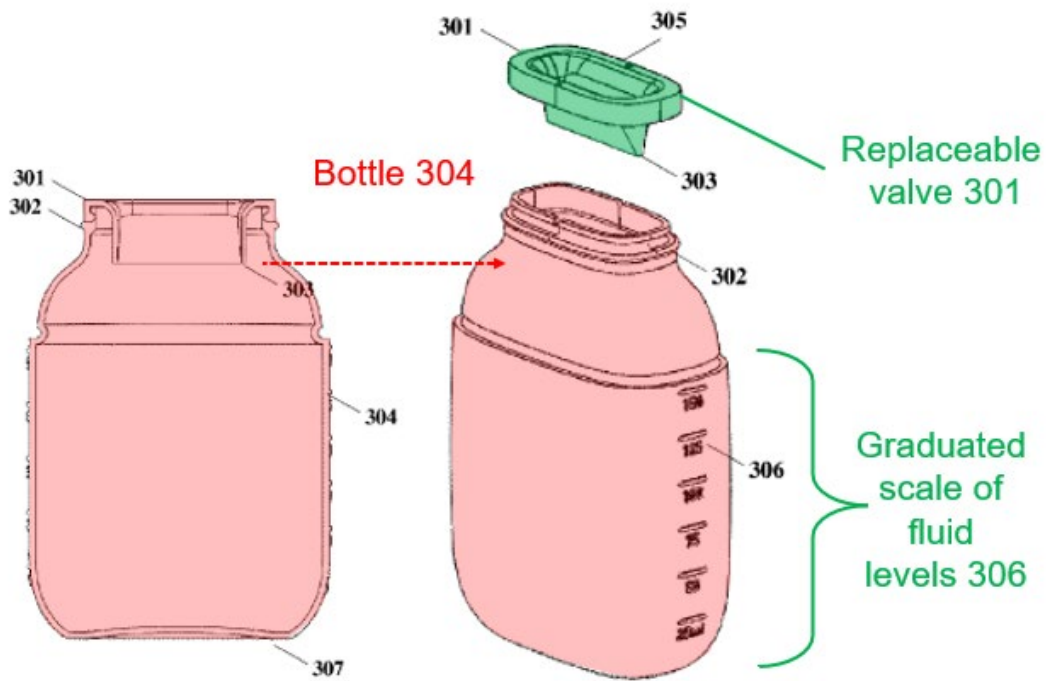
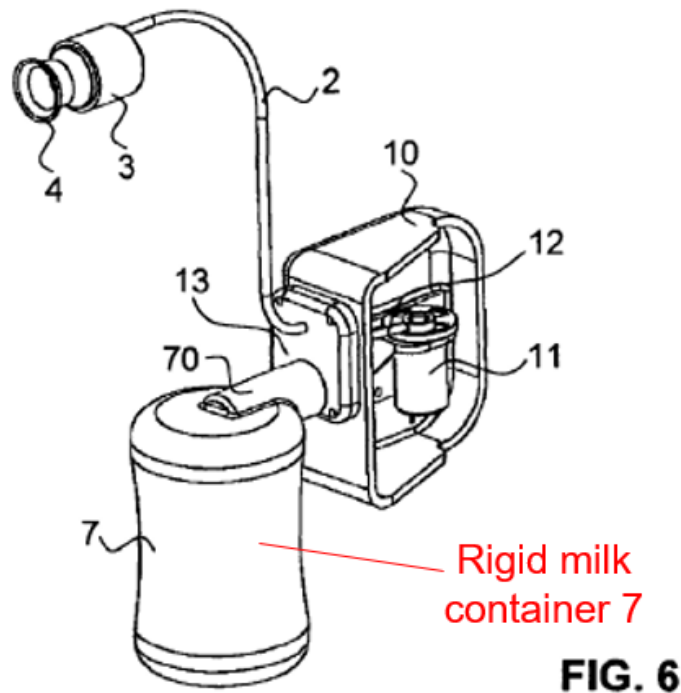


FIG. 3A

FIG. 3B

Id., Figs. 3A-B. A POSITA would have understood that Guthrie's milk collection container is rigid because it can be used as a hand-held feeding bottle.

160. Third, Weber discloses these claims. For example, Weber's Figures 1, 2, and 6 show a milk container that stands upright. My annotated version of Figure 6 (below) identifies this feature:



Weber, Fig. 6. From this disclosed orientation, it is my opinion that a POSITA would have known that Weber's milk container is substantially rigid.

161. Also as I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang with Guthrie or Weber.

10. Claim 9: The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the pump housing and to form a flat bottomed base for the breast pump device.

162. In my opinion, Guthrie discloses claim 9. Guthrie teaches a breast pump with integrated pump and bottle 304, the latter detachable from a milk capture and collection unit. Guthrie, ¶¶35, 37. As shown in my annotated version of Figure

3A (below), Guthrie teaches a bottle with “a *flat base* 307 to allow bottle 304 to stably stand whether or not it contains milk, ensuring that bottle 304 does not tip or spill milk that has been collected.” *Id.*

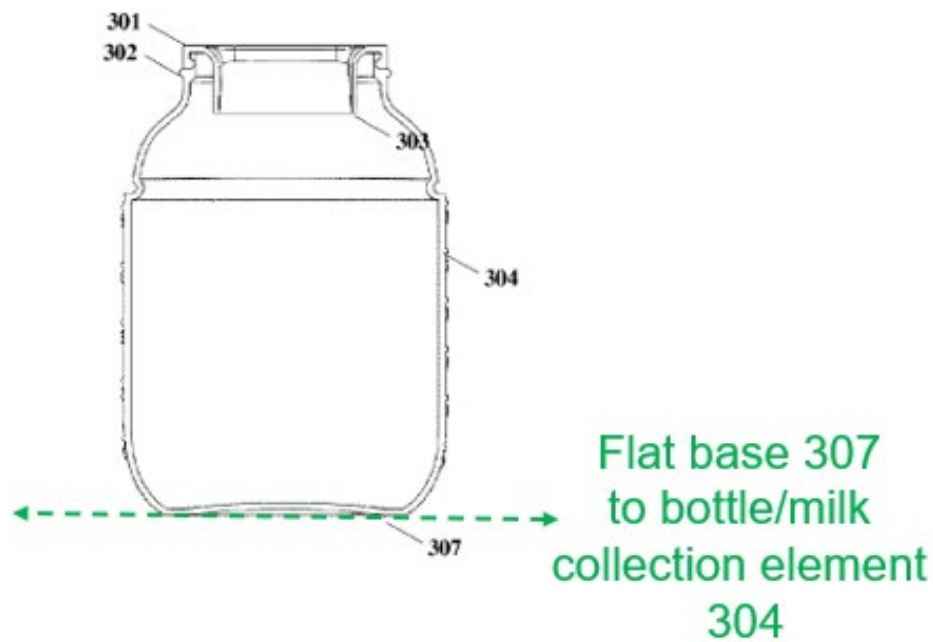


FIG. 3A

Id., Fig. 3A.

163. As shown in my annotated version of Figure 2C (below), Guthrie’s bottle (red) is configured to attach to a lower part of the pump housing and to form a flat-bottomed base for the breast pump device.

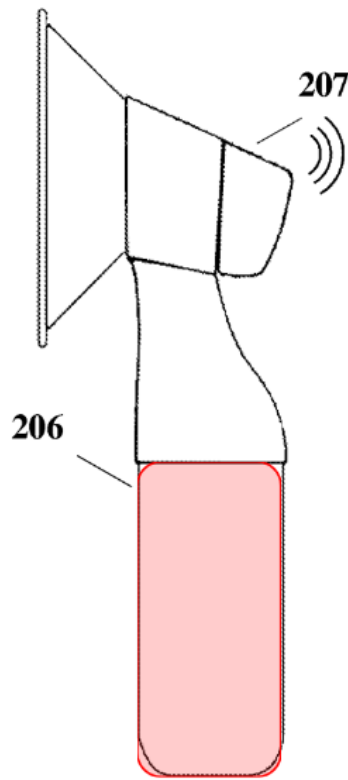


FIG. 2C

Id., Fig. 2C.

164. As discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Guthrie.

- 11. Claims 11, 37: The breast pump device of claim [1/29], wherein the milk container is attachable to the [pump housing/housing] with a mechanical or magnetic mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the [pump housing/housing] with a single push action.**

165. In my opinion, Guthrie discloses claims 11 and 37. Guthrie discloses that “types of connections between various portions of milk capture and collection element 101 may include *snaps, quick connects*, or twist (threaded) attachments.” *Guthrie* ¶24 (emphasis added). My annotated version of Figure 3A shows Guthrie’s milk collection element:

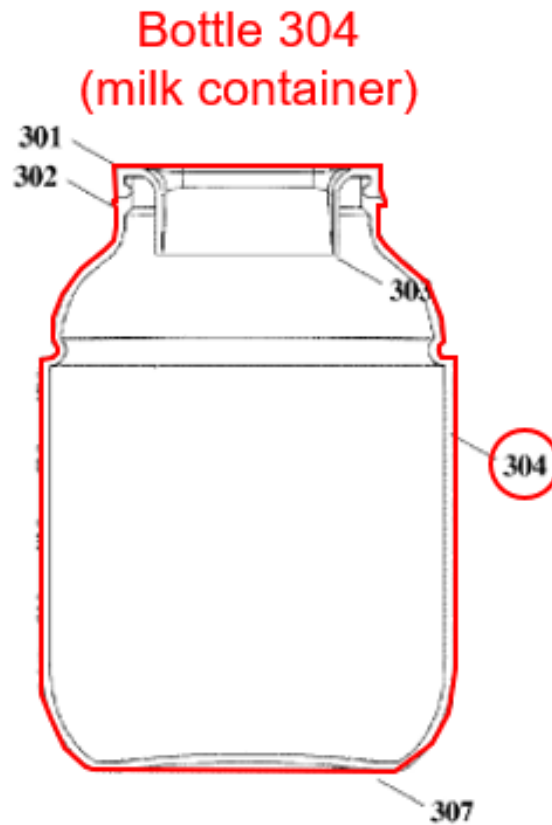


FIG. 3A

Id., Fig. 3A.

166. Guthrie states, “the milk collection element shown in FIG. 3A may attach to milk capture and collection element 101 in a manner that is substantially leak proof.” A POSITA would have known from Guthrie’s teachings that the milk collection element is attachable to the pump housing with a mechanical mechanism (such as a snap or quick connect) that releasably attaches or latches when the

collection element is sufficiently pressed on to the pump housing with a single push action.

167. As I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Guthrie.

12. Claims 12, 38: The breast pump device of claim [1/29], wherein the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows under gravity into the milk container.

168. In my opinion, Guthrie discloses claims 12 and 38. Guthrie discloses a “cup portion” that provides an interface for the user’s breast and nipple. Guthrie, ¶22. Guthrie states:

Cup portions may attach to a pump portion of milk capture and collection element 101. A pump portion of milk capture and collection element 101 comprises a vacuum pump and a vacuum chamber through which milk can flow uninterrupted as it is expressed into a milk collection portion of milk capture and collection element 101.... Accordingly, the cup portions funnel milk into the pump portion as it pumped from a woman's breast. The pump portion allows the milk to drain into a milk collection portion of milk capture and collection element 101.

Id., ¶24.

169. As shown in my annotated version of Figure 2C (below), Guthrie shows a “milk collection element” or container that is connected to the pump portion of the breast pump and sits below the pump portion. *E.g., id.*, ¶¶24, 35, Figs. 1, 2C.

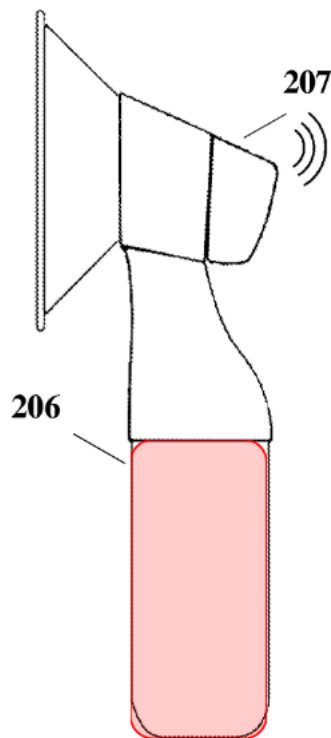


FIG. 2C

Id., Fig. 2C. Thus, milk extracted from the nipple flows downward under gravity through an opening in the lower portion of the vacuum chamber into the milk collection element.

170. As I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Guthrie.

- 13. Claims 13, 39: The breast pump device of claim [1/29], wherein the [diaphragm/membrane] defines a milk-flow side chamber on one side of the [diaphragm/membrane] and an air-side chamber on the other side of the [diaphragm/membrane].**

171. In my opinion, Weber discloses claims 13 and 39 for the same reasons I explained with respect to claim limitation 1[e], above. For example, Weber discloses:

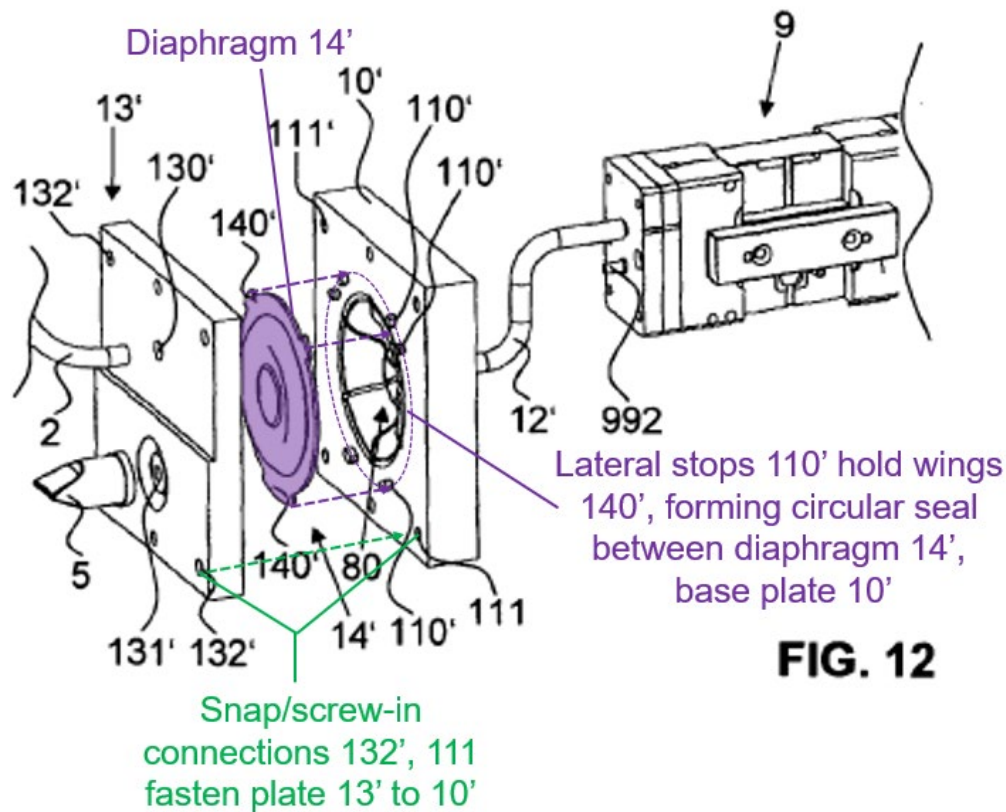
[T]he diaphragm 14' has the function of separating media and serves as a partition wall between the breast-shield-side part 81, which is filled with milk during use, and the unit- or pump-side part 80, which has a negative pressure and is filled with air.

Weber, ¶96; *see also id.* ¶71 (“The diaphragm 14 is arranged in a recess 112 of the housing 10, which forms part of a pump chamber.”), ¶16 (“The two regions are completely separated from each other and are connected to each other only via the diaphragm. Thus, milk does not pass into the drive-side region of the vacuum pump, nor does dirt or air pass from the drive-side region pass into the milk-conducting line and therefore into the breast shield and the milk collecting container”).

- 14. Claims 14, 40: The breast pump device of claim [1/29], wherein the [diaphragm/membrane] is configured to self-seal under negative pressure around its outer edge, to form a watertight and airtight seal around the recess or cavity in the [pump housing/housing].**

172. In my opinion, Weber discloses claims 14 and 40. As I explained for claim limitation 1[e], Weber's pump has a diaphragm that "has the function of separating media and serves as a partition wall between the breast-shield-side part 81, which is filled with milk during use, and the unit- or pump-side part 80, which has a negative pressure and is filled with air. Weber, ¶96.

173. As shown (below) in my annotated version of Figure 12, Weber discloses that the diaphragm has "wings" for securing it in the recess of the pump housing: "The base plate 10', which in turn may be part of a vacuum pump housing has lateral stops 110' between which the wings 140' are held. *Id.*, ¶97. As a result, the diaphragm 14' can be held in an unambiguous position in the chamber 8." *Id.*

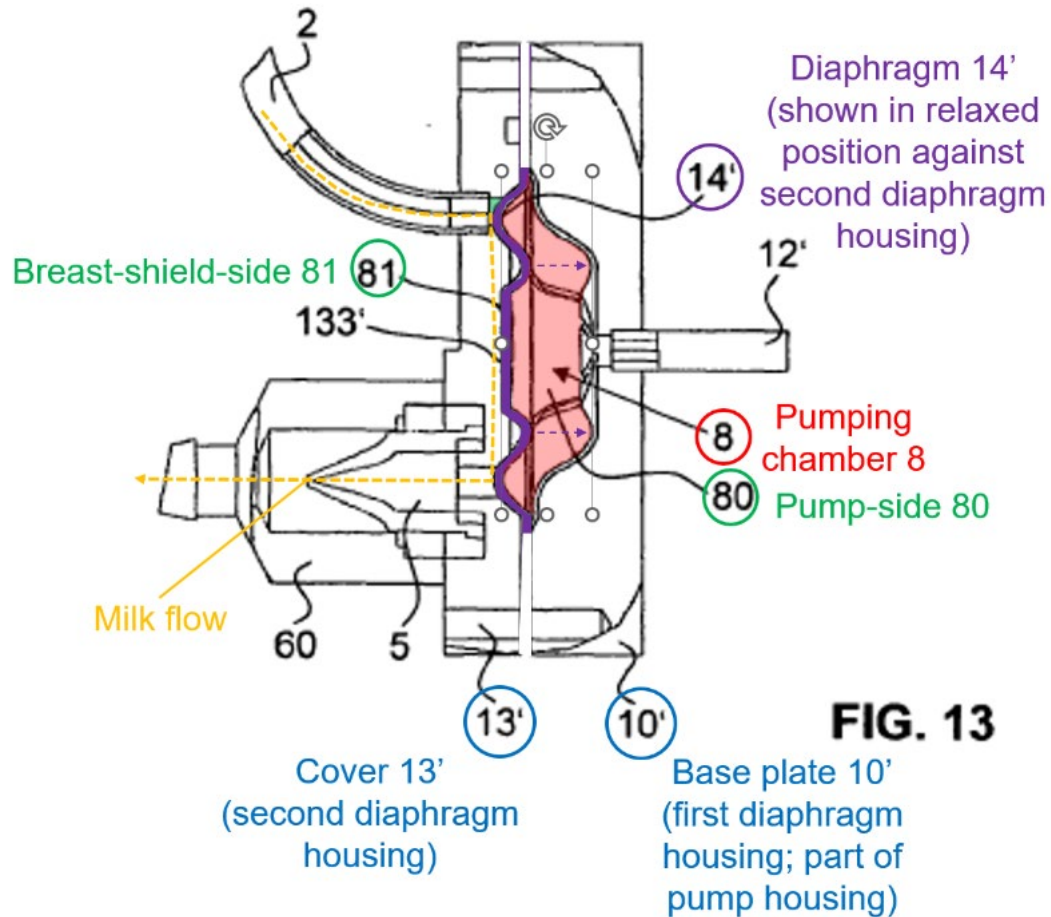


Id., Fig. 12.

174. Thus, it is my opinion that Weber teaches that the diaphragm is configured to self-seal under negative pressure around its outer edge, to form a watertight and airtight seal around the recess or cavity in the pump housing.

- 15. Claim 15: The breast pump device of claim 1, wherein the diaphragm housing is a first diaphragm housing, and wherein the breast pump device further comprises a second diaphragm housing attached to the nipple tunnel and configured to define a milk-flow side chamber, the diaphragm being configured to be positioned between the first diaphragm housing and the second diaphragm housing.**

175. In my opinion, Weber discloses claim 15. As I explained above for claim limitations 1[b][vi], 1[e] and claims 7 and 34, the diaphragm is held in a diaphragm housing comprising the cover 13' (second diaphragm housing) and base plate 10' (first diaphragm housing), which is part of the pump housing 9. Weber ¶97, ¶99, Figs. 12-13. When the cover and base plate are mated together, the diaphragm sits in a space with a circular outline that forms a pumping chamber 8. *Id.*, ¶95, ¶97, Figs. 12, 13. I show this in my annotated version of Figure 13 (below):



Id., Fig. 13.

176. When the cover and base plate are mated together, the recesses form a pumping chamber in which the diaphragm sits. *Id.* ¶¶95, 97, Figs. 12, 13. As I explained above for claims 14 and 40, the diaphragm serves as media separation between a milk-flow side (breast side) and a side with air (pump side). The cover 13' defines the milk-flow side of the pumping chamber.

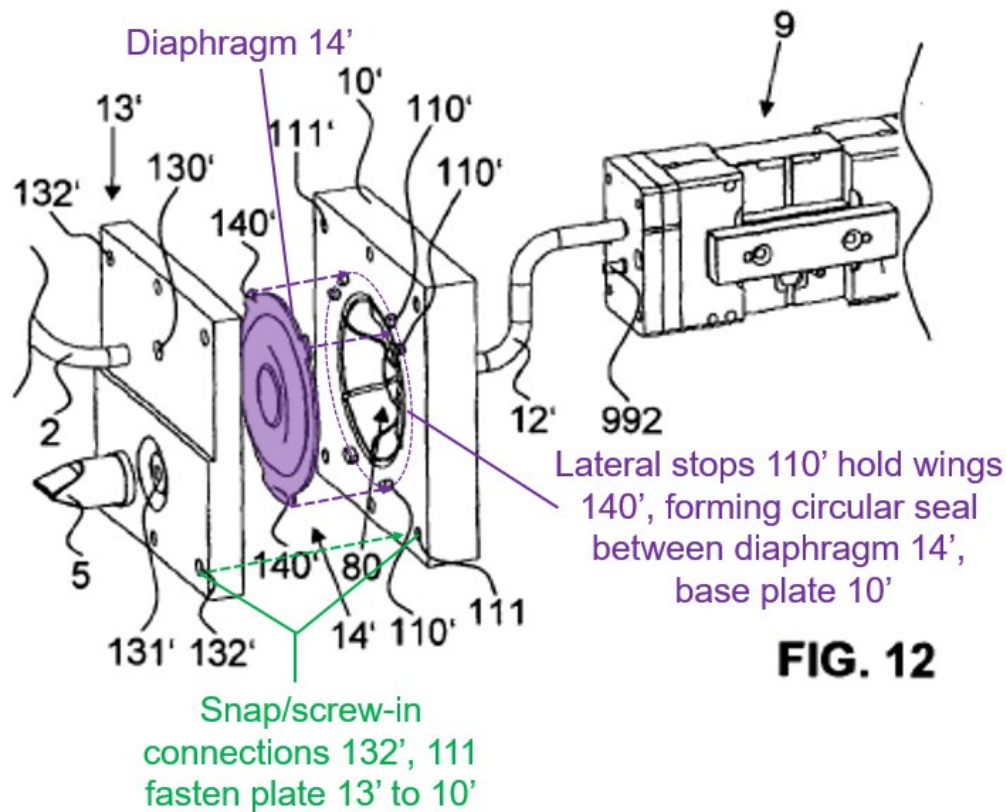
177. Further, I see that Weber discloses the breast shield can be “connected directly to the first port of the chamber” (*id.*, ¶21) which is on the cover 13’—

meaning that the breast shield and its nipple tunnel are attached to the milk-flow side of the chamber.

178. As I explained above at the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to implement Weber's two-part diaphragm housing in Chang's breast pump device. In such combination, a POSITA would have understood that the second diaphragm housing, which houses the breast-shield-side (milk) region, is attached to the nipple tunnel so that milk flows into the breast-shield-side (milk) region.

16. Claim 16: The breast pump device of claim 15, wherein the diaphragm is configured to be releasably secured around an edge of the second diaphragm housing.

179. In my opinion, Weber discloses claim 16. As shown in my annotated version of Figure 12 (below), Weber discloses a diaphragm 14' with circular outline held by its wings 140' to lateral stops 110' of base plate 10' as shown below. Weber, ¶97.

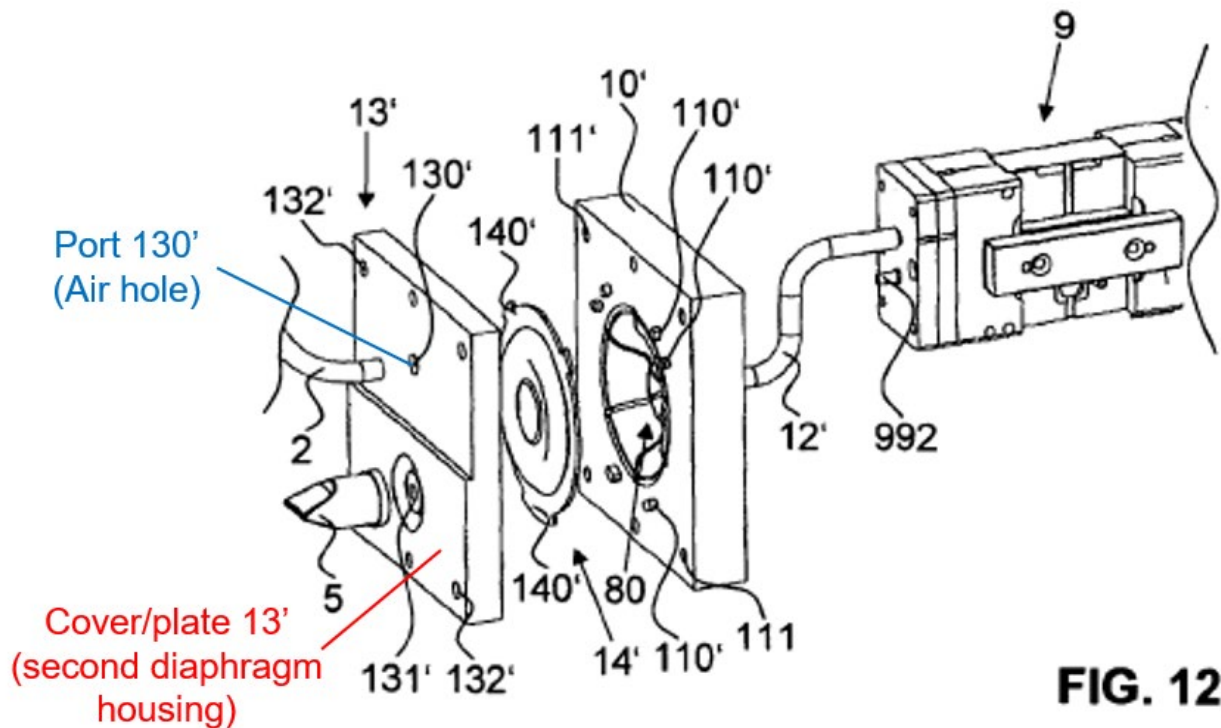


Id., Fig. 12. Weber states, “A cover 13 that is **detachably connectable** to the housing 10 **secures the diaphragm 14 in its position.**” *Id.*, ¶71 (emphasis added). As shown in annotated version of Figure 12 above, connection between cover 13' (second diaphragm housing) and base plate 10' “takes place via snap-in or screw connections, wherein the corresponding holes are provided with the designations 132' and 111'.” *Id.*, ¶99.

180. As I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Weber.

17. **Claim 18: The breast pump device of claim 15, wherein the second diaphragm housing includes an air hole to transfer negative air pressure to the nipple tunnel.**

181. In my opinion, Weber discloses claim 18. As shown in my annotated version of Figure 12 (below), Weber discloses that second diaphragm housing's cover 13' contains ports 130' and 131' to connect first and second milk lines 2, 6. Weber, ¶13.



Id., Fig. 12.

182. A POSITA would have understood that at the onset of pumping, only air would occupy milk line 2 connected to port 130', which therefore serves as an air hole facilitating the exchange of air fluid pressure until milk expression leads to the exchange of liquid fluid pressure for pump operation.

183. As I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Weber. In such a combination, Weber's port 130' ("air hole") would transfer negative air pressure from the vacuum pump to Chang's nipple tunnel to generate suction on the nipple.

18. Claim 19: The breast pump device of claim 15, wherein the diaphragm is a flexible and generally circular diaphragm and the second diaphragm housing has a corresponding generally circular shape.

184. In my opinion, Weber discloses claim 19 for the reasons I explained with respect to claims 7 and 34 and element 1[e], discussed above.

19. Claim 20: The breast pump device of claim 15, wherein the second diaphragm housing is an integral part of the breast shield.

185. In my opinion, Weber discloses claim 20. Weber's breast shield 4 includes continuous passage 43 extending through connector 40 and connects to plate 13' ("second diaphragm housing") via suction line 2 as shown in annotated Figure 13 below. Weber, ¶¶75-81. Weber discloses that the breast shield can be "connected directly to the first port of the chamber" (*id.*, ¶21) which is on the cover 13'—meaning that the breast shield and its nipple tunnel are attached to the second diaphragm housing. It would have been obvious to a POSITA to attach the breast shield to the cover such that it is an integral part of the breast shield. *Id.*, ¶XX.

20. Claim 21: The breast pump device of claim 15, wherein the diaphragm is configured to be attached around an edge of the second diaphragm housing.

186. By my review, claim 21 is similar to and broader than claim 16. Claim 16 requires “releasably secured around an edge,” whereas claim 21 requires “attached around an edge.” A POSITA would have understood releasably securing is a form of attaching. Therefore, it is my opinion that Weber discloses claim 16 for the same reasons as I explained for claim 16, above.

21. Claim 22: The breast pump device of claim 15, wherein the diaphragm is configured to seal, self-seal, self energizing seal or interference fit seal against the first diaphragm housing.

187. In my opinion, Weber discloses claim 22. As I explained in claims 14 and 40, Weber’s diaphragm self-seals against both the first and second housing during pump operation. Therefore, Weber discloses claim 22 for the same reasons as I explained with respect to claims 14 and 40, above.

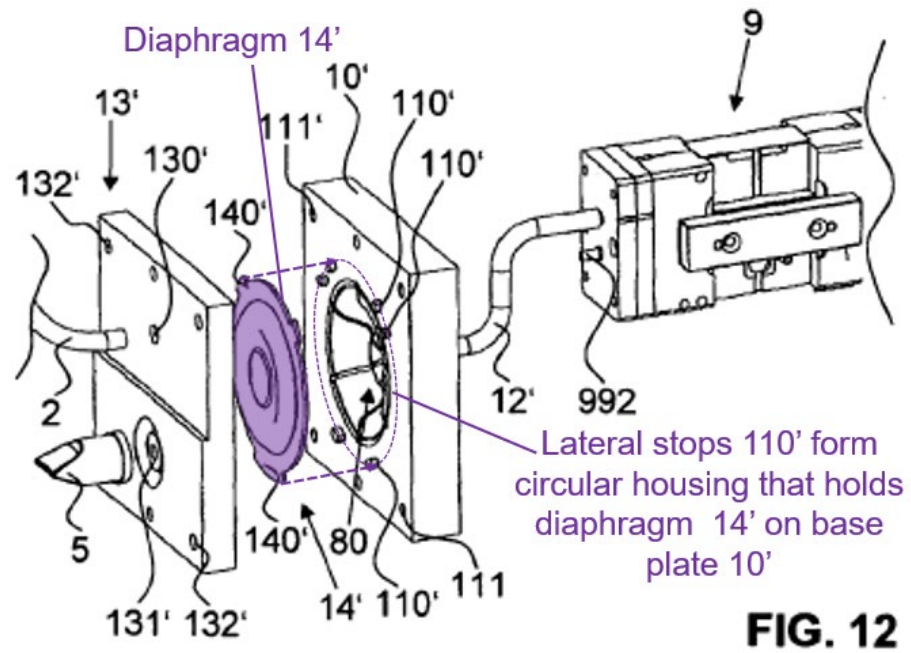
188. Additionally, as I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to implement Weber’s self-sealing diaphragm in Chang’s breast pump device.

- 22. Claim 23, 41: The breast pump device of claim 1, wherein the diaphragm is a flexible and generally circular diaphragm (Claim 23) / The breast pump device of claim 29, the membrane is a flexible membrane (Claim 41).**

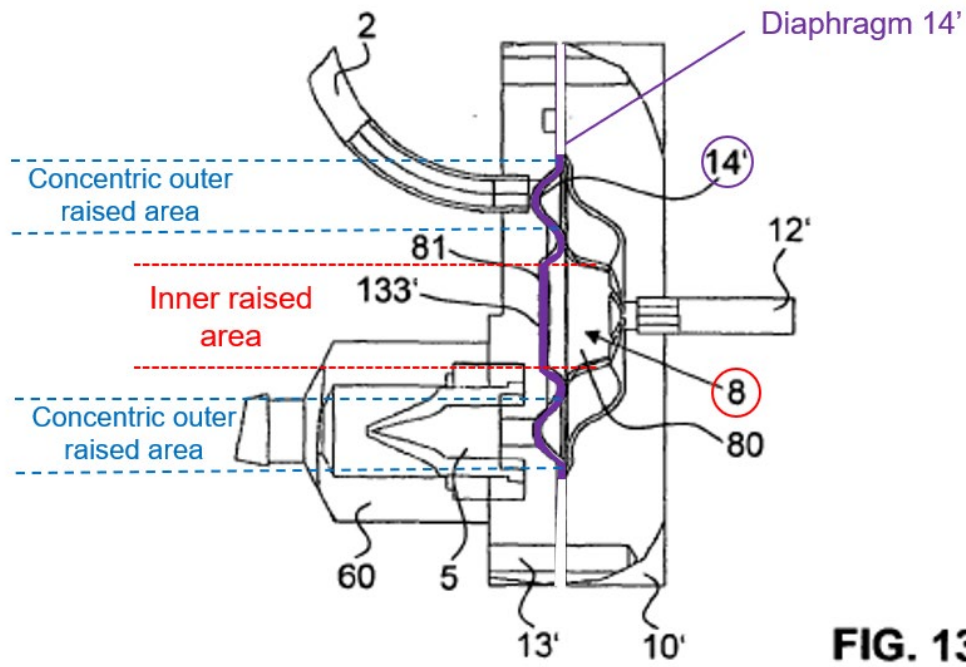
189. By my review, claims 23 and 41 include substantively similar language that is recited in claim 19, but do not include the “second diaphragm” limitations. Therefore, it is my opinion that Weber discloses claims 23 and 41 for the same reasons as I explained with respect to claim 9, above.

- 23. Claims 24, 42: The breast pump device of claim [1/29], wherein the [diaphragm/membrane] is a flexible and generally circular diaphragm/membrane] that, in a relaxed state, includes an inner raised area and a concentric outer raised area.**

190. By my review, claims 24 and 42 are the same as claims 23 and 41, but additionally require that “in a relaxed state, [the diaphragm] includes an inner raised area and a concentric outer raised area.” In my opinion, Weber teaches this additional limitation for the same reasons as I explained with respect to claim limitation 1[b][vi] and claims 7, and 34 above. Additionally, my annotated versions of Figures 12-13 (below) show Weber’s circular diaphragm in a relaxed state, which includes an inner and outer raised concentric area following the shape of the diaphragm. Weber, ¶¶23, 96-97.



191.



Id., Figs. 12-13.

192. As I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Weber.

24. Claims 25, 43: The breast pump device of claim [1/29], wherein the milk container is configured to be pressed or pushed into engagement with the [pump housing/housing].

193. Guthrie discloses claims 25 and 43 for the same reasons as I explained with respect to claims 11 and 37 above.

25. Claims 26, 44: The breast pump device of claim [1/29], wherein the self-contained, in-bra wearable device is configured so that expressed milk flows under gravity through an opening in the nipple tunnel and into the milk container through a duck-bill valve that stays sealed when there is negative air pressure being applied by the pump to ensure that negative air pressure is not applied to the milk container.

194. In my opinion, Guthrie discloses these claims. As I explained in claims 12 and 38, the combination of Chang and Guthrie teaches that expressed milk flows under gravity through an opening in Chang's nipple tunnel and into Guthrie's milk container. Chang discloses, the milk collection container can include a "a duckbill valve" that is "a one-way valve that permits milk inflow into the milk collection container but prevents milk backflow from the milk collection container to the conduit," i.e., it prevents milk from flowing back to the pump. Chang ¶21. Similarly, Guthrie discloses "a valve 301 which can be inserted into bottle 304

["milk container"] and mate in a leak proof fashion" as shown in my annotated versions of Figures 3A-B (below). Guthrie, ¶36.

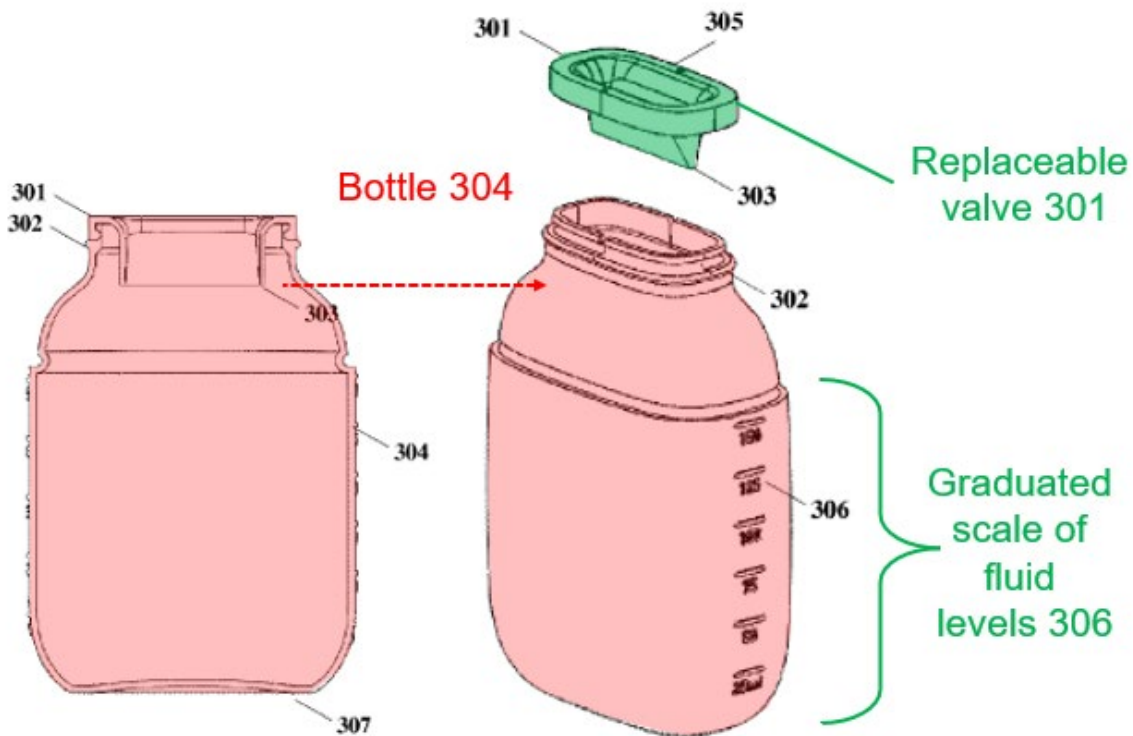


FIG. 3A

FIG. 3B

195. Guthrie specifically discloses that “[v]alve 301 may be implemented as a duckbill valve.” *Id.* The valve is “configured to open and close as...vacuum pump...cycles during regular use.” *Id.* The duckbill valve closes “while suction is present during a pump cycle.” *Id.* A POSITA would have understood that the purpose of the duckbill valve is to ensure that negative air pressure is not applied to

the milk container, which allows milk to flow into the container but prevents milk from flowing back into the pump.

196. As I explained above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang and Weber.

B. Obviousness of Claims 5, 10-12, 17, 25-28, 36-38, 43-46 Based On Chang, Weber, Guthrie, and Khalil

197. Claims 5, 10-12, 17, 25-28, 36-38, 43-46 are obvious in light of Chang, Weber, Guthrie and Khalil.

1. Motivation To Combine Chang, Weber, Guthrie, Khalil

198. A POSITA would have been motivated to combine the Chang, Weber, Guthrie and Khalil references for the reasons discussed below.

199. As I discussed above in the Motivation to Combine Chang, Weber, Guthrie section above, a POSITA would have been motivated to combine Chang, Weber, and Guthrie. For the reasons below, a POSITA would have been further motivated to combine the teachings of Khalil.

200. As previously discussed, Chang is related to and discloses an integrated breast pump device where all its components fit entirely within in a user's bra. *See, e.g.,* Chang, ¶11 (“fit[s] comfortably and conveniently into a bra of a user”), ¶19 (the components of the system “are all contained within a cup of a brassiere”). Chang discloses an embodiment where its pump generates suction by cyclical compression

and decompression of a conduit or flex-tube. *See e.g., Id.* ¶22 (“According to another aspect of the present disclosure, a system for pumping milk from a breast includes one or more of: a flange or skin contact member configured to form a seal with the breast; a conduit in fluid communication with and connected to the skin contact member; a driving mechanism configured to establish a vacuum profile within the conduit by cyclically compressing and allowing decompression of a portion of the conduit; and an external shell containing the conduit and the driving mechanism and supporting the skin contact member.”); *see also id.* ¶¶25, 28, 84-86. Chang also indicates that its embodiments are not limited to that design and suggests the use of other pump designs, such as ones that generate suction using a flexible member having a non-tubular shape:

Although both portions 32S and 32L [of the flex-tube] are shown as tubular portions, the present disclosure is not limited to such, as one or both portions could be shaped otherwise.”

Id. ¶79.

201. When considering other types of pumps that could be used with Chang, a POSITA would have been familiar with the use of a diaphragm pumps in breast pumping applications. In diaphragm pumps, a diaphragm (or membrane) deforms in response to changes in air pressure caused by the pump to generate suction. Khalil discloses a diaphragm pump with specific diaphragm shapes and locations (e.g.,

annular or arc shaped and located around or over the nipple tunnel) that a POSITA would have been motivated to use with the diaphragm pump of Weber and the breast pump of Chang. *See, e.g.*, Khalil Figs. 6-8, ¶67 (“The vacuum pump 81 is preferably a diaphragm vacuum pump of a known type, which is operated by means of an electric motor.”); ¶21 (“In a preferred embodiment, the membrane is formed in one piece and has an annular shape.”); ¶65 (“Here, the membrane 3 is once again designed in one piece but forms only a partial area of a ring. The membrane 3 can also be kidney-shaped.”). A POSITA would have been motivated to consider such pumps, because as I discussed above in the in the Technology Background, a POSITA would have been quite familiar with diaphragm pumps and their use in breast pump applications at the time of the ’380 patent.

202. Chang also discloses an embodiment of its device that has a flexible milk collection container, e.g., a bag, that is located within the housing and is configured to be attached to and removed from a flex-tube so that milk that is pumped by the tube flows into the container. *See, e.g.*, Chang ¶¶102-107. Chang further indicates that its disclosure is not limited to such a configuration, and suggests that other types of containers and locations for the container are possible, including “rigid” containers. For example, Chang states that “[i]t is to be recognized that the collection or container assembly can be placed in alternative locations as

well” (*id.* ¶105) and that “the container can be flexible or rigid, or disposable or reusable” (*id.* ¶21).

203. Chang does not, however, disclose any detail regarding a design that includes the suggested “rigid” container design. *See, e.g., id.* ¶105-107, Figs. 11B-D. As such, a POSITA would have been motivated to look elsewhere for such teachings.

204. Khalil discloses such an embodiment. Khalil, like Chang, is generally directed to an integrated breast pump device (referred to as a “breastshield” or “breastpump”) that is also designed to be worn in a bra. Khalil discloses that its design includes an integrated milk container:

The breastshield unit according to the invention can be designed as a hands-free unit and worn under a bra. In a preferred embodiment, a milk collection container is integrated in the housing of the unit or can be coupled directly thereto.

Khalil ¶32. Khalil further discloses that its milk container is a “rigid.” *Id.* ¶69 (“[The milk collection container] is preferably made of plastic like the cover 6.”), ¶50 (“The shell [i.e., cover] 6 is preferably in one piece and rigid, and usually made of a plastic”); *see also id.* ¶67. Khalil discloses that the milk container can be attached to the breast pump below the pump housing. *Id.* ¶69 (“A milk collection container 7' is arranged in the lower area adjoining the cover 6''.”); *see also id.* Figs. 9-11.

205. Thus, a POSITA would have been motivated to incorporate the design of Khalil's rigid milk container into the breast pump design of Chang. Both references are in the same field (in-bra breast pumps), and Chang suggests, but does not describe, a design that includes rigid milk containers which would have motivated a POSITA to look to Khalil.

2. Claim 5: The breast pump device of claim 1, wherein the breast shield is configured to slide in and out from the pump housing, together with the diaphragm that prevents milk from reaching the pump.

206. In my opinion, Khalil discloses claim 5. Khalil discloses that breast interface 1 ("breast shield") has a stub 10 with an "annular receiving groove" for passing through a membrane 3 ("diaphragm") and its two housing parts 2, 4 when connecting to shell 6', as shown in my annotated versions of Figures 11 and 5 (below). Khalil, ¶¶49, 55. The receiving stub 44 of membrane housing 4 is pushed over stub 10 as shown in my annotated versions of Figures 11 and 5 (below). *Id.*, ¶¶29, 55, 59.

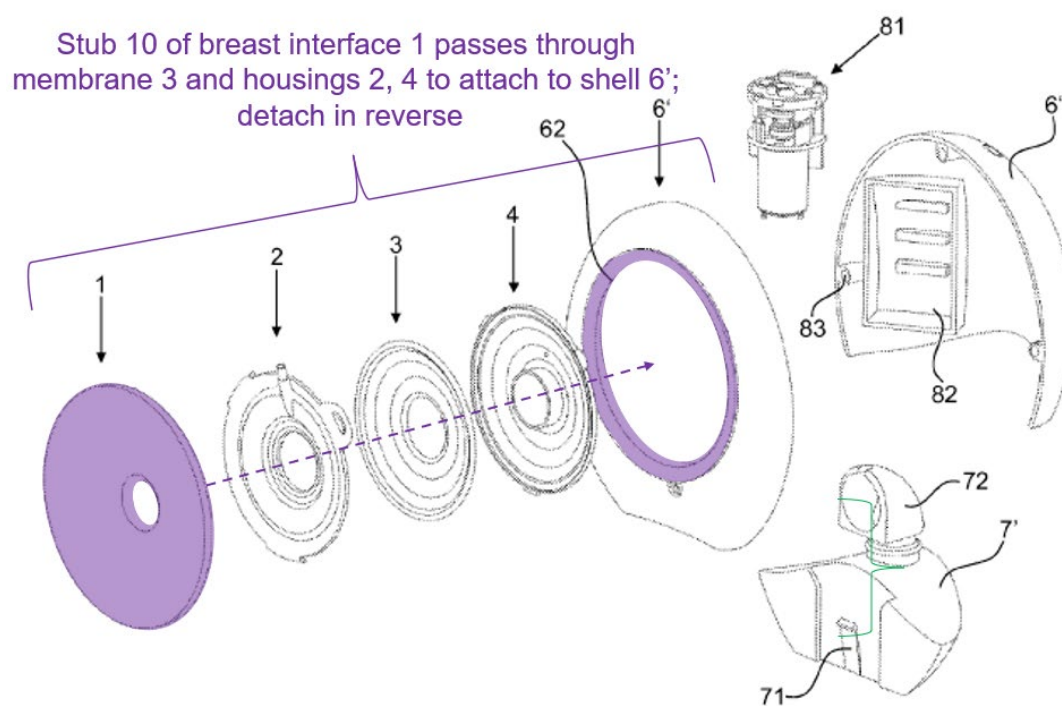


FIG. 11

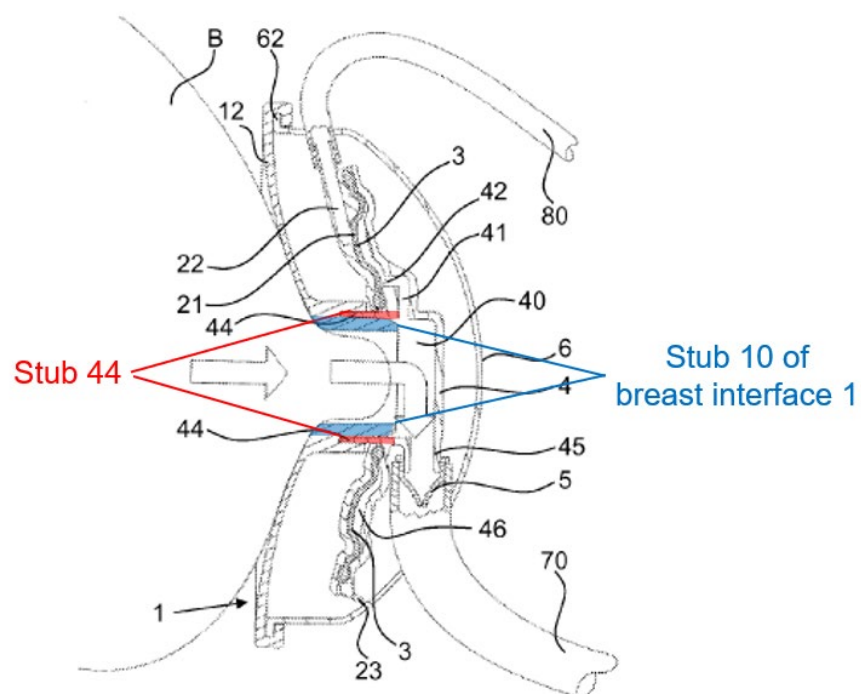


FIG. 5

207. A POSITA would have understood that Khalil's two circular, connected stubs 10 (of breast interface 1) and 44 push together to hold the 3-piece membrane component together and seal for proper pressure and vacuum operation, but may be pulled apart for cleaning so that breast interface 1 ("breast shield") and membrane 3 ("diaphragm") could slide in and out from the pump housing. *See, e.g., id.*, Fig. 5, ¶70.

208. As I explained above in the Motivation to Combine Chang, Weber, Guthrie, Khalil section above, a POSITA would have been motivated to use teachings regarding Khalil's diaphragm pump with Chang.

3. Claims 10, 36: The breast pump device of claim [1/29], wherein the milk container has a surface shaped to continue a curved shape of the [pump housing/housing] so that the breast pump device can be held comfortably inside a bra.

209. In my opinion, Khalil discloses these claims. Khalil discloses a breast shield unit (or breast pump) "designed as a *hand-free unit and worn under a bra*" and including a "milk collection container...*integrated in the housing of the unit* or...coupled directly thereto." Khalil, ¶32, 70 (my emphasis added). To achieve this design goal, Khalil's milk container (green) assumes a curved shape that continues the curved shape of the pump housing, as shown in my annotated versions of Figures 9 and 11 (below).

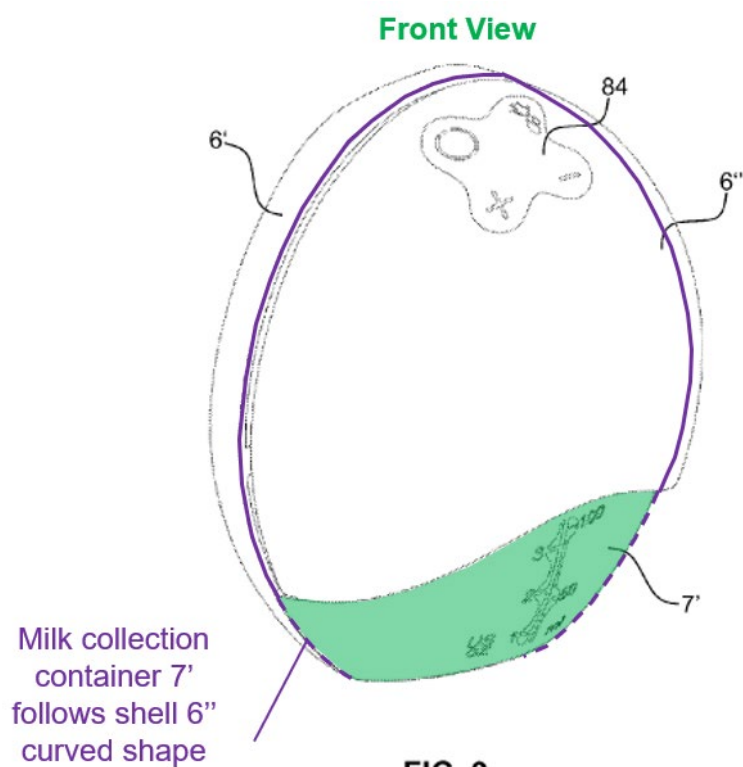


FIG. 9

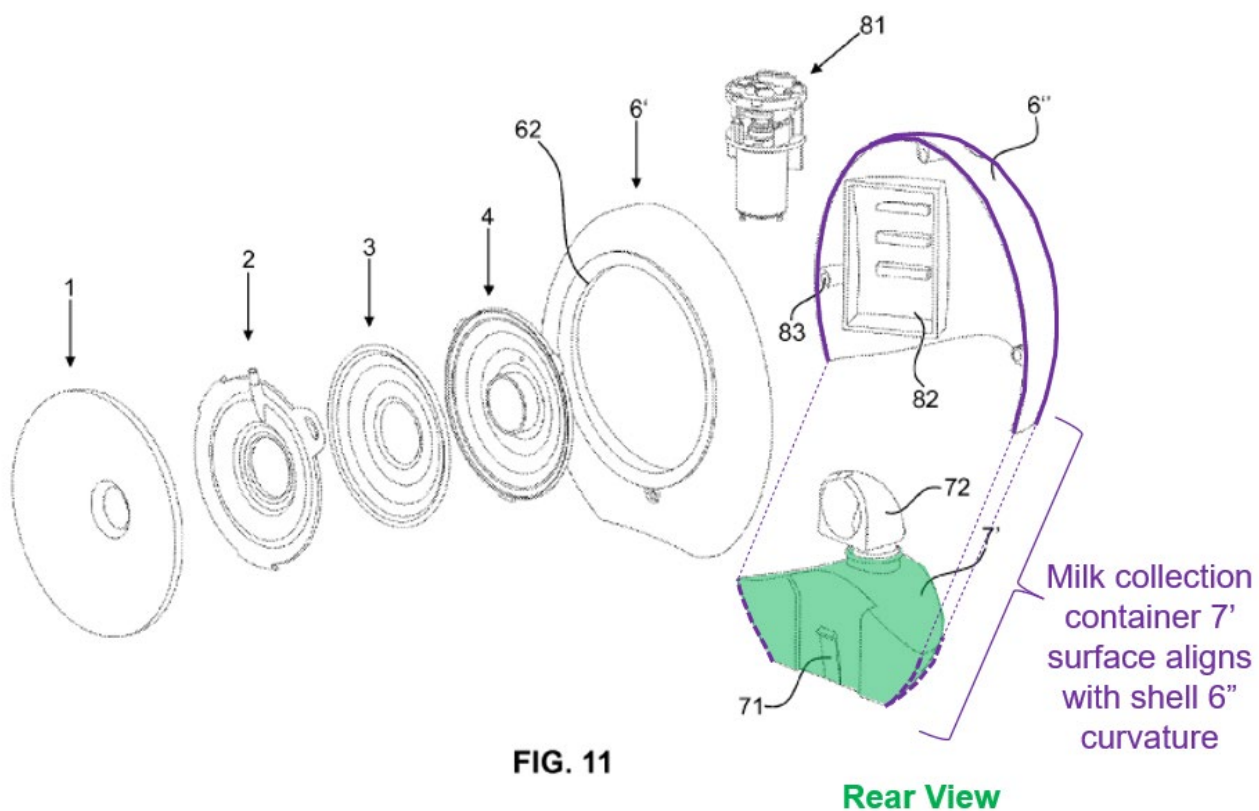


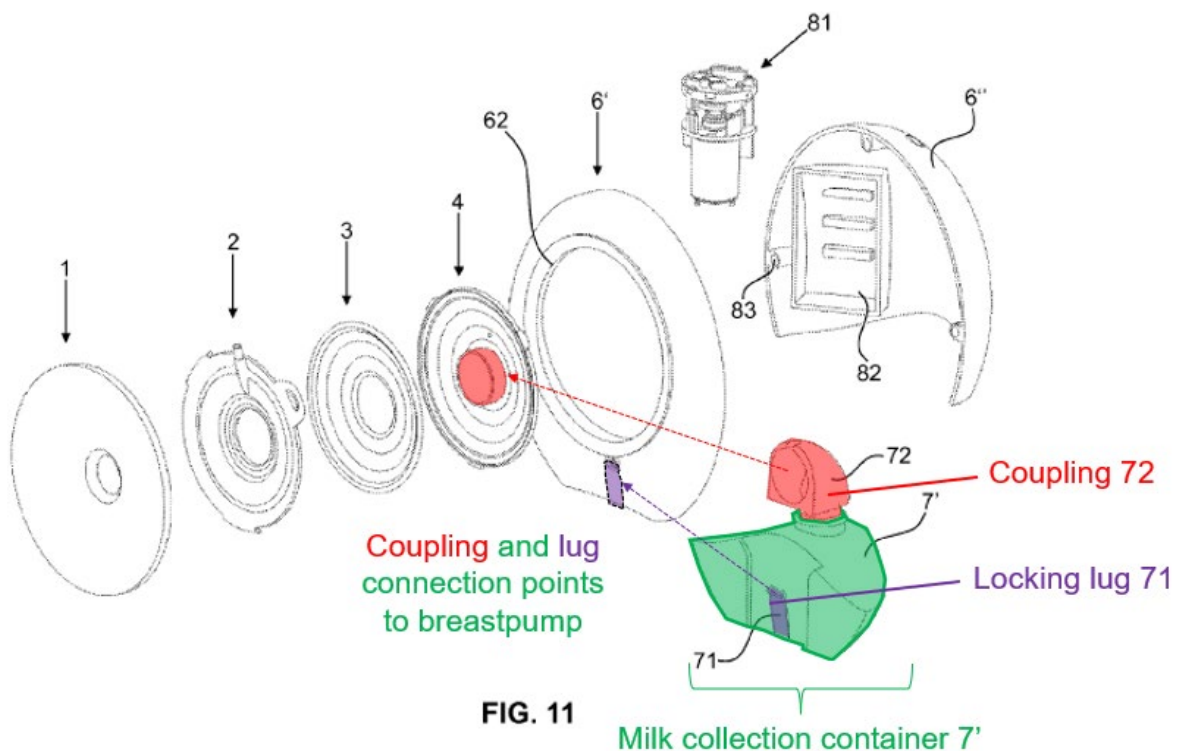
FIG. 11

Id., Figs. 9, 11 (annotated).

210. As I explained above in the Motivation to Combine Chang, Weber, Guthrie, Khalil section above, a POSITA would have been motivated to combine Chang and Khalil to use a rigid milk container that fits in a bra.

- 4. Claims 11, 37: The breast pump device of claim [1/29], wherein the milk container is attachable to the [pump housing/housing] with a mechanical or magnetic mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the [pump housing/housing] with a single push action.**

211. In my opinion, Khalil discloses claims 11 and 37. My annotated version of Figure 11 (below) shows that the milk container releasably attaches to the housing (6' and 6'') by a locking lug (71):



Khalil, Fig. 11. Additionally, Khalil discloses:

A milk collection container 7' is arranged in the lower area adjoining the cover 6". It is preferably made of plastic like the cover 6". A locking lug 71 is integrally formed on this milk collection container 7' and can engage in a corresponding recess (not shown in the Figures) of the shell ring 6'. In this way, the milk collection container 7' is connected releasably to the shell ring 6'.

Id. ¶69. Thus, it is my opinion that Khalil discloses that the milk container is attachable to the pump housing with a mechanical mechanism that releasably attaches when the milk container is sufficiently pressed on to the pump housing with a single push action.

212. As I explained above in the Motivation to Combine Chang, Weber, Guthrie, Khalil section above, a POSITA would have been motivated to combine Chang and Khalil to use a rigid milk container that is located below the pump housing.

5. **Claims 12, 38: The breast pump device of claim [1/29], wherein the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows under gravity into the milk container.**

213. In my opinion, Khalil discloses claims 12 and 38. Khalil discloses that expressed milk flows through an opening on the lower surface of the connected stubs 10, 44 ("nipple tunnel") into underpressure chamber 40 and down through non-

return valve 5 into milk line 70 as shown in my annotated version of Figure 5 (below). Khalil, ¶ 61-62.

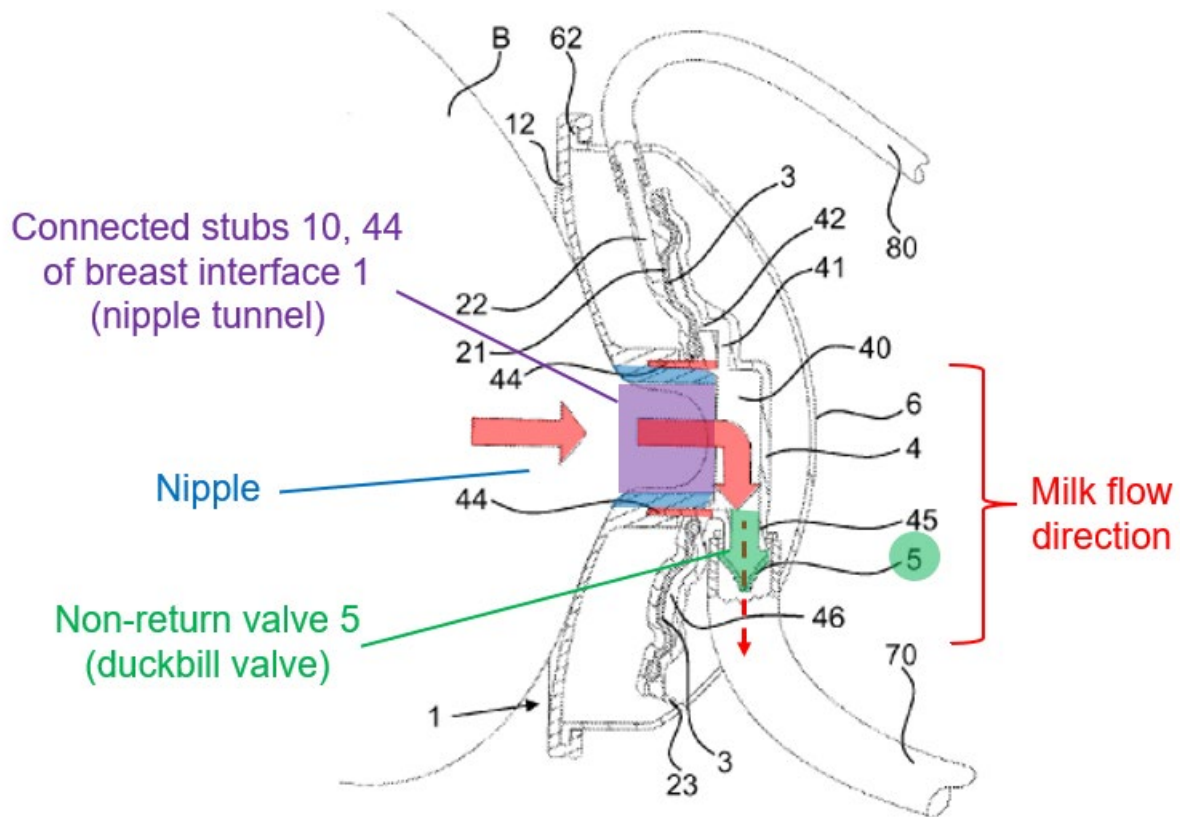


FIG. 5

Id., Fig. 5 (annotated).

214. Khalil's Figure 5 embodiment is incorporated into the Figure 10 in-bra design, in which "milk can flow from the underpressure chamber 40 into the interior of the milk collection container 7" rather than milk line 70 as shown in my annotated version below. *Id.*, ¶¶ 66, 69.

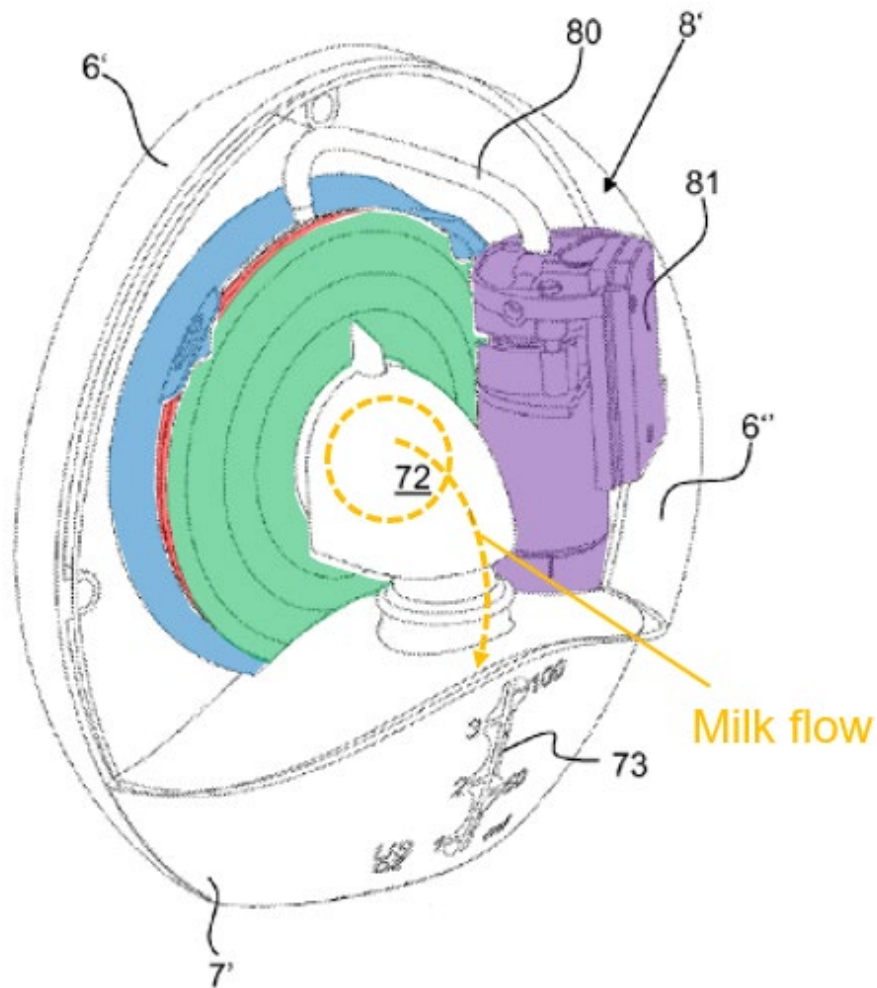


FIG. 10

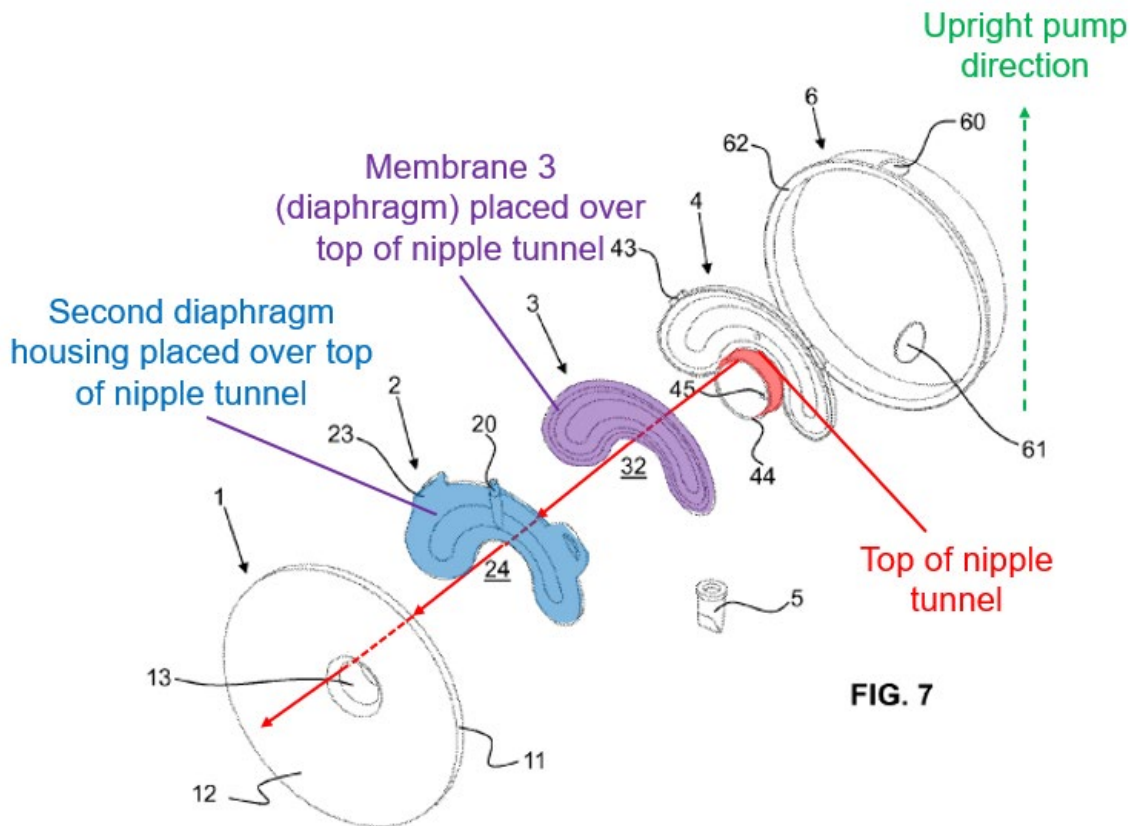
Id., Fig. 10 (annotated).

215. A POSITA would have understood that milk would be expressed by the vacuum pump-generated underpressure applied in the underpressure chamber, but also that the chamber returns to atmospheric or increase pressure subject to normal gravitational pull and directing the milk downward through the non-return valve into the milk collection container 7'. *Id.*, ¶62.

216. As I explained above in the Motivation to Combine Chang, Weber, Guthrie, Khalil section above, a POSITA would have been motivated to combine Chang and Khalil to use a rigid milk container that is located below the pump housing.

6. Claim 17: The breast pump device of claim 15, wherein the second diaphragm housing is positioned, when the breast pump device is upright, over a top surface of the nipple tunnel.

217. In my opinion, Khalil discloses claim 17. Khalil discloses an embodiment where the membrane (“diaphragm”) in the membrane housing part 2 (“second diaphragm housing”) has a “cross section in the shape of a partial circle” that partially encloses the top surface above connected stubs 10, 44 (“nipple tunnel”) shown in my annotated version of Figure 7 (below). *Khalil*, ¶65.



Id., Fig. 7 (annotated).

218. A POSITA would have recognized the orientation displayed in Figure 7 as upright because a milk port 61 sits at the bottom of shell 6 to receive non-return valve 5 and facilitate the same pressure- and gravity-based milk flow as described in claim 12. *Id.*, ¶52-55. Figure 8 (below) shows components of Figure 7 in an assembled and upright state. *Id.*, ¶43.

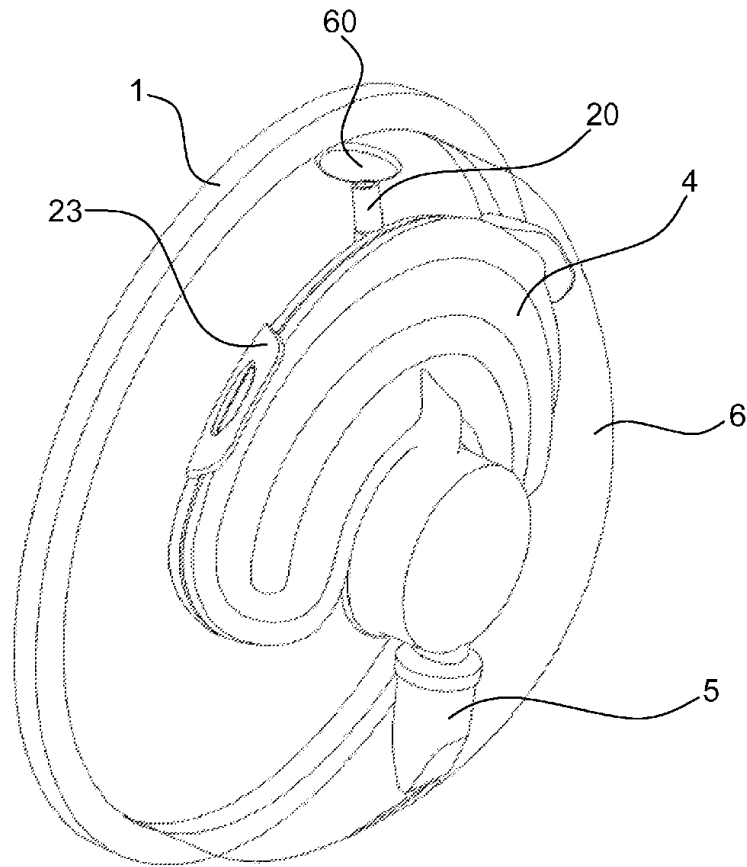


FIG. 8

Id., Fig. 8.

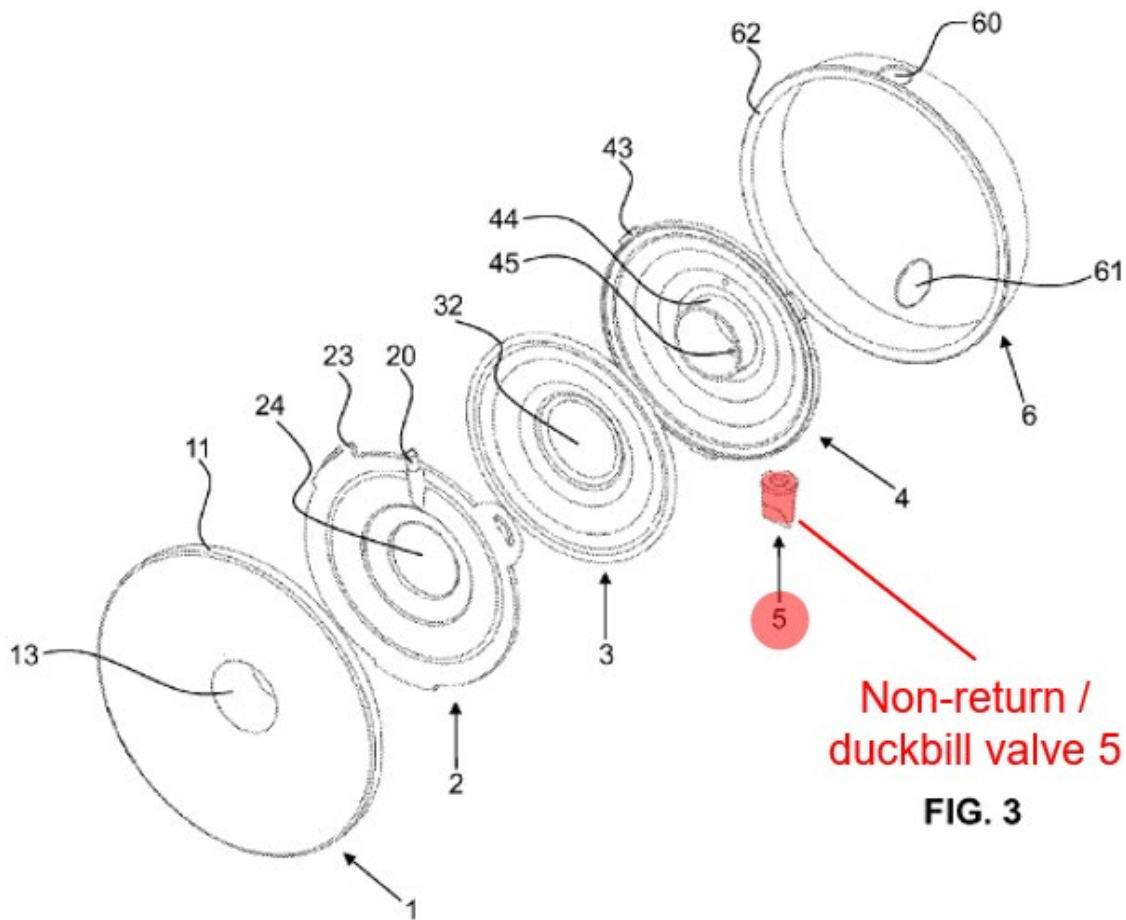
219. As I explained above in the Motivation to Combine Chang, Weber, Guthrie, Khalil section above, a POSITA would have been motivated to use teachings regarding Khalil's diaphragm pump with Chang.

7. **Claims 25, 43: The breast pump device of claim [1/29], wherein the milk container is configured to be pressed or pushed into engagement with the [pump housing/housing].**

220. In my opinion, Khalil discloses claims 35 and 43 for the same reasons as I explained with respect to claims 11 and 37, above.

8. **Claims 26, 44: The breast pump device of claim [1/29], wherein the self-contained, in-bra wearable device is configured so that expressed milk flows under gravity through an opening in the nipple tunnel and into the milk container through a duck-bill valve that stays sealed when there is negative air pressure being applied by the pump to ensure that negative air pressure is not applied to the milk container.**

221. In my opinion, Khalil discloses these claims. As discussed above for claims 12 and 38, the prior art discloses that expressed milk flows under gravity through an opening in the nipple tunnel into the milk container. Chang discloses, the milk collection container can include a “a duckbill valve” that is “a one-way valve that permits milk inflow into the milk collection container but prevents milk backflow from the milk collection container to the conduit,” i.e., it prevents milk from flowing back to the pump. Chang ¶21. Similarly, Khalil discloses that the membrane assembly is bounded by the breast interface 1 and shell 6 as outer walls and includes the membrane 3, membrane housings 2, 4, and duckbill/non-return valve 5 as shown in my annotated version of Figure 3 (below). Khalil, ¶53.



Id., Fig. 3 (annotated). Khalil's duckbill valve 5 is used for the in-bra embodiment to direct milk from underpressure chamber into the interior of milk collection container 7'. *Id.*, ¶69. As shown in Figures 4 and 5 below, during pumping, an overpressure is generated in vacuum chamber 40, which opens duckbill valve 5 to allow milk to flow into the milk container, but an underpressure closes duckbill valve 5 to seal off the milk collection container. *Id.*, ¶58.



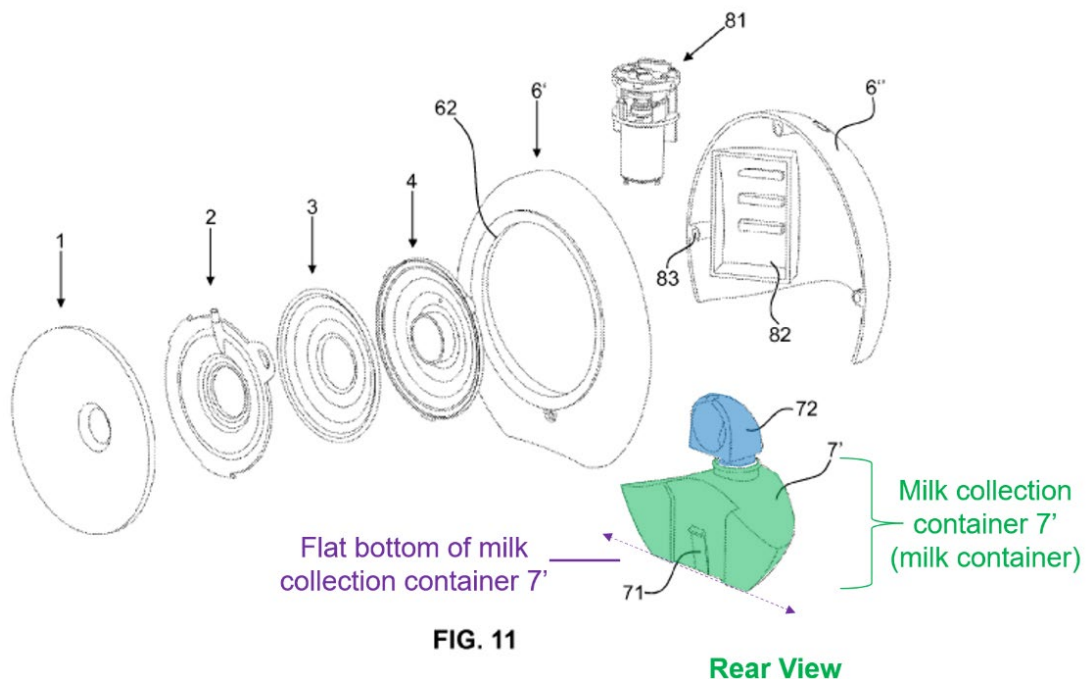
Id., Figs. 4-5.

222. Notably, Khalil’s Figure 5 embodiment is incorporated into the Figure 10 in-bra design. *Id.*, ¶66 (“FIGS. 9 to 11 show another illustrative embodiment in which [various components] correspond to the embodiment according to FIGS. 1 to 5.”).

223. As I explained above in the Motivation to Combine Chang, Weber, Guthrie, Khalil section above, a POSITA would have been motivated to combine Chang and Khalil to use a rigid milk container that is located below the pump housing.

9. **Claims 27, 45: The breast pump device of claim [1/29], wherein the milk container comprises a curved surface that includes a flat area that serves as a base for the milk container.**

224. In my opinion, Khalil discloses these claims. As I explained regarding claims 10 and 36, Khalil's milk container has a curved surface. Additionally, as I shown in my annotated version of Figure 11 below, Khalil's milk container has a flat base.



Khalil, Fig. 11 (annotated).

225. As I explained above in the Motivation to Combine Chang, Weber, Guthrie, Khalil section above, a POSITA would have been motivated to combine Chang and Khalil to use a rigid milk container that is located below the pump housing.

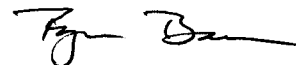
- 10. Claims 28, 46: The breast pump device of claim [1/29], wherein the milk container has a curved surface configured to enable the breast pump device to be held comfortably in a bra.**

226. In my opinion, Khalil discloses claims 28 and 46 for the same reasons as I explained with respect to claims 10 and 36, above.

227. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

* * *

Date: May 31st, 2024



Ryan Bauer