

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

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,413,380**

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Chiaro Technology EX2002
IPR2024-01296
U.S. Patent No. 11,413,380

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LISTING OF CHALLENGED CLAIMS

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.

I. INTRODUCTION

Petitioner Shenzhen Root Technology Co., Ltd., requests *inter partes* review (“IPR”) of claims 1-46 (“Challenged Claims”) of U.S. Patent 11,413,380 (EX-1001; “the ’380 patent”). Petitioner submits the declaration of Ryan Bauer (EX-1005; “Bauer”), an expert in the field of the ’380 patent, in support of this Petition.

II. GROUNDS FOR STANDING

Petitioner certifies the ’380 patent is available for IPR and Petitioner is not barred or estopped from requesting IPR on the grounds herein. Patent Owner Chiaro Technology (“PO”) served its answer and counterclaims alleging that Petitioner infringes the ’380 patent on August 14, 2023. Petitioner files this Petition within one year of that event.

III. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner respectfully requests review and cancellation under 35 U.S.C. §311 of the Challenged Claims in view of the following references and grounds:

Prior Art
U.S. Patent Application Publication 2018/0333523 , continuation of PCT/US/17/17112 filed February 9, 2017; prior art at least under §102(a)(2) (EX-1007; “ <i>Chang</i> ”)
U.S. Patent Application Publication 2012/0277728 , published on November 1, 2012; prior art at least under §§102(a)(1), (a)(2) (EX-1008; “ <i>Weber</i> ”)
U.S. Patent Application Publication 2016/0082166 , published on March 24, 2016; prior art under at least §§102(a)(1)-(a)(2) (EX-1009; “ <i>Guthrie</i> ”)
U.S. Patent Application Publication 2013/0023821 , published on January 24, 2013; prior art at least under §§102(a)(1), (a)(2) (EX-1010; “ <i>Khalil</i> ”)

Grounds (35 U.S.C. §103)	Claims	Prior Art References
1A	1-4, 6-9, 11-16, 18-26, 29-35, 37-44	<i>Chang, Weber, Guthrie</i>
1B	5, 10-12, 17, 25-28, 36-38, 43-46	<i>Chang, Weber, Guthrie, Khalil</i>

IV. OVERVIEW OF THE ’380 PATENT

A. Specification

The ’380 patent relates to a breast pump that is wearable inside a bra. EX-1001, 3:57-62. The specification acknowledges that fully integrated in-bra breast pumps existed in the prior art, including as disclosed by U.S. Application Publication 2016/0206794 (“Makower”). *Bauer*, ¶36. The ’380 patent asserts the Makower device’s disadvantages were a collapsible bag as the milk container, a noisy and

complex pump mechanism, and limited milk capacity. The '380 patent also discusses the breast pump of U.S. Application Publication 2013/0023821 ("Khalil"). The '380 patent asserts the Khalil device's disadvantages were an annular diaphragm resulting in a large, bulky device. The '380 patent purports to overcome such disadvantages. EX-1001, 2:5-57; *Bauer*, ¶37.

The '380 patent claims are generally directed to "a self-contained, in-bra wearable" breast pump device with a 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. EX-1001, claims 1, 29; *see also Bauer*, ¶38. The specification discloses the breast shield engages with the user's breast and is connected to the milk container for collecting milk expressed by the user. *E.g.*, EX-1001, 5:40-47. The housing includes one or more pumps, as well as a rechargeable battery and control electronics. *E.g.*, *id.*, 5:47-49, 5:58-59; *see also Bauer*, ¶39. The breast shield and milk container are removably connected to the housing. *E.g.*, EX-1001, 5:58-6:3; *see also Bauer*, ¶39.

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

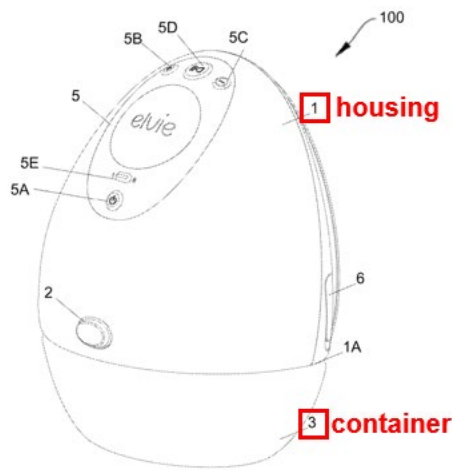


FIGURE 1

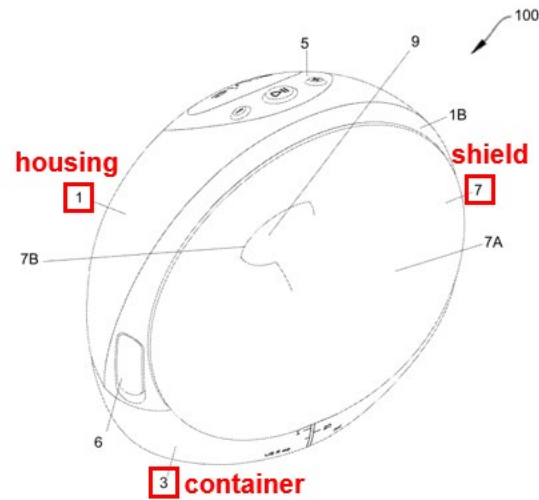
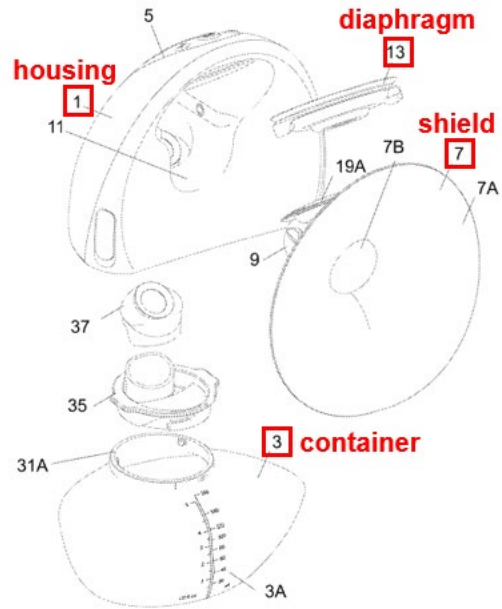
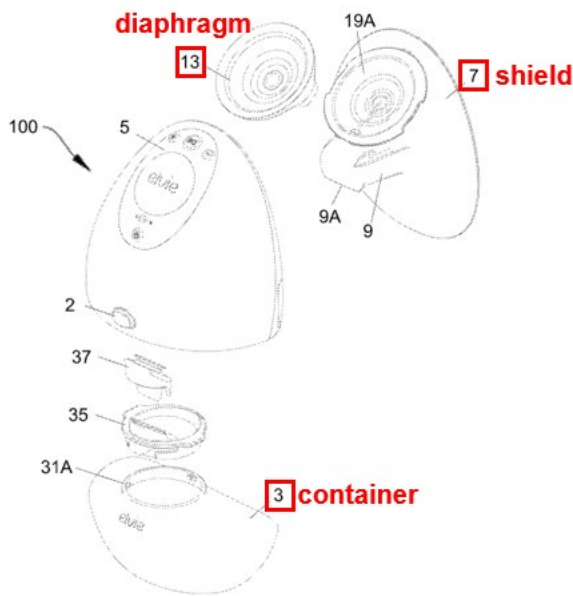


FIGURE 2

EX-1001, Figs. 1, 2 (annotated), 5:56-6:3, 6:14-21. 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, 9:28-31. 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. *Bauer*, ¶40-41.

The breast pump system includes a “diaphragm” (or “membrane” or “barrier”) for transferring negative air pressure (or suction or vacuum) from the pump to the milk-collection side (i.e., breast side) of the system. EX-1001, 10:25-29; 11:18. Figures 5 and 6 below show front and rear exploded views of the breast pump system, with housing 1, milk container 3, breast shield 7, and diaphragm 13:



Id., Figs. 5, 6 (annotated). *Bauer*, ¶42.

Diaphragm 13 is held in diaphragm housing and transfers negative pressure generated by the pump into nipple tunnel 9, which imposes a sucking action on the user's nipple. EX1001, 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:

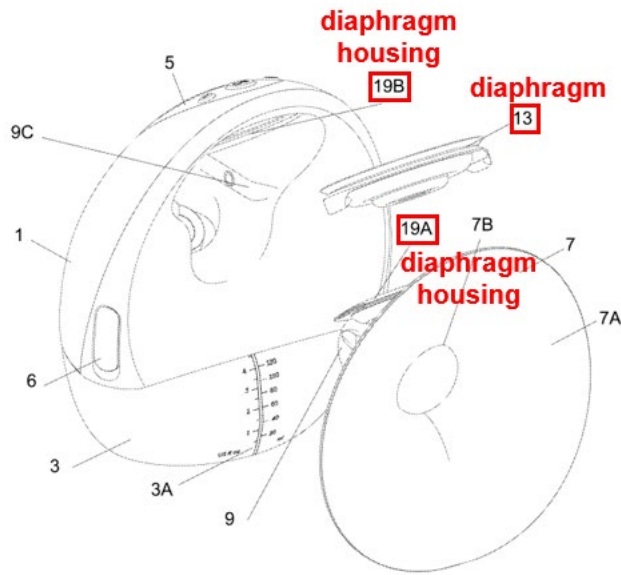


FIGURE 4

Id., Fig. 4 (annotated), 11:23-27. *Bauer*, ¶43.

B. Prosecution History

The '380 patent issued from Application 17/203,327 ("327 application"; EX-1002) filed on March 16, 2021, which is a continuation of Application 17/181,057 ("057 application"; EX-1003), which is a continuation of Application 16/009,547 ("547 application"; EX-1004). The earliest priority date on the '380 patent's face is June 15, 2017. Petitioner applies that date here because all references qualify as prior art assuming that date. Petitioner reserves the right to challenge priority in other proceedings.

The '380 patent has two similar independent claims, claims 1 and 29. These claims were allowed after multiple obviousness rejections based on the addition of limitations for structural features specifying how the diaphragm of the pump is held

in the device. As explained below, claim 1 was allowed based on the diaphragm housing being fixed to a recessed surface of the pump housing, and claim 29 was allowed based on the diaphragm (membrane) defining a pumping chamber at least in part with an external surface of the housing of the device.

During prosecution of the '327 application, the Examiner rejected originally-filed independent claim 1 as obvious over Khalil combined with other references. EX-1002, 482-484. PO subsequently amended the claim to include a “diaphragm...configured to prevent milk from reaching the pump,” where the diaphragm is “a membrane that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel,” and is “seated against a diaphragm housing that is formed around an edge of the recess or cavity in the pump housing.” *Id.*, 623. PO also added new independent claim 47, which ultimately issued as independent claim 29, and recited “a membrane that is configured to define an air pumping chamber with a 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.” *Id.*, 627-628.

During an interview, the Examiner stated claim 1 would be allowable if PO amended it to “indicat[e] that the diaphragm housing is fixed to a surface of the pump housing.” *Id.*, 655. According to the Examiner, “the configuration of the diaphragm housing 19B in [’380 Fig. 4] which is a recess in the rear surface of the housing was

unique relative to the prior art.” *Id.* Similarly, the Examiner stated pending claim 47 would be allowable if PO amended it to “clarify that the surface [of the housing] is an exterior surface of the housing.” *Id.*

After subsequent amendments, the Examiner allowed claim 1 because “Khalil fails to teach...a diaphragm housing fixed to a recessed surface of the pump housing,” and allowed pending claim 47 because “Khalil fails to teach...a membrane that forms an air pumping chamber at least in part with an external surface of the pump housing.” *Id.*, 1056, 781. The Examiner indicated Khalil taught a “membrane” (citing Khalil’s Fig. 11, element 3) that “forms an air pumping chamber with diaphragm housing members” (citing Khalil’s Fig. 11, elements 2, 4), but “these housing members are not shown to be a part of an external surface of the pump housing.” *Id.*, 781.

V. LEVEL OF ORDINARY SKILL

A POSITA as of June 15, 2017 (the earliest filing date to which the ’380 patent could claim priority) would have had at least a bachelor’s degree in mechanical engineering or a similar field and at least two years of experience designing human breast pump equipment. More education could substitute for experience and vice versa. *Bauer*, ¶15-18.

VI. CLAIM CONSTRUCTION

During prosecution of the '057 application, 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, 2167. PO did not dispute this construction, and Petitioner applies it herein.

The other terms of the Challenged Claims should be construed according to their plain and ordinary meaning.

VII. TECHNOLOGY BACKGROUND

Breast pumps extract milk from users’ breasts. The breast pump industry has been significantly influenced by government policies and related market forces. For example, the USA is by far the leading market for breast pumps in the world, in part because of a large number of women in the workforce and limited maternity benefits. In 2010, the enactment of the Affordable Care Act (“ACA”) revolutionized the industry by mandating health insurance plans to cover breastfeeding equipment. The ACA significantly increased demand for all types of breast pumps and accessories, which attracted new participants to the market and significantly expanded the commercial market for breast pumps. *Bauer*, ¶19-21.

After the ACA, consumers demanded better products through media and feedback, which increased competition among manufacturers and caused them to develop improved products to address unmet needs. One significant industry event

was the 2014 MIT Hackathon “Make The Breast Pump Not Suck.” Participants in the Hackathon sought to improve breast pumps by addressing features such as making them fashionable, discreet, hands-free and wearable, easily cleanable, “smart” to make use of data to communicate, facilitate connections to others in the community, etc. A notable example was the Willow Breast Pump, which was shown at the Consumer Electronics Show (CES) in January 2017 and garnered significant media attention as an integrated, in-bra wearable, hands-free device. Technology publication Engadget recognized it as a winner of their “Best Digital Health and Fitness Product” and “Best Wearable” awards. *Id.*, ¶22-27.

Breast pumps typically have a localized volume in which the nipple is inserted and a vacuum (or negative pressure or suction) is applied so that milk is ejected into the localized volume, the vacuum is released, and the milk is evacuated to a collection container. This cycle is repeated at frequencies designed to emulate the sucking of a nursing baby. The milk accumulates in the collection container. *Id.*, ¶28.

Major components of the pump include a breast shield that engages the breast and presents the localized volume for the nipple, a pump to generate negative pressure (i.e., vacuum or suction), and a milk collection container. A one-way valve is often used with the localized volume to minimize its size and to allow extracted milk to escape between vacuum cycles and flow to the container. *Id.*

A common arrangement in the prior art was for the breast pump to use a membrane or diaphragm to define the localized volume on one side (milk side) and to be in mechanical or fluid communication with the pump on the other side. Such a diaphragm is commonly referred to as a media separation because it keeps milk away from the pump mechanism. Many different types of pumps have been used in breast pumps to generate suction to extract milk—for example, diaphragm pump, bellows pump, piston pump, reciprocating pump, peristaltic pump. *E.g.*, EX-1011, ¶45. Breast pumps with diaphragm pumps were well known in the prior art. Examples include Weber (EX-1008), Khalil (EX-1010), and U.S. Application Publications 2012/0116299 (EX-1012) and 2015/0157775 (EX-1013). *Bauer*, ¶29-31.

Breast pumps are relatively simple electromechanical devices that can be configured in a variety of ways. The components of breast pumps can be combined and attached to each other or separated and connected by lines, hoses, or wires, as desired. In this crowded field, a POSITA knew that there is no single design or configuration that is ideal for all purposes. Rather, a POSITA knew the various combinations of components at their disposal and selected a configuration for a particular device based on desired commercial and clinical requirements—for example, weight distribution, cleanability, power consumption, anatomical variation. All four prior art references relied on in this Petition reflect this flexibility by

disclosing multiple configurations with various components alternatively combined and separate. *Chang*, ¶19; *Weber*, ¶¶21, 67-69, Figs. 1, 2, 6; *Guthrie*, ¶¶24, 27, 33-35, Figs. 1, 2A-2C; *Khalil*, ¶¶32, 33, 51, 66, Figs. 1, 2, 9-11; *see also Bauer*, ¶32-34.

All challenged claims of the '380 patent are directed to a “self-contained, in-bra wearable device.” Such devices, worn and held entirely in a bra, were well-known in the prior art, of which Makower, Chang, and Khalil are examples. In addition, other prior art devices, worn by a user and held mostly in a bra with a component outside the bra, were also well-known. For example, breast pumps with the milk collection container outside the bra included PCT Publications WO 2002/102437 (EX-1014) and WO 2008/137678 (EX-1015) and Guthrie. *Id.*, ¶35.

VIII. THE ASSERTED PRIOR ART

A. Chang

Chang discloses “portable breast pump systems...for collecting milk from a breast of a nursing mother.” *Chang*, ¶1. Chang’s breast pump “is contemplated to fit comfortably and conveniently into a bra” (*id.*, ¶11) such that “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” (*id.*, ¶19). As shown in Figure 1A, Chang’s breast pump 10 includes “housing or outer shell 12” (blue) and “flange 14” (purple):

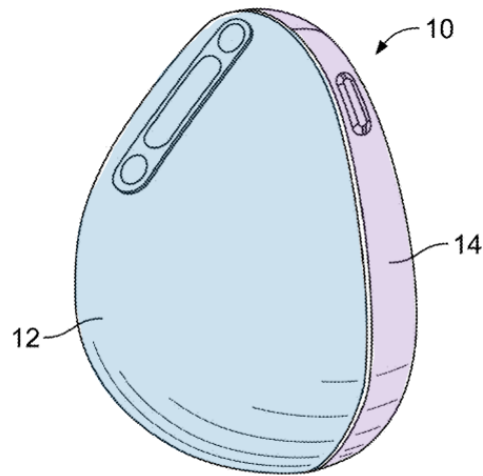
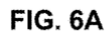


FIG. 1A

Id., Fig. 1A (annotated), ¶71. *Bauer*, ¶62-64.

The flange “is sized and shaped to engage a breast...to provide structure for sealingly engaging with breast tissue.” *Chang*, ¶71. It includes a “nipple receiving portion...contoured to more closely match the natural shape of the nipple.” *Id.*, ¶90. The shape of flange 14 is illustrated in Figure 6A below.



Id., Fig. 6A (annotated); *id.*, Figs. 1, 2, 4, ¶¶71-72, 80. *Bauer*, ¶64.

In Chang, all pumping system components may be contained under the housing, between housing 12 and the flange 14. *Chang*, Fig. 6A, ¶¶72, 80. The components include “rechargeable battery” 48 for powering the system, 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.* Chang’s “pump” can be “one or more pumps and equivalents thereof known to those skilled in the art.” *Id.*, ¶68. *Bauer*, ¶66.

Chang's system includes a "milk collection container." *Chang*, Figs. 8, 11B, ¶¶81, 86, 99-101, 105-106. Chang's collection container may include "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." *Id.*, ¶21. The valve may "assume a myriad of shapes and kinds" and the container may be "flexible or rigid, or disposable or reusable" (*id.*) and may be "inside or outside of the pump housing" (*id.*, ¶101). *Bauer*, ¶65.

B. Weber

Weber discloses a "device for expressing human breast milk" having a diaphragm-type "vacuum pump," which "can be battery operated." *Weber*, ¶¶2, 70. "The breast shield can be designed to be small and can be fixed in a bra." *Id.*, ¶13.

The 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. *Bauer*, ¶73-74. Figure 6 below shows an embodiment:

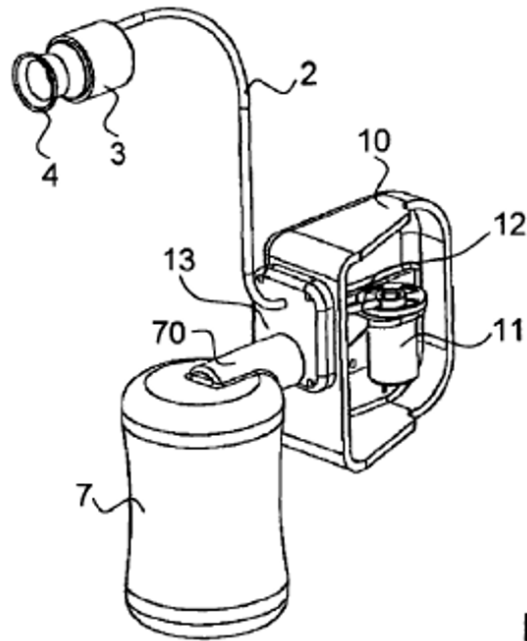


FIG. 6

In Weber, diaphragm 14' is driven by and connected to vacuum pump 9 via a vacuum line 12:

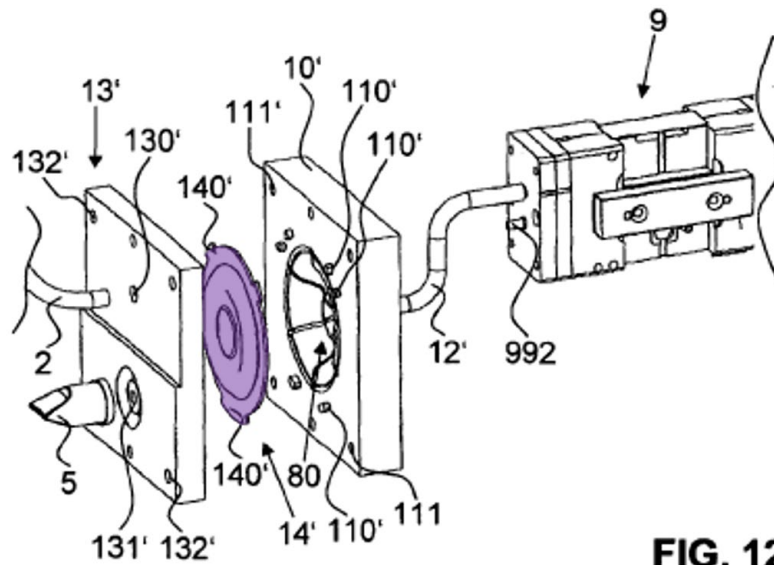


FIG. 12

Weber, Fig. 12 (annotated), ¶98; *Bauer*, ¶75.

The diaphragm rests in a recessed part of base plate 10' which “may be part of a vacuum pump housing” and is “held in an unambiguous position in the chamber 8” (*Weber*, ¶97):

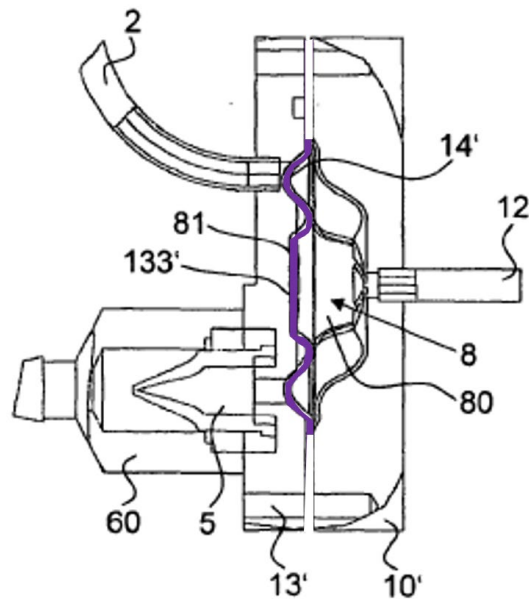


FIG. 13

Id., Fig. 13 (annotated), ¶¶95-97. 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.” *Id.*, ¶96. The diaphragm “is moved cyclically” which “transports the milk from the breast shield 4 [(connected via line 2)] through the breast-shield-side part 81 into the milk collecting container 7 [(connected via nonreturn valve 5)].” *Id.*; see *id.*, ¶76. *Bauer*, ¶75-76.

The elements of Weber’s device “can be combined with one another individually or in groups in order to form further embodiments.” *Weber*, ¶111. For

example, Figures 12 and 13 show a connection to the breast shield via “vacuum-transmitting line” 2, but Weber also states the breast shield can be connected directly to the pump housing, where “the vacuum pump for the breast shield is connected directly to the first port of the chamber.” *Id.*, ¶¶21, 99. Furthermore, Weber’s milk collecting container 7 “may...be fastened directly to the vacuum pump.” *Id.*, ¶69; *see* Fig. 6 (above). *Bauer*, ¶77.

Weber discloses its embodiments “can also be used in known breast pumps.” *Weber*, ¶110; *Bauer*, ¶78.

C. Guthrie

Guthrie discloses a “smart breast pump system” that has “milk capture and collection elements” with an “integral smart sensor and internal pump 207,” which may be a “vacuum pump.” *Guthrie*, ¶35; *Bauer*, ¶80.

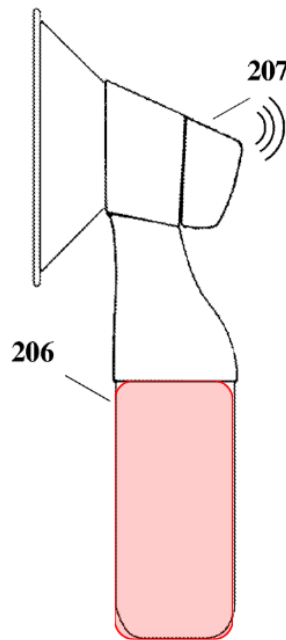
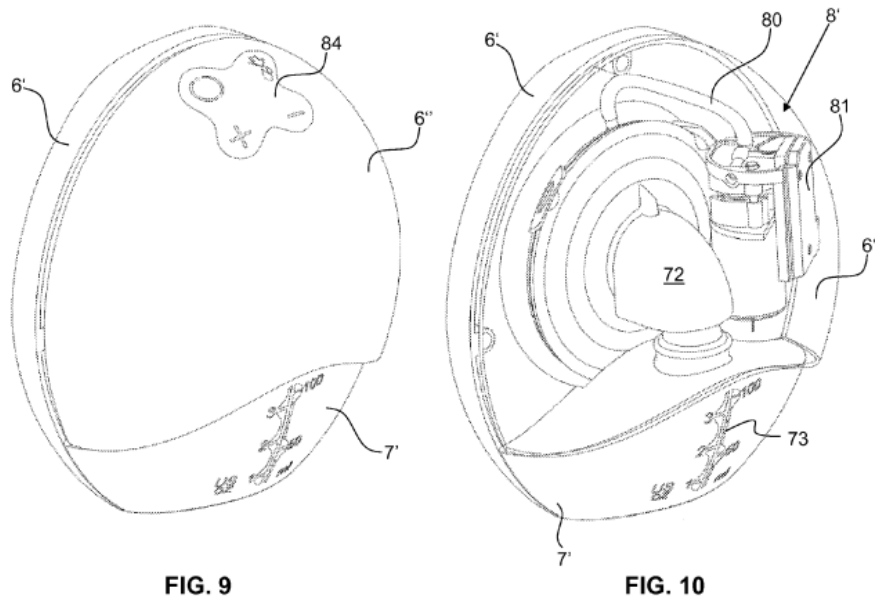


FIG. 2C

Guthrie, Fig. 2C. Guthrie uses rechargeable batteries to power its pump, and its batteries can be charged via a USB cable. *Id.*, ¶40. Guthrie’s milk container shown above (in pink) is below the pump housing and has a flat base, allowing it to “stably stand whether or not it contains milk, ensuring that bottle 304 does not tip or spill milk that has been collected.” *Id.*, ¶37. *Bauer*, ¶80-81.

D. Khalil

Khalil discloses an integrated breast pump, referred to as a “breastshield unit.” *Khalil*, Abstract. The breastshield unit is “designed as a hands-free unit” that can be worn “under” or “in” a bra (*id.*, ¶¶32, 70):



Id., Figs. 9, 10, Abstract, ¶66. The unit includes a shell (cover 6'' and shell ring 6'), milk container 7' and integrated pump unit 8', including vacuum pump 81. *Id.*, ¶¶66-67. The pump "is preferably a diaphragm vacuum pump of a known type, which is operated by means of an electric motor." *Id.*, ¶67. The pump may be powered by an integrated "power source." *Id.* Milk collection container 7' is "arranged in the lower area adjoining the cover (6'')" and uses locking lug 71, "integrally formed" on it, to "engage in a corresponding recess...of the shell ring (6')" as shown below. *Id.*, ¶69. *Bauer*, ¶¶67-71.

The breastshield unit includes "breast interface 1 for placing on a human mother's breast." *Khalil*, ¶¶48, 66. The breast interface is "slightly funnel-shaped" and includes a "receiving part" (stub 10) where the user's "nipple B protrudes into":

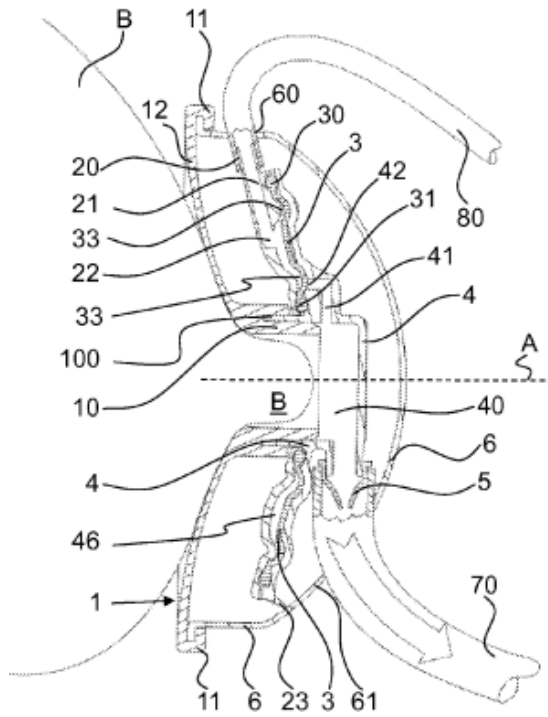


FIG. 4

Id., ¶60, Fig. 4. *Bauer*, ¶72.

Khalil's breastshield may include "membrane 3" located between "membrane housing parts 2, 4," which are attached to the shell via cover ring 6':

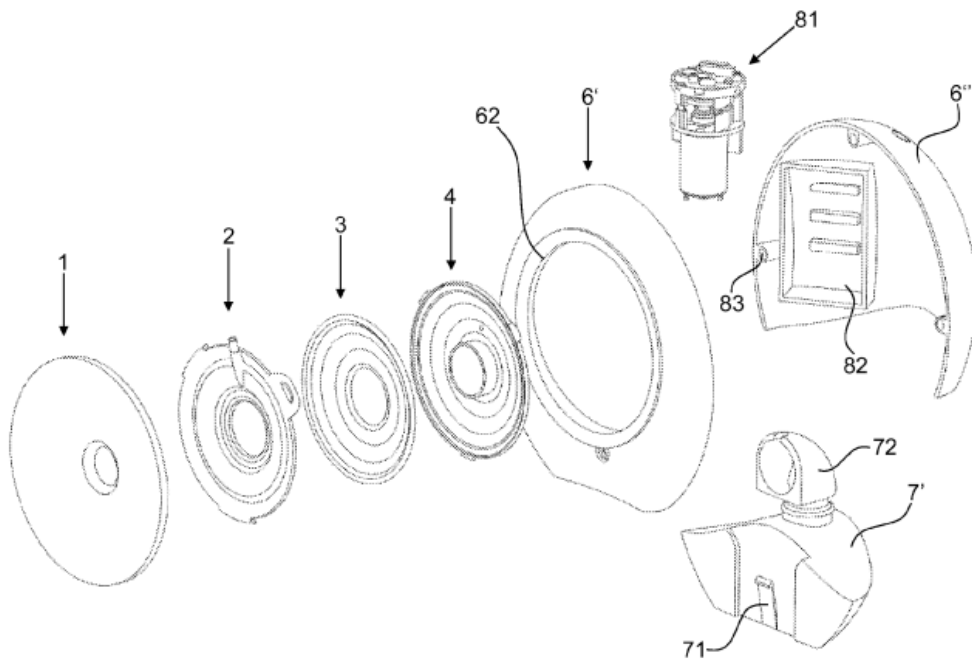


FIG. 11

Khalil, Fig. 11, ¶¶66-67, ¶¶53-58.

IX. DETAILED EXPLANATION OF GROUNDS

A. Claims

The '380 patent has two independent claims, claims 1 and 29, which are very similar to each other. Claims 2-28 depend from claim 1 and claims 30-46 depend from claim 29. Each dependent claim that depends from claim 29 has a counterpart that depends from claim 1.

B. Ground 1A: Obviousness Based On Chang, Weber, Guthrie (Claims 1-4, 6-9, 11-16, 18-26, 29-35, 37-44)

1. Motivation To Combine Chang, Weber, Guthrie

A POSITA would have been motivated to combine Chang, Weber, and Guthrie. *Bauer*, ¶¶84-98.

A POSITA would have been motivated to use Weber's pump in Chang's breast pump device. Chang discloses a preferred embodiment having a pump that generates suction by cyclical compression and decompression of a conduit or flex-tube. *E.g.*, *Chang*, ¶¶22, 25, 28, 84-86. Chang states that its teachings are not limited to that kind of pump: "reference to 'the pump' includes reference to ***one or more pumps and equivalents thereof known to those skilled in the art...***" *Id.*, ¶68.¹ Chang states, "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. Accordingly, Chang affirmatively teaches that its breast pump device can be used with pumps of known design that generate suction using a flexible member having a non-tubular shape. *Bauer*, ¶85.

A POSITA would have known that an example of a pump of known design that would work with Chang's breast pump is a diaphragm pump having a diaphragm that deforms in response to changes in air pressure caused by the pump to generate suction. As discussed in the Technology Background section above, such diaphragm pumps were well-known in the prior art. Weber discloses such a diaphragm pump. *See, e.g.*, *Weber*, ¶22; *see also Bauer*, ¶86-87.

¹ All emphases are added unless otherwise specified.

Weber discloses embodiments of a breast pump having a separate breast shield, pump, and milk container but also states, “The elements of the above-described embodiments can be combined with one another individually or in groups in order to form further embodiments.” *Weber*, ¶111. For example, Weber discloses that the breast shield and pump may be connected: “In another embodiment, the vacuum pump for the breast shield is connected directly to the first port of the [vacuum-generating] chamber” of the pump. *Id.*, ¶21. Weber also discloses an embodiment in which the milk container is “fastened directly to the vacuum pump.” *Id.*, ¶69, Fig. 6. *Bauer*, ¶88.

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. *Id.*, ¶89.

Significantly, Weber teaches that its pump “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. Accordingly, Weber affirmatively teaches that its pump can be used in breast pump systems of known design. *Bauer*, ¶87.

A POSITA would have known that breast pumps of known design suitable for use with Weber’s pump design would have included integrated in-bra breast pumps. *Id.*, ¶90. For example, Weber discloses as examples of prior art the “hands-free”

breast pumps of WO 02/102437 and WO 2008/137678, about which Weber states, “the breast shield is in each case integrated into a pump housing” (*Weber*, ¶6) and worn in a bra. *Bauer*, ¶90. 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.” *Weber*, ¶47. Chang is an example of a known breast pump that a POSITA would have been motivated to use with Weber’s pump design. *Bauer*, ¶90.

The foregoing shows that Chang and Weber provided motivation to a POSITA to use the known diaphragm pump of Weber in the known breast pump of Chang. *Id.*, ¶89-91; *KSR Int’l Co., v. Teleflex, Inc.*, 550 U.S. 398, 416-17 (2007) (obvious to combine familiar elements according to known methods to yield predictable results and to improve similar devices in the same way); *id.* at 416 (“[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.”); *id.* at 417 (“If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability.”).

A POSITA also would have been motivated to combine the breast pump of Chang with the milk container of Weber. *Bauer*, ¶88. 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, “It 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. *Bauer*, ¶88; *KSR*, 550 U.S. at 416-17.

A POSITA also would have been motivated to combine the breast pump device of *Chang* with the power charging circuit of *Guthrie*. *Bauer*, ¶92-97. *Chang* discloses that its breast pump can be powered by a rechargeable battery that “is configured to be plugged into a power source for charging.” *Chang*, ¶72. A POSITA would have understood that a device with a rechargeable battery has a power charging circuit for controlling charging of the battery. *Bauer*, ¶92. *Chang* does not expressly refer to such a power charging circuit, but they were well-known in the prior art. *Id.*

Rechargeable batteries are often charged using household electricity, which in the U.S. is alternating current and 120 volts. *Id.*, ¶93. Rechargeable batteries for devices such as breast pumps operate using direct current and low voltages (e.g., 3 volts). *Id.* Therefore, 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. *Id.* 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. *Id.*

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. *Id.*, ¶94 Such modifications are typically carried out by a power charging circuit that is embodied by electrical components on one or more printed circuit boards inside the device. *Id.* Without such a power charging circuit, the battery would not charge, could be damaged, and could catch fire or explode. *Id.*

Chang does not expressly describe the power charging circuitry 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 breast pump system having a power charging circuit for controlling charging of a rechargeable battery. *Id.*, ¶95.

Guthrie discloses an external 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 a charging cable having a USB-A style adapter and 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. *Bauer*, ¶96.

The foregoing shows that Chang and Guthrie provided teaching, suggestion, and motivation to a POSITA to use the power charging circuit of Guthrie to control charging of the rechargeable battery in the breast pump of Chang. *Bauer*, ¶97; *KSR*,

550 U.S. at 416-17 (obvious to combine familiar elements according to known methods to yield predictable results and to improve similar devices in the same way); *see also id.* at 421 (obvious to try “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions” and a POSITA has “known options within his or her technical grasp”).

A POSITA also would have been motivated to combine the breast pump of Chang with the milk container of Guthrie. *Bauer*, ¶98. 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, “It 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. Guthrie is an example of a prior art breast pump having a rigid container located below the pump housing. *Bauer*, ¶98; *KSR*, 550 U.S. at 416-17.

2. Claim 1

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

If the preamble is limiting, Chang discloses it. *See Bauer*, ¶99. Chang discloses “portable breast pump systems and methods for collecting milk from a breast of a nursing mother.” *Chang*, ¶1, Abstract; *Bauer*, ¶99.

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

Chang discloses this limitation—i.e., a breast pump device that is ““complete, or having all that is needed, in itself” and is capable of being worn in a bra.” *See* Claim Construction above; *See Bauer*, ¶100-101. Chang discloses “a small, portable, self-powered, energy efficient, *wearable* breast pump system” (*Chang*, ¶4) that “is contemplated to *fit comfortably and conveniently into a bra of a user*” (*id.*, ¶11), with the components of the device “*all contained within a cup of a brassiere.*” *Id.*, ¶19. *Bauer*, ¶100-101.

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

Chang discloses this limitation. *See Bauer*, ¶102. Chang discloses a “*housing* or outer shell 12 of” the breast pump device as shown in Figures 1A and 6A (annotated in blue below). *Chang*, ¶71; *Bauer*, ¶102.

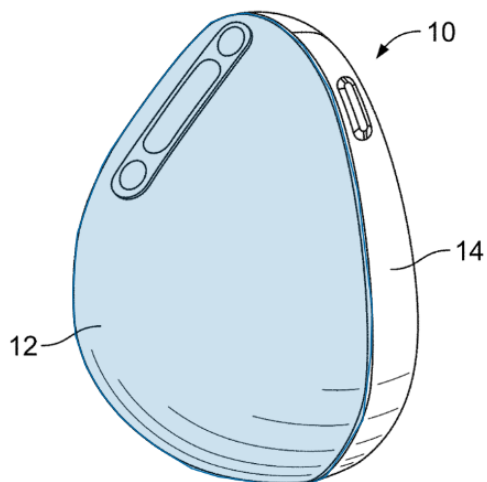


FIG. 1A

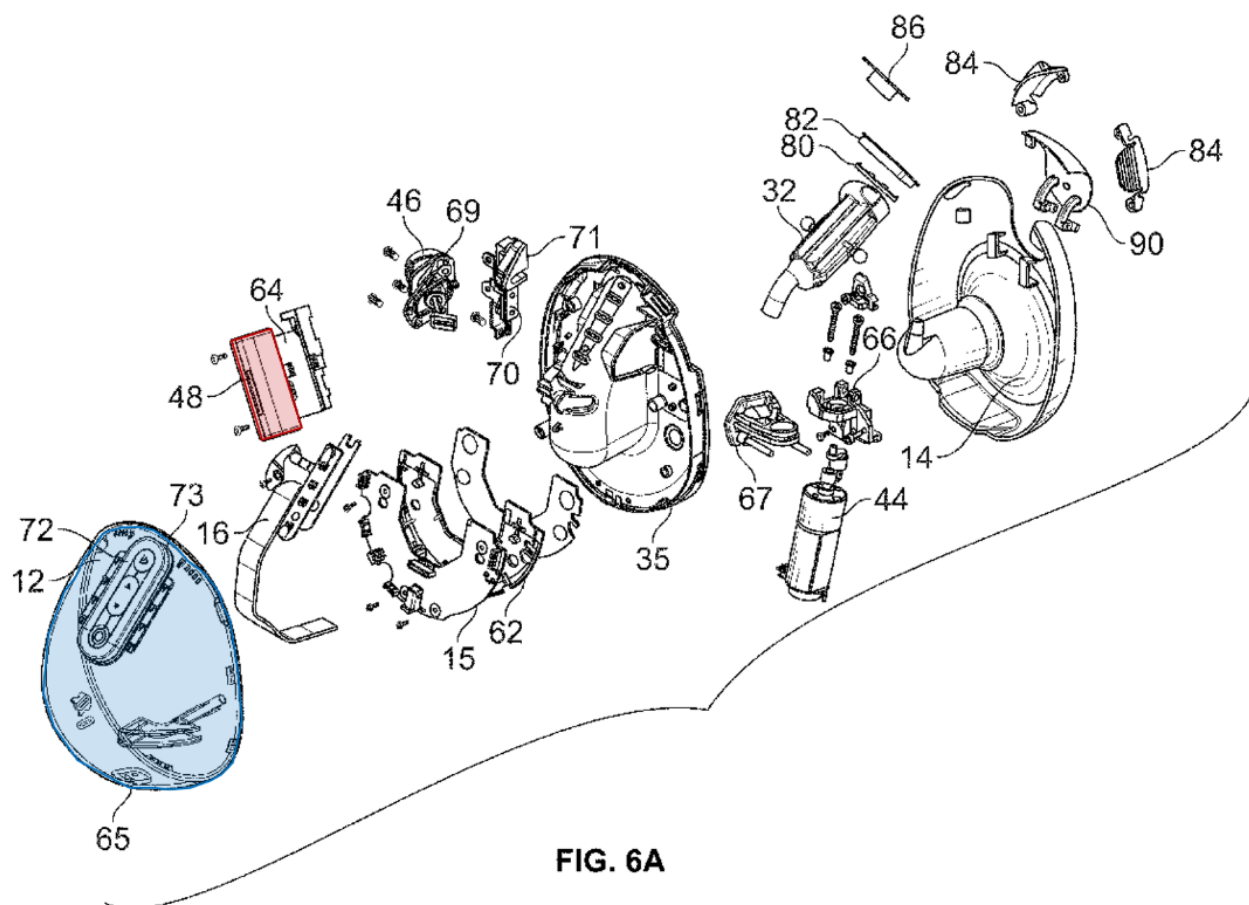


FIG. 6A

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

Chang discloses this limitation. *See Bauer*, ¶103. Chang’s breast pump device “is battery powered” and “compris[es] a battery, wherein the battery is received in the compartment of the external shell.” *Chang*, ¶20. “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. “A battery bracket 64A” within the chassis inside housing 12 is “sized and shaped to receive a **rechargeable battery** 48 assembly that powers” the breast pump device. *Id.*, ¶80, Fig. 6A above (item 48 annotated in red). *Bauer*, ¶103.

Guthrie also discloses this limitation. *See Bauer*, ¶104-105. Guthrie discloses an integrated design in which “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....” *Guthrie*, ¶¶27, 35, Fig. 2C. Guthrie discloses “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. *Bauer*, ¶104-105.

As discussed above at pages 26-29, a POSITA would have been motivated to combine Chang and Guthrie. *Id.*, ¶106.

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

Chang alone or in combination with Guthrie teaches this limitation. *See Bauer*, ¶¶107-113. Chang discloses a breast pump device with a rechargeable battery “configured to be plugged into a power source for charging.” *Chang*, ¶¶4, 20, 72; *Bauer*, ¶107.

A POSITA would have understood, and found it obvious, that a device with a rechargeable battery has a power charging circuit for controlling charging of the battery. *Id.*, ¶108. Rechargeable batteries are often charged using household electricity, which in the U.S. is alternating current and 120 volts. *Id.* Rechargeable batteries for devices such as breast pumps operate using direct current and low voltages (e.g., 3 volts). *Id.* Therefore, 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. *Id.* 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. *Id.*

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. *Id.*, ¶109. Such modifications are carried out by a power charging circuit comprising electrical components on one or more printed circuit boards, typically inside the device. *Id.* 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. *Id.*

If the Board finds that Chang does not disclose or suggest 1[b][ii], the combination of Chang and Guthrie teaches it. Chang does not expressly refer to a power charging circuit for controlling charging of the rechargeable battery, and so a POSITA would have looked elsewhere for information about a power charging circuit. *Id.*, ¶110. Guthrie discloses a breast pump system having a power charging circuit for controlling charging of a rechargeable battery. *Guthrie*, ¶40. A POSITA would have been motivated to combine the breast pump device of Chang with the power charging circuit of Guthrie for the teaching of such a circuit to charge either reference's rechargeable battery. *Bauer*, ¶110.

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 discussed in the Motivation To Combine section 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. *Bauer*, ¶111.

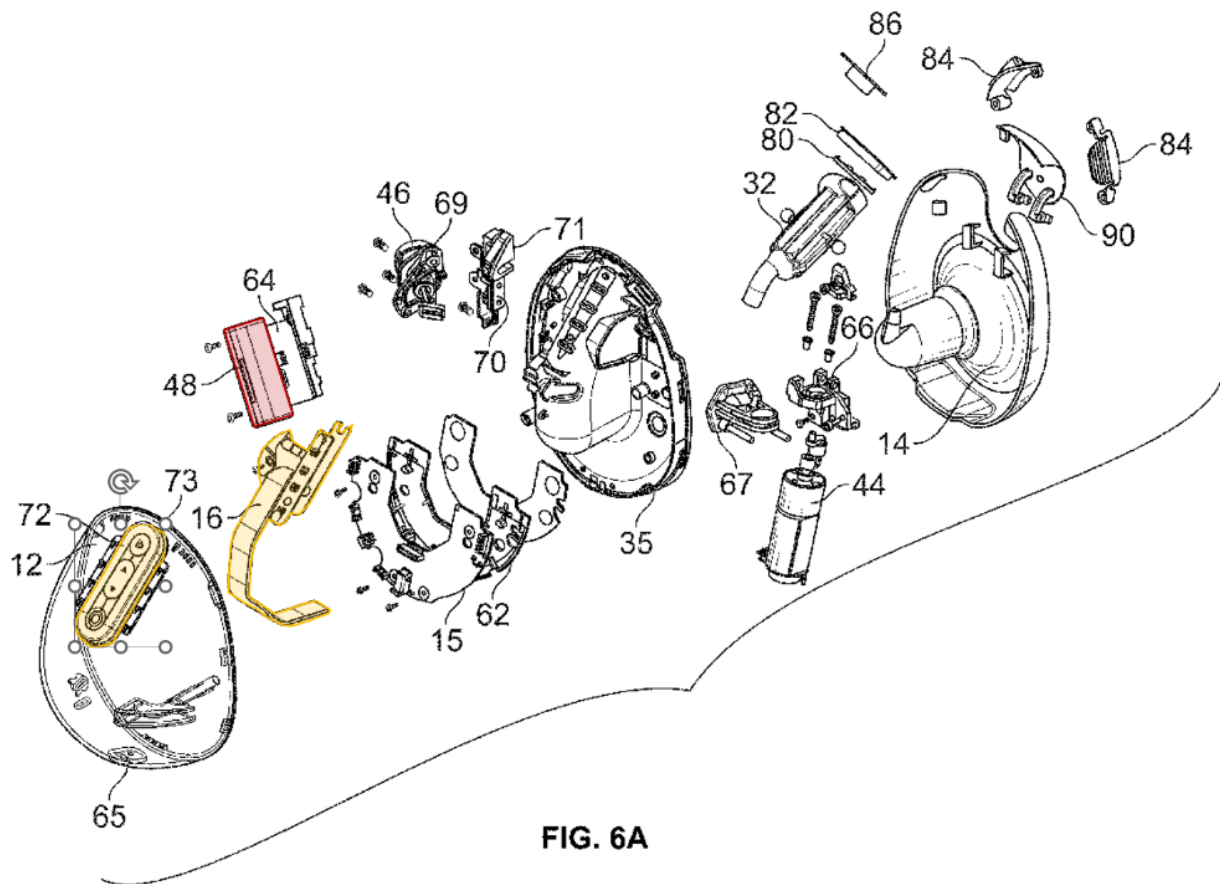
Guthrie discloses that its breast pump device can have a USB-A style adapter to receive the charging cable. A USB-A style adapter is a type of industry standard connector for transmitting power and data. Because it is a standard interface, it was foreseeable that users of the Guthrie breast pump might 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 should be located inside the breast pump—i.e., on the device-side of the USB-A adapter—to account for electricity of varying characteristics being supplied to the device. *Id.*, ¶112.

As discussed above at pages 26-29, a POSITA would have been motivated to combine Chang and Guthrie. *Id.*, ¶113.

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

Chang discloses this limitation. *See Bauer*, ¶114-115. Chang discloses control electronics powered by rechargeable battery 48. For example, Chang states, “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.” *Chang*, ¶72. “A battery 48 is included to provide a rechargeable power source and is configured to be plugged into a power source for charging.” *Id.* Referring to Figure 6A (annotated in red and yellow below), *Chang* states, “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. *Bauer*, ¶114-115.



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

The combination of Chang and Weber teaches this limitation. *See Bauer*, ¶116-119.

Chang discloses a pump that generates a vacuum with a compressible conduit or “flex-tube.” *Chang*, ¶¶72-75. But Chang is not limited to such a pump design and states its pump includes “one or more pumps and equivalents thereof known to those skilled in the art” (*id.*, ¶68) and that the pump need not rely on a tubular structure (*id.*, ¶79). Weber discloses a specific kind of diaphragm pump, which was a common type of pump used in breast pumps. *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.”); *Bauer*, ¶117. Weber states its pump design can be used in known breast pumps and specifically cites examples of breast pumps in which the breast shield and pump are both worn in a bra as prior art. *Weber*, ¶6. Weber also states that the motor of its pump can be battery operated. *Id.*, ¶70. *Bauer*, ¶118.

As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. *Id.*, ¶119.

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

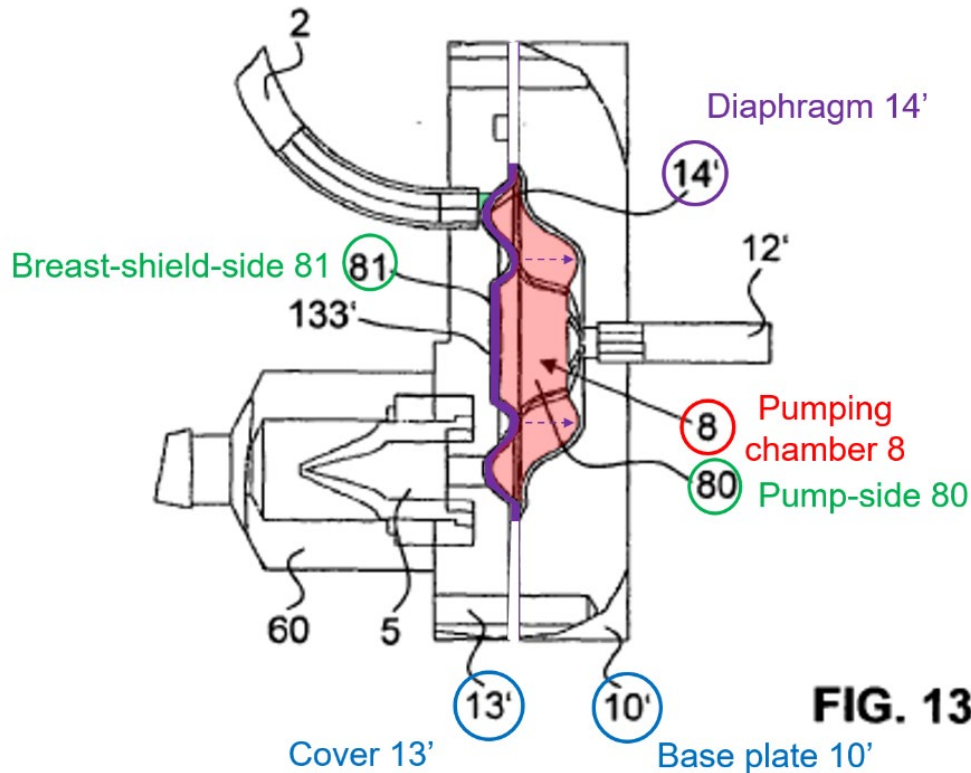
The combination of Chang and Guthrie teaches this limitation. *See Bauer*, ¶120-122.

Chang discloses a breast pump having a housing with a “cover jack...for accepting a power cord connector” for charging the rechargeable battery (*Chang*, ¶80) but does not specify any interface by which the battery is charged, so a POSITA would have looked elsewhere for such an interface. As discussed above for 1[b][ii], Guthrie discloses a USB-A type charging socket for transferring power to the power charging circuit and the rechargeable battery. *Bauer*, ¶121.

As discussed above at pages 26-29, a POSITA would have been motivated to combine Chang and Guthrie. *Id.*, ¶122.

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

Weber discloses this limitation. *See Bauer*, ¶123-124. Weber discloses a “vacuum-generating *pump chamber* of [a] vacuum pump.” *Weber*, ¶19. As shown in annotated Figure 13 below, Weber discloses a pumping chamber 8 that is defined by a recess or cavity between cover 13’ and base plate 10’. *Bauer*, ¶123. A diaphragm (shown in a relaxed position in annotated Figure 13 below) divides pumping chamber 8 into a breast-shield-side 81 and a pump-side 80. *Weber*, ¶¶95-96; *Bauer*, ¶123.



As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. *Id.*, ¶124.

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

Chang discloses this limitation. *See Bauer*, ¶125-127. Chang discloses that its breast pump device “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.” *Chang*, ¶71. The flange has two parts—a “nipple receiving portion...contoured to more closely match the natural shape of the nipple” (*id.*, ¶90), and “surfaces that extend outwardly from a nipple receiving portion of the flange to

engage breast tissue, thus providing extra surface area for comfortably contacting tissue” (*id.*, ¶71). “The nipple receiving portion can be cylindrical in the portion adjoining the breast contact portion.” *Id.*, ¶90. The flange comprising the nipple receiving portion (in green) and breast-engaging surface (in purple) can be seen in Chang’s annotated Figure 4 below. *Bauer*, ¶125-126.

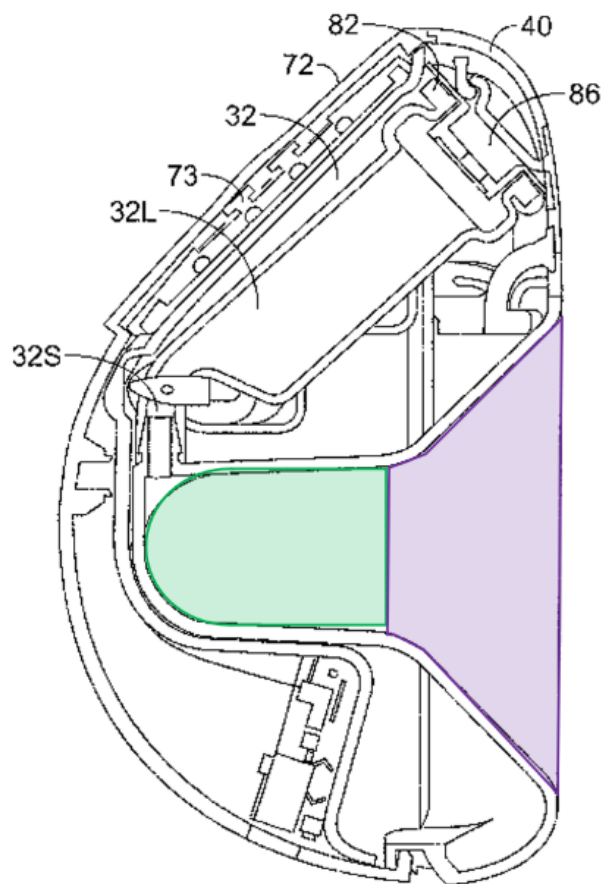


FIG. 4

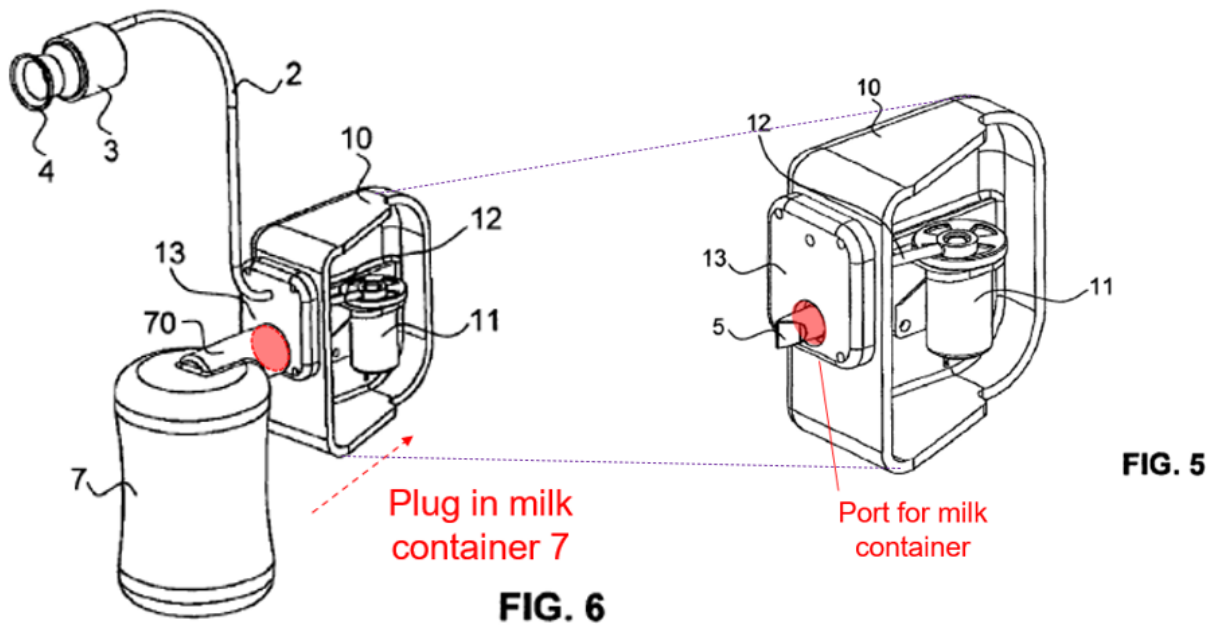
A POSITA would have understood that Chang’s flange 14 and extended portion for receiving the nipple disclose this breast shield element. *Id.*, ¶127.

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

The combination of Chang and Weber teaches this limitation. *See Bauer*, ¶128-132.

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, “It 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. *Bauer*, ¶129.

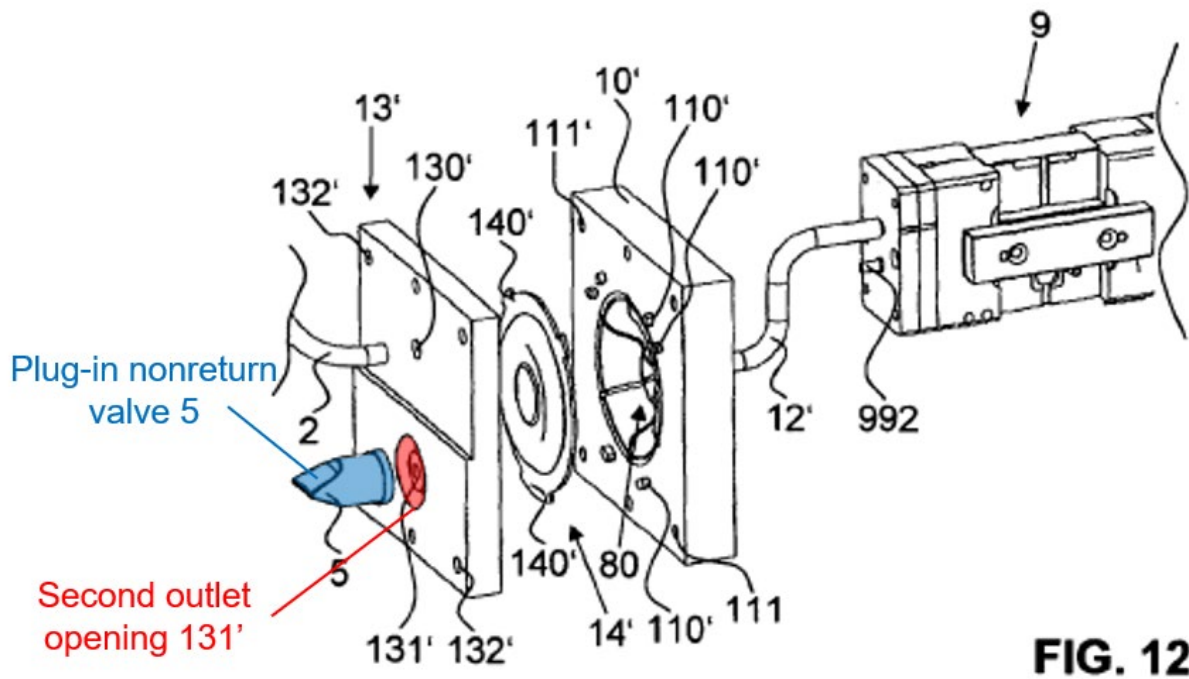
Weber discloses that the milk container can be attached to and removed from the pump housing. Annotated Figures 5 and 6 show such an arrangement:



Weber explains:

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.

Weber, ¶69. This same “detachably connectable” milk container configuration is used in Weber’s other embodiments as shown in annotated Figure 12 below. *Id.*, ¶75. *Bauer*, ¶130-131.



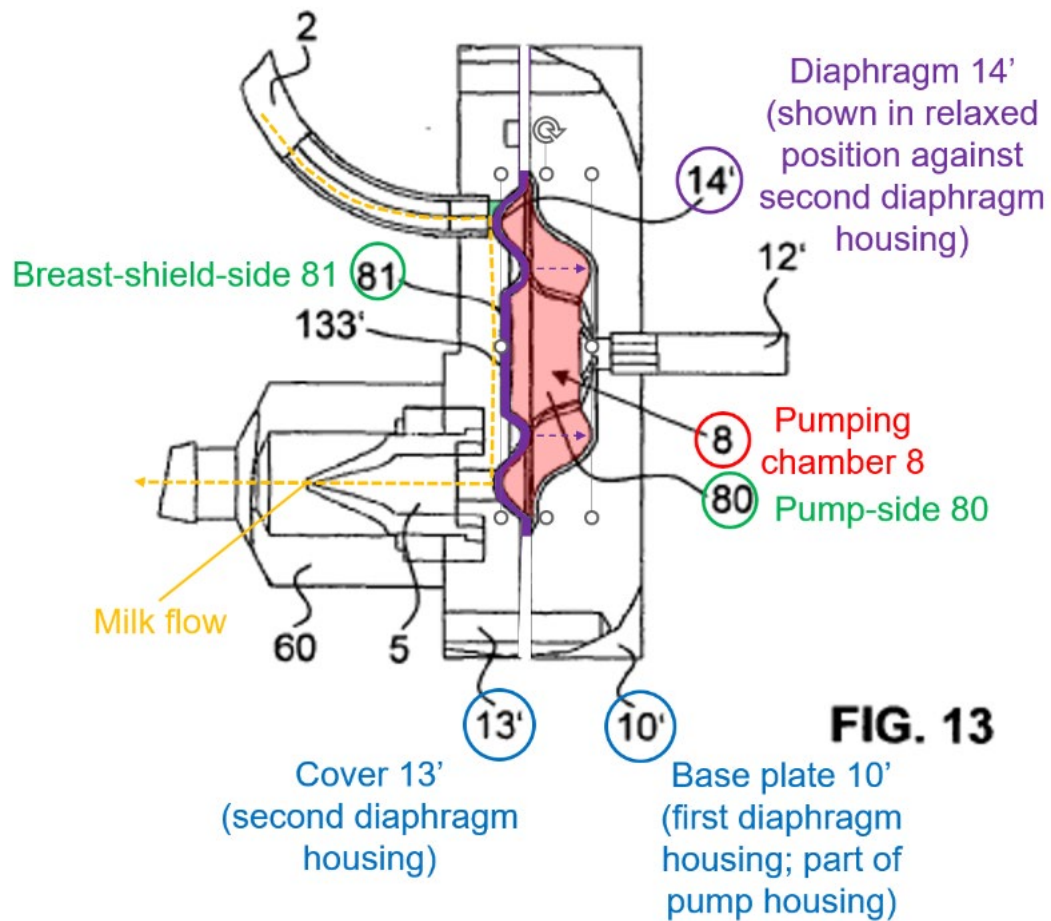
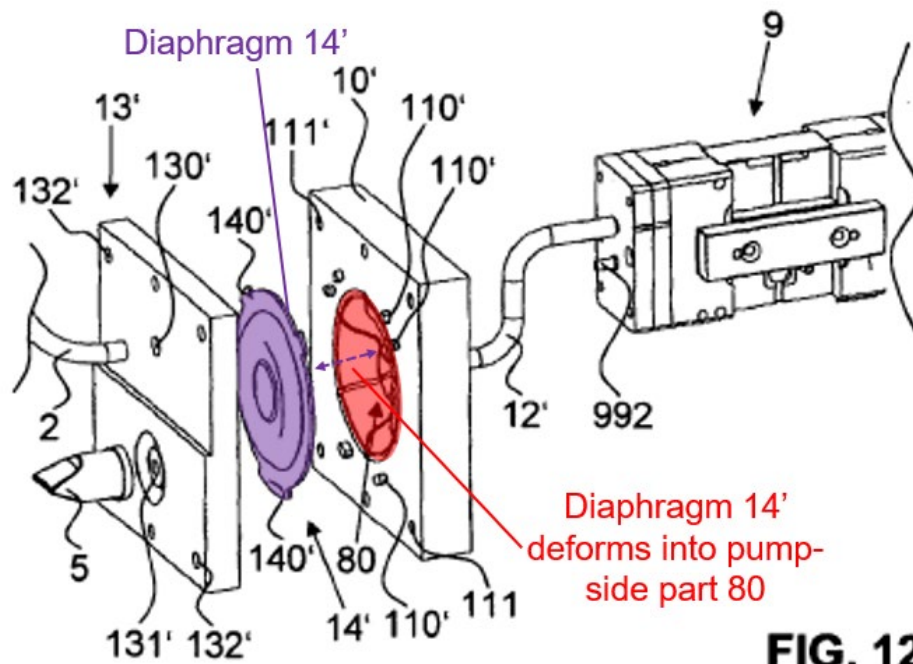
As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. As also discussed above, Chang's teachings would have motivated a POSITA to put a milk container in an alternative location such as below the pump housing. Weber is an example of a prior art breast pump having a container that is configured to be attached to and removed from the pump housing. *Id.*, ¶132.

- l. 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.**

Weber discloses this limitation. *Weber*, ¶¶16-17, 23, 71, 95-96; *see also Bauer*, ¶¶133-138. Referring to Figures 12 and 13 below, Weber states that the diaphragm prevents milk from reaching the pump:

[T]he diaphragm 14' is not the diaphragm of the vacuum pump, as in the previous examples, but an additional diaphragm. As before, 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.

Weber, ¶¶96. *Bauer*, ¶¶134-135.



Weber discloses that the diaphragm is seated against diaphragm housing that is fixed to a surface of the housing as follows: “The *diaphragm 14 is arranged in a recess 112 of the housing 10*, which forms part of a pump chamber.” *Weber*, ¶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. *Bauer*, ¶136.

Weber discloses that the diaphragm is a membrane that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. *Weber*, ¶¶95-96.

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.

...

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., ¶¶96, 98. *Bauer*, ¶137.

As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. *Id.*, ¶138.

3. Claim 29

Claim 29 is broader than claim 1. The combination of Chang, Weber, and Guthrie discloses and teaches claim 29 for essentially the same reasons that it discloses and teaches claim 1, as explained below by reference to the elements of claim 1. A POSITA would have understood that the “membrane” required by claim 29 and its dependents is taught by the same prior art disclosures that teach a “diaphragm.” *Bauer*, ¶139, 150.

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

29[pre] corresponds to 1[pre] and 1[a]. *Id.*, ¶140.

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

29[a] is the same as 1[a]. *Id.*, ¶141.

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

29[b] is the same as 1[b] except it refers to “housing” instead of “pump housing.” *Id.*, ¶142.

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

29[b][i] is the same as 1[b][i]. *Id.*, ¶143.

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

29[b][ii] is the same as 1[b][ii]. *Id.*, ¶144.

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

29[b][iii] is the same as 1[b][iii]. *Id.*, ¶145.

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

29[b][iv] is the same as 1[b][iv]. *Id.*, ¶146.

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

29[b][v] is the same as 1[b][v]. *Id.*, ¶147.

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

29[c] is the same as 1[c]. *Id.*, ¶148.

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

29[d] is the same as 1[d]. *Id.*, ¶149.

- 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.**

29[e] corresponds to and is broader than 1[b][vi] and 1[e]. 1[e] requires “a diaphragm housing that is fixed to a recessed surface of the pump housing,” whereas 29[e] requires “a pumping chamber at least in part with an external surface of the housing.” *Id.*, ¶150.

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.**

Chang discloses these limitations. *See Bauer*, ¶151. Chang’s breast shield is “symmetrical about the nipple receiving portion” which is “cylindrical.” *Chang*, ¶90. In addition, 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 if the flange (“breast shield”) is symmetrical about the cylindrical nipple receiving portion and has an operating position, the flange is configured to rotate smoothly around a nipple inserted into the nipple receiving portion (“nipple tunnel”) so that the flange is positioned into a correct operating position onto a breast. *See Bauer*, ¶151.

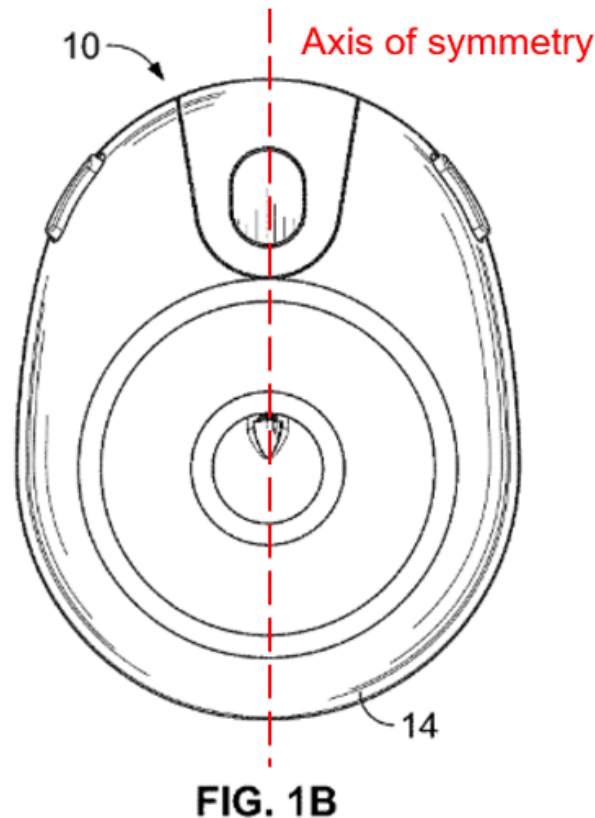
- 5. Claims 3, 31: The breast pump device of claim [1/29], wherein the breast shield is a one piece item that in use presents a single continuous surface to a nipple and a breast.**

Chang discloses these limitations. *See Bauer*, ¶152. Chang discloses that the breast shield is a “skin contact member or flange configured to form a seal with the breast.” *Chang*, ¶8. 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 item that presents a single continuous surface to a nipple and breast to “form a seal with the breast.” *Id.*, ¶22; *Bauer*, ¶152.

- 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.**

Chang discloses these limitations. *See Bauer*, ¶153. 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.* Annotated Figure 1B below shows the breast shield has a top and bottom and is symmetrical about a center-line running

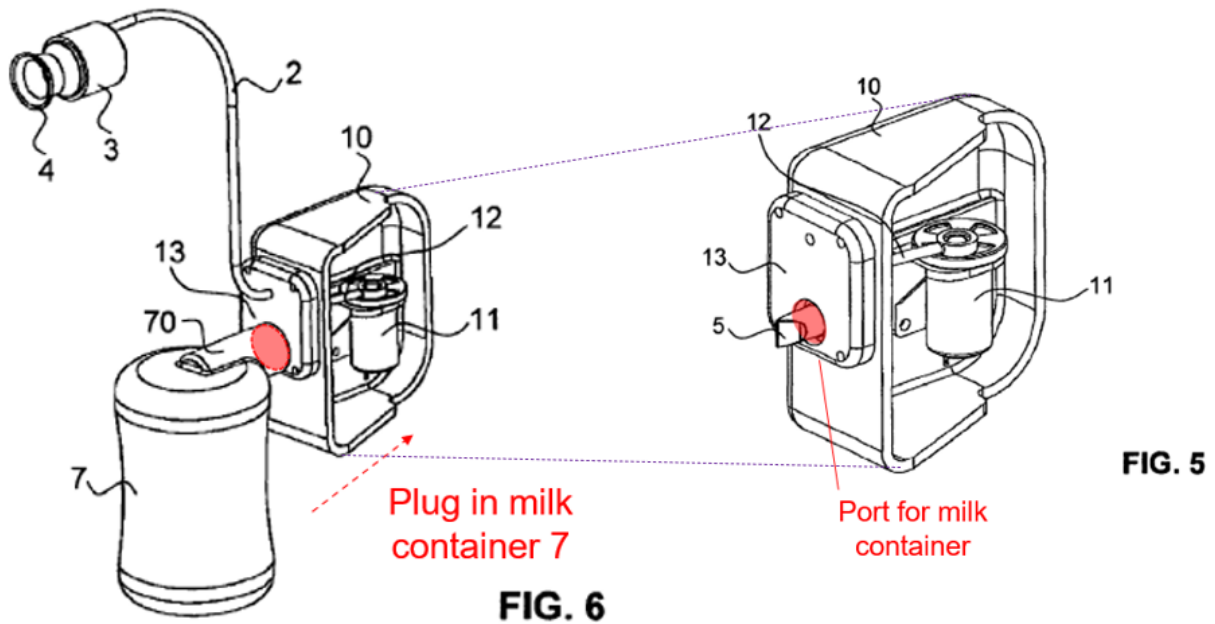
from the top to the bottom of the breast shield when positioned upright for normal use.



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.**

The combination of Chang and Weber teaches these limitations. *See Bauer*, ¶154-155. Chang's breast shield can be "removed from engagement with the remainder of the" breast pump device. *Chang*, ¶105. As described for 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 annotated Figures 5 and 6 below:



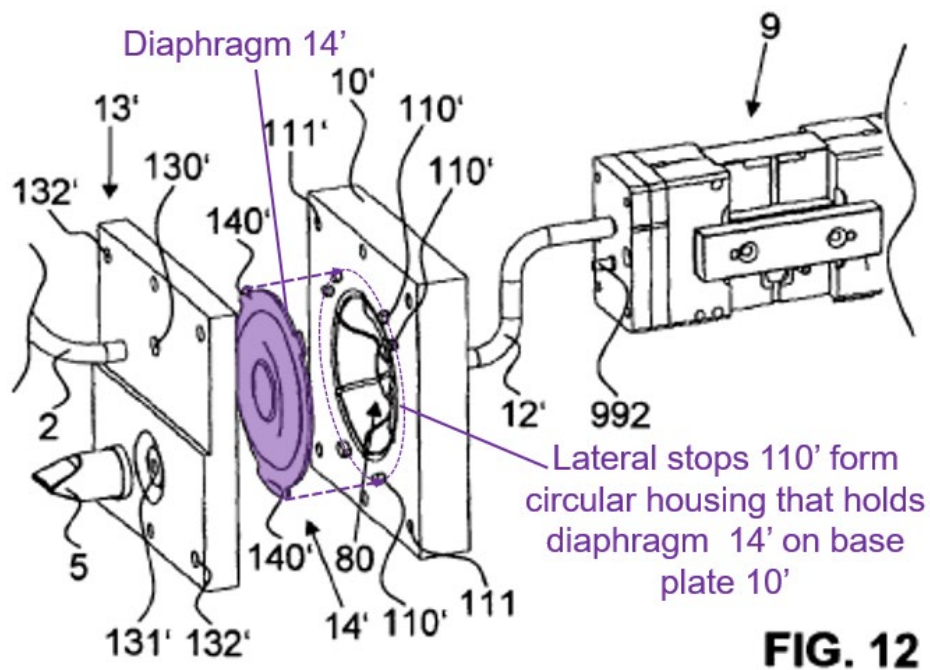
As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. As also discussed above, Chang's teachings would have motivated a POSITA to put a milk container in an alternative location such as below the pump housing. Weber is an example of a prior art breast pump having a container that is directly removable from the pump housing in normal use or disassembly. *Bauer*, ¶55. Therefore, the combination of Chang and Weber discloses breast shield and milk container that are directly removable from the pump housing in normal use or normal disassembly.

8. **Claim 7: The breast pump device of claim 1, wherein the diaphragm is substantially circular and the diaphragm housing is substantially circular.**

Claim 34: The breast pump device of claim 29, wherein the membrane is substantially circular.

Weber discloses these limitations. *See Bauer*, ¶156-157. For example,

Figure 12 of Weber shows circular diaphragm 14':



Weber, Fig. 12 (annotated), ¶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' have recesses with circular outlines 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. *Bauer*, ¶156.

As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. *See Bauer*, ¶156-157.

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

Chang discloses these limitations. *See Bauer*, ¶158. Chang states, “the container can be flexible or *rigid*, or disposable or reusable.” *Chang* ¶21.

Guthrie also discloses these limitations. *See Bauer*, ¶159. As shown in annotated Figure 3A and 3B below, Guthrie teaches a bottle 304 (red) and a valve 301 (green) that may be replaced with a rubber nipple for feeding a baby. *Guthrie*, ¶¶37-38.

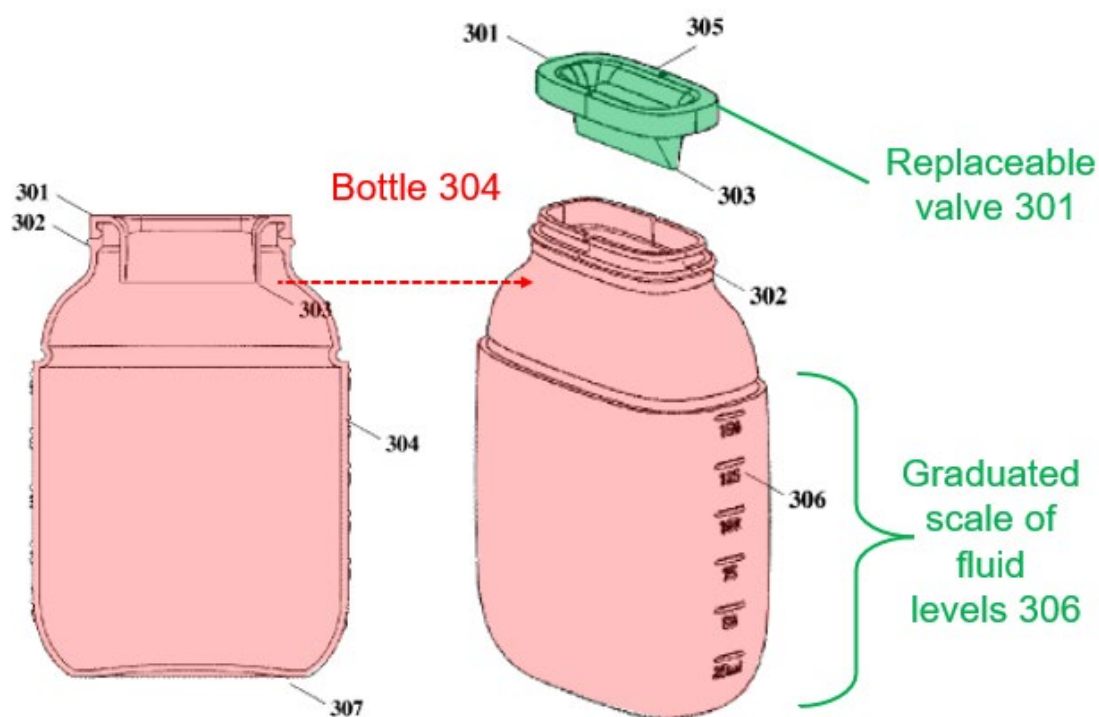
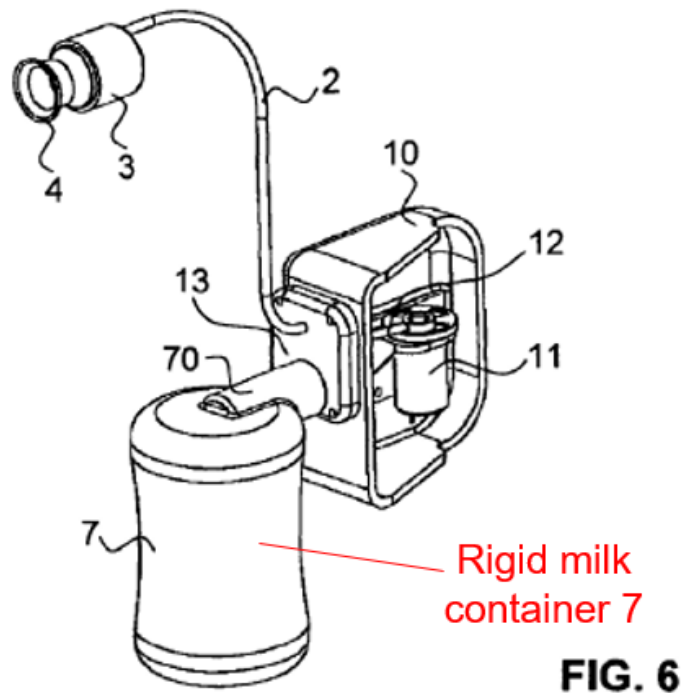


FIG. 3A

FIG. 3B

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

Weber also discloses these limitations. See *Bauer*, ¶160. For example, Figures 1, 2, and 6 show a milk container that stands upright. A POSITA would have known that Weber’s milk container is substantially rigid.

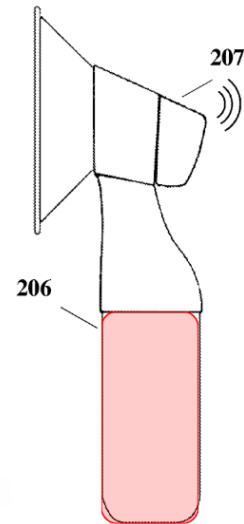
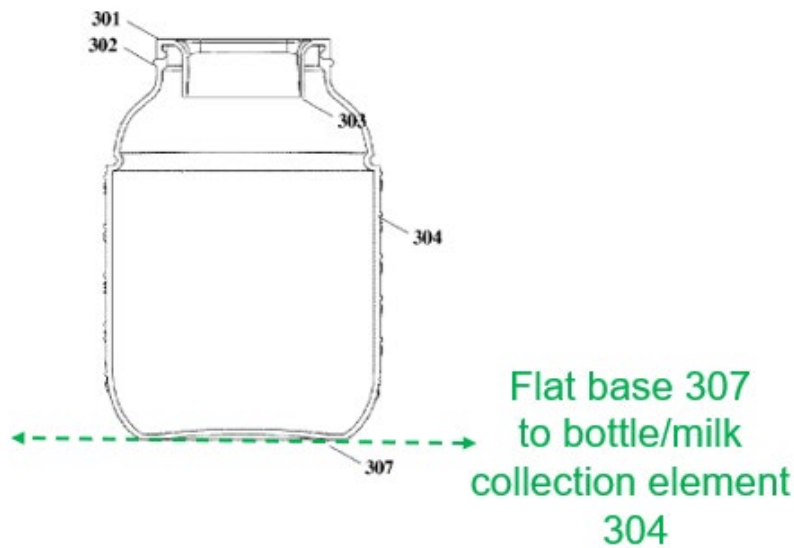


As discussed above at pages 22-29, a POSITA would have been motivated to combine Chang with Guthrie or Weber, including with respect to the milk container. *See Bauer*, ¶158-161.

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.**

Guthrie discloses this limitation. *See Bauer*, ¶162-164. 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 annotated 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.*



As shown in annotated Figure 2C above, 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.

As discussed above at pages 26-29, a POSITA would have been motivated to combine Chang and Guthrie, including with respect to the milk container. *See Bauer*, ¶162-164.

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.**

Guthrie discloses these limitations. *See Bauer*, ¶¶165-167. 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. Annotated Figure 3A shows Guthrie’s milk collection element:

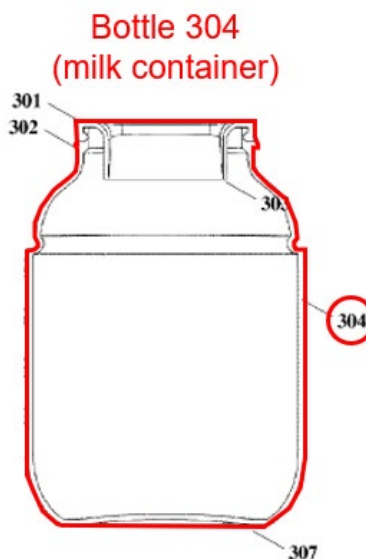


FIG. 3A

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.” *Id.*, ¶37. 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. *Bauer*, ¶166.

As discussed above at pages 26-29, a POSITA would have been motivated to combine Chang and Guthrie, including with respect to the milk container. *See Bauer*, ¶165-167.

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.

Guthrie discloses these limitations. *See Bauer*, ¶168-170. 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.

As shown in annotated 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.

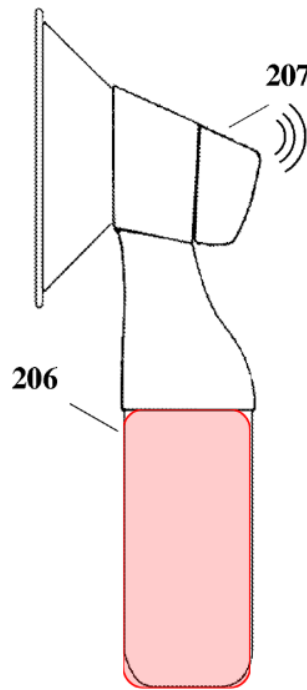


FIG. 2C

Accordingly, 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. *Bauer*, ¶169.

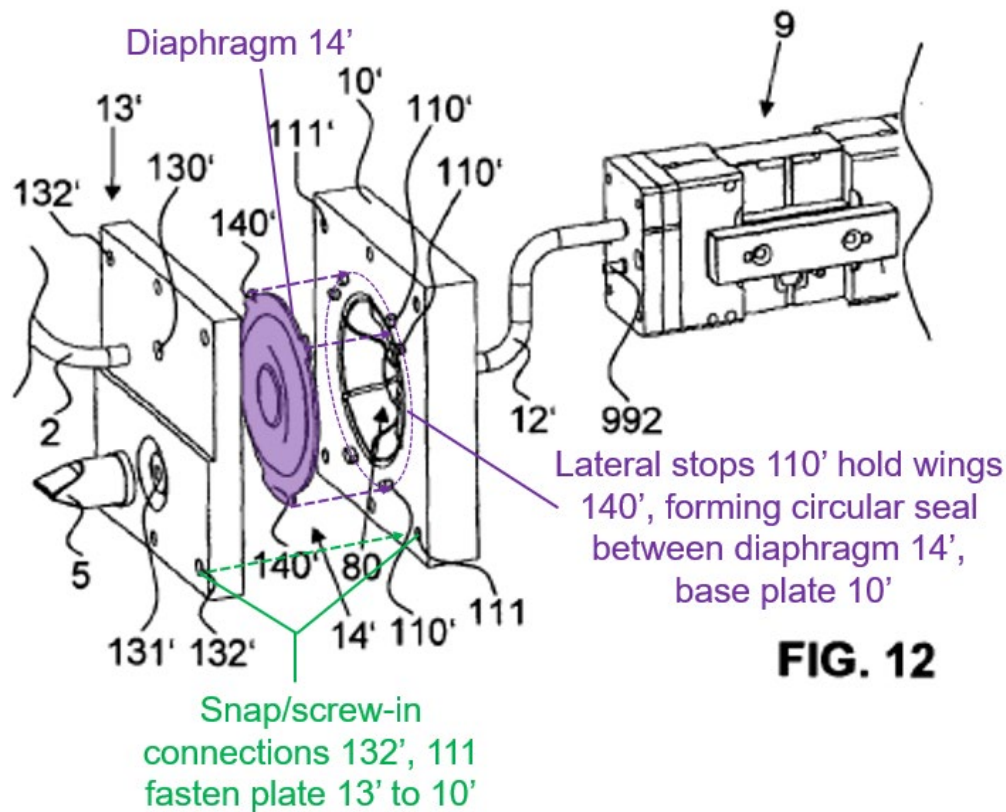
As discussed above at pages 26-29, a POSITA would have been motivated to combine Chang and Guthrie, including with respect to the milk container. *See Bauer*, ¶168-170.

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].**

See discussion of 1[e] above. *See Bauer*, ¶171.

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].**

Weber discloses these limitations. *See Bauer*, ¶172-174. As discussed above for 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.



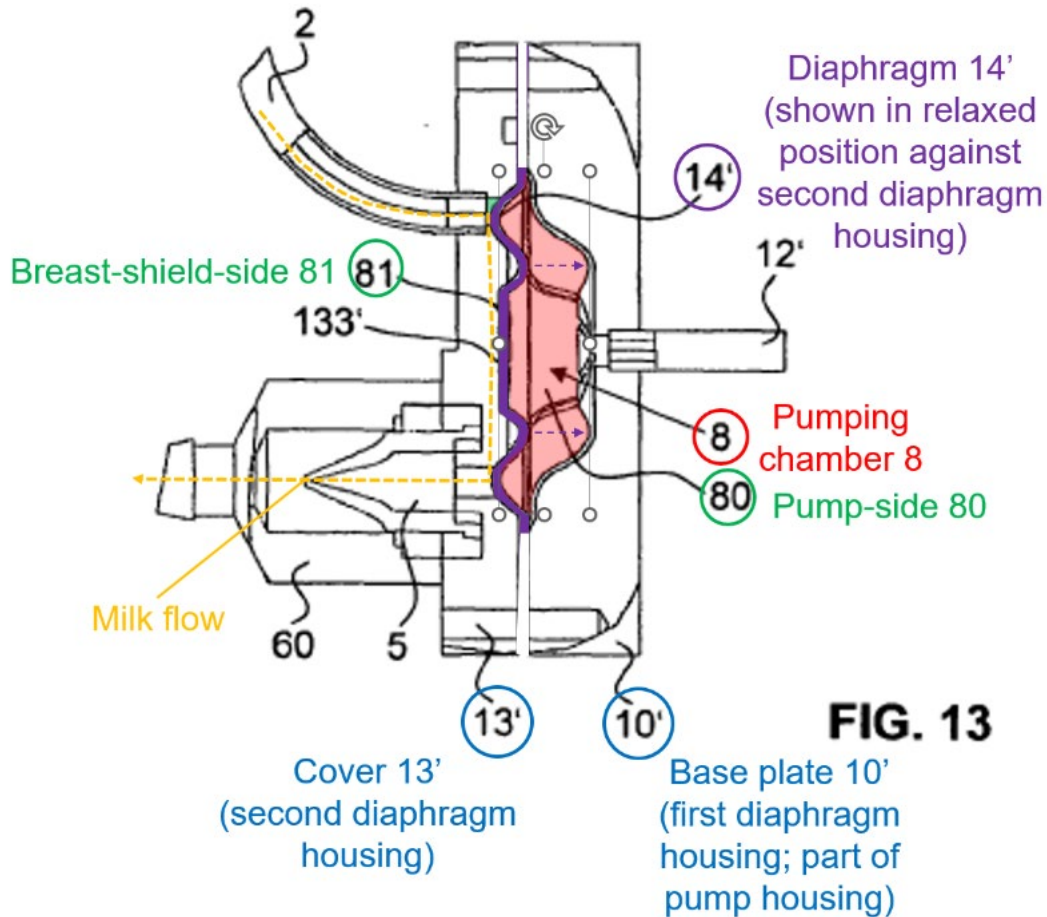
As shown above in Figure 12, Weber discloses that the diaphragm has “wings” for securing it in the recess of the pump housing: “The base plate 10’, which in turn may be part of a vacuum pump housing has lateral stops 110’ between which the wings 140’ are held. As a result, the diaphragm 14’ can be held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

Accordingly, 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. *Bauer*, ¶174.

As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. *See Bauer*, ¶172-174.

- 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.**

Weber discloses this limitation. *See Bauer*, ¶¶175-178. As discussed above for claims 7, 34, 1[b][vi], and 1[e], Weber's 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 (annotated below):



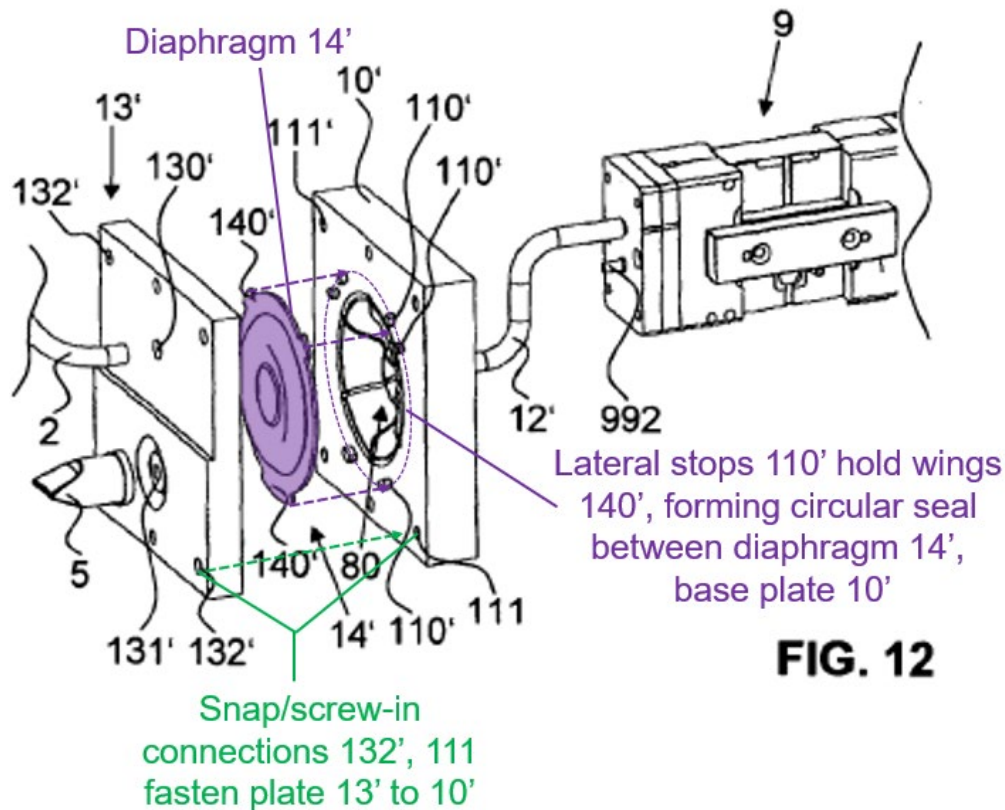
When the cover and base plate are mated together, the recesses form a pumping chamber in which the diaphragm sits. *Id.*, ¶¶95, 97, Figs. 12, 13. As discussed above for claims 14 and 40, the diaphragm serves as media separation between a milk-flow side (breast side) and a side with air (pump side). The cover 13' defines the milk-flow side of the pumping chamber. *Bauer*, ¶¶175-176.

Weber discloses that the breast shield can be “connected directly to the first port of the chamber” (*Weber*, ¶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. *Bauer*, ¶177.

As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. *See Bauer*, ¶¶175-178.

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.

Weber discloses this limitation. *See Bauer*, ¶¶179-180. As shown in annotated 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.



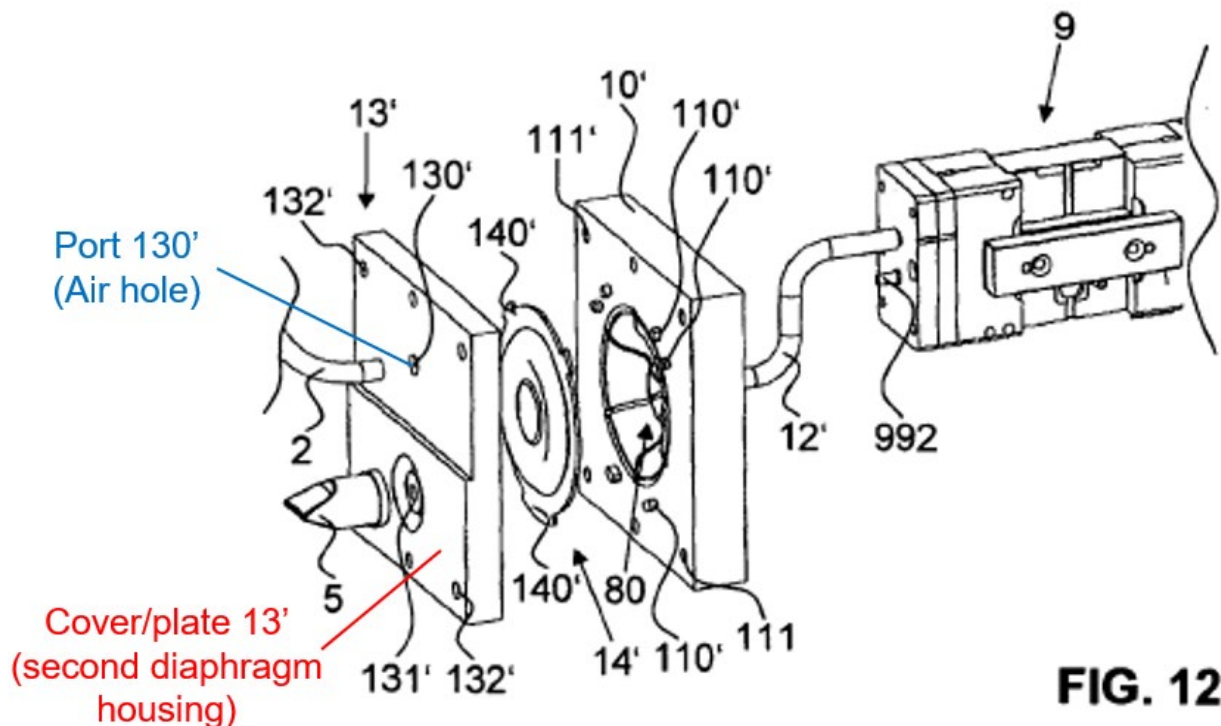
Weber states, “A cover 13 that is *detachably connectable* to the housing 10 secures the diaphragm 14 in its position.” *Id.*, ¶71. As shown in annotated Figure 12 above, connection between cover 13' (“second diaphragm housing”) and base plate 10'

“takes place via snap-in or screw connections, wherein the corresponding holes are provided with the designations 132’ and 111’.” *Weber*, ¶99. *Bauer*, ¶179.

As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. *See Bauer*, ¶179-180.

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.

Weber discloses this limitation. *See Bauer*, ¶¶181-183. As shown in annotated 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*, ¶99.



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. *Bauer*, ¶182.

As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. *See Bauer*, ¶181-183.

- 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.**

See discussion of claims 1[e], 7, 34 above. *See Bauer*, ¶184.

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

Weber discloses this limitation. *See Bauer*, ¶185. 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. *Bauer*, ¶185. 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.*

As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber.

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.**

See discussion of claim 16 above. *See Bauer*, ¶186.

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.**

See discussion of claims 14 and 40 above. *See Bauer*, ¶187-188.

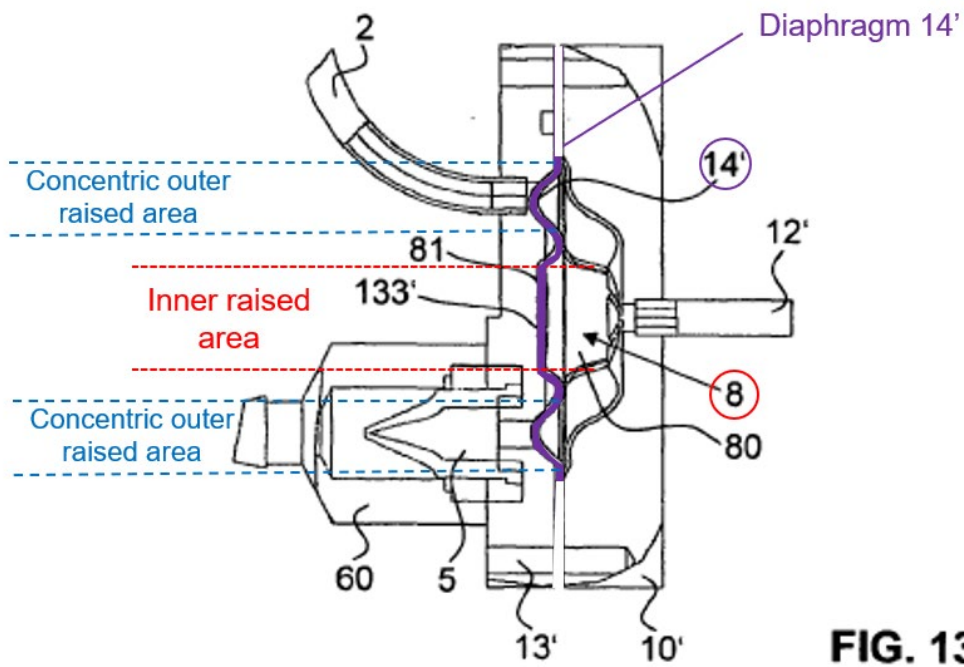
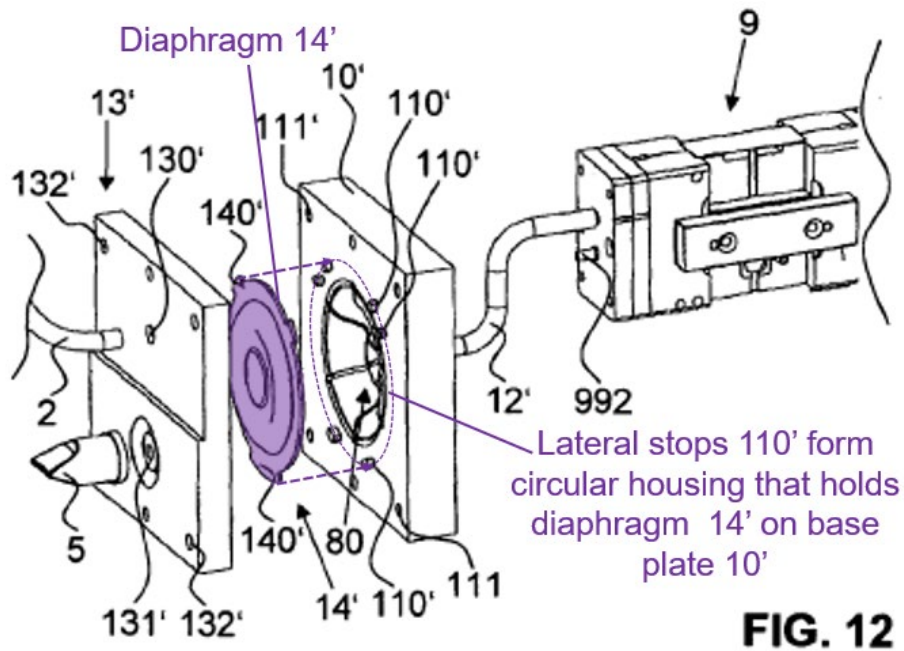
22. **Claim 23: The breast pump device of claim 1, wherein the diaphragm is a flexible and generally circular diaphragm.**

Claim 41: The breast pump device of claim 29, the membrane is a flexible membrane.

See discussion of claims 1[e], 7, 34 above. *See Bauer*, ¶189.

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.**

Weber discloses these limitations. *See Bauer*, ¶190-192. See discussion of claims 1[b][vi], 7, and 34 above. Furthermore, annotated Figures 12 and 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; *Bauer*, ¶¶190-191.



As discussed above at pages 22-26, a POSITA would have been motivated to combine Chang and Weber. *See Bauer*, ¶190-192.

- 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].**

See discussion of claims 11 and 37 above. *See Bauer*, ¶193.

- 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.**

Guthrie discloses these limitations. *See Bauer*, ¶194-196. As described in claims 12 and 38, the Chang-Guthrie combination teaches that expressed milk flows under gravity through an opening in Chang’s nipple tunnel and into Guthrie’s milk container. Furthermore, Chang itself discloses that “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” (i.e., back to the pump), and the valve can be “a duckbill valve.” *Chang*, ¶21. Guthrie similarly discloses “a valve 301 which can be inserted into bottle 304 [“milk container”] and mate in a leak proof fashion” as shown in annotated Figure 3B below. *Guthrie*, ¶36.

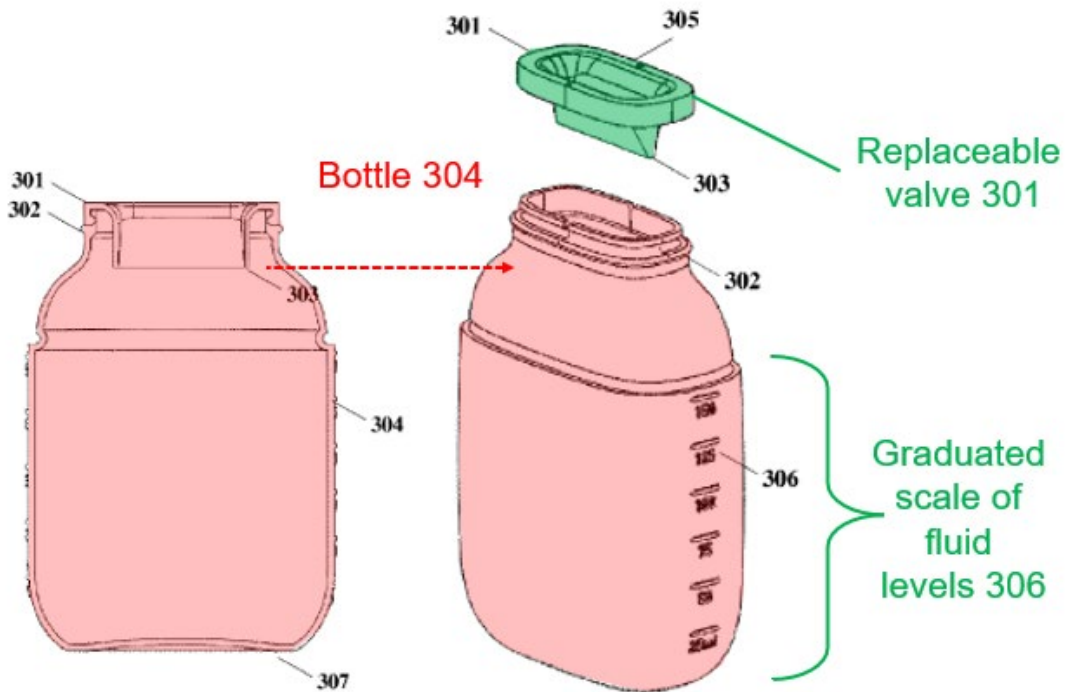


FIG. 3A

FIG. 3B

“Valve 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 known that the purpose of the duckbill valve is to ensure that negative air pressure is not applied to the milk container so that milk can flow into the container but cannot backflow back to the pump. *Bauer*, ¶194-195.

As discussed above at pages 26-29, a POSITA would have been motivated to combine Chang and Guthrie, including with respect to the milk container. *See Bauer*, ¶194-196.

**C. Ground 1B Based On Chang, Weber, Guthrie, Khalil
(Claims 5, 10-12, 17, 25-28, 36-38, 43-46)**

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

As discussed above for Ground 1A, a POSITA would have been motivated to combine Chang, Weber, and Guthrie. *See* pages 22-29 above. Beyond that basic combination, Khalil discloses additional limitations that are part of the claims challenged in Ground 1B—for example, concerning the relationship between the diaphragm or diaphragm housing and other parts of the breast pump and concerning the milk container. A POSITA would have been motivated to combine Chang, Weber, Guthrie, and Khalil in the manner described below. *Bauer*, ¶198-205.

As discussed above for Ground 1A, Chang discloses an in-bra wearable breast pump that generates suction by cyclical compression and decompression of a conduit or flex-tube, but its teachings are not limited to that kind of pump. *See* pages 12-14 above. Chang affirmatively teaches that its breast pump can be used with pumps of known design that generate suction using a flexible member having a non-tubular shape. *Id.*

A POSITA would have known that an example of a pump of known design that would work with Chang’s breast pump is a diaphragm pump having a diaphragm

that deforms in response to changes in air pressure caused by the pump to generate suction. *Bauer*, ¶¶200-201. As discussed above for Ground 1A, Weber discloses such a pump. Khalil also discloses such a diaphragm pump, with specific diaphragm shapes (e.g., annulus or arc) and locations (e.g., 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. A POSITA would have been motivated to combine the teachings of Chang, Weber, and Khalil in designing an integrated breast pump with the breast shield, diaphragm pump, and milk container physically combined to fit in a bra. *Id.*

Chang discloses an embodiment having 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, “It is to be recognized that the collection or container assembly can be placed in alternative locations as well.” *Id.*, ¶105. Furthermore, Chang discloses that its invention can be used with a milk container that “can be flexible or rigid, or disposable or reusable” (*Chang*, ¶21), but does not provide detail as to a “rigid” container design. *See, e.g., id.* ¶¶105-107, Figs. 11B-D. Thus, a POSITA would have been motivated to look elsewhere for such an embodiment. *Bauer*, ¶¶202-203.

Khalil discloses a breast pump (referred to as a “breastshield” or “breastpump”) that, similar to Chang, is also “designed as a hands-free unit and worn under a bra.” *Khalil*, ¶32 (“the invention can be designed as a hands-free unit and worn under a bra”). Khalil discloses the use of a rigid “milk collection container...integrated in the housing of the unit or coupled directly thereto.” *Id.*; *see also*, ¶69 (“[The milk collection container] is preferably made of plastic like the cover 6.”), ¶50 (“The shell 6 is preferably in one piece and rigid, and usually made of a plastic”), ¶67. As discussed above at pages 19-22, Khalil discloses an embodiment in which the milk container is attached to the breast pump below the pump housing. *Khalil*, ¶69, Fig. 11; *see also Bauer*, ¶204.

Thus, a POSITA would have been motivated to incorporate the design of Khalil’s milk container into the breast pump design of Chang. *Bauer*, ¶205. Both references are in the same field, related to in-bra breast pumps, and a POSITA would have been motivated to look to Khalil based on Chang’s suggested teachings to use a rigid milk container in its invention. *Id.*; *KSR*, 550 U.S. 416-17 (obvious to combine familiar elements according to known methods to yield predictable results and to improve similar devices in the same way); *id.* at 416 (“[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.”).

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.**

Khalil discloses this limitation. *See Bauer*, ¶¶206-208. 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 annotated Figure 11 below. *Khalil*, ¶¶49, 55, 59.

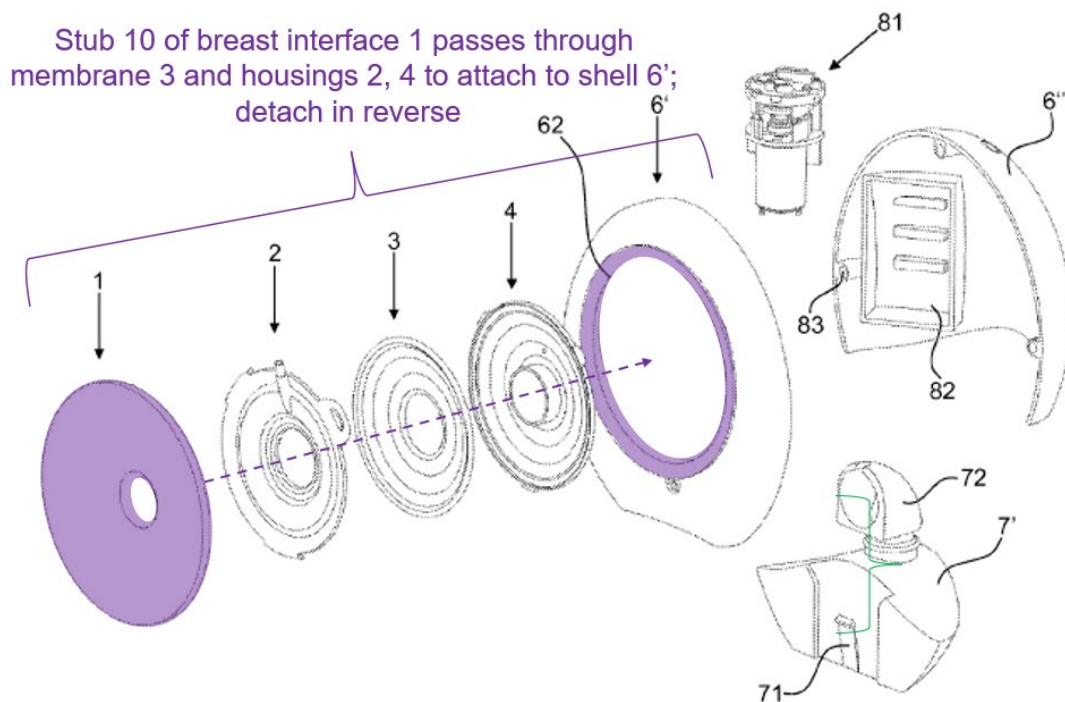


FIG. 11

The receiving stub 44 of membrane housing 4 is pushed over stub 10 as shown in annotated Figure 5 below. *Id.*, ¶¶29, 55, 59.

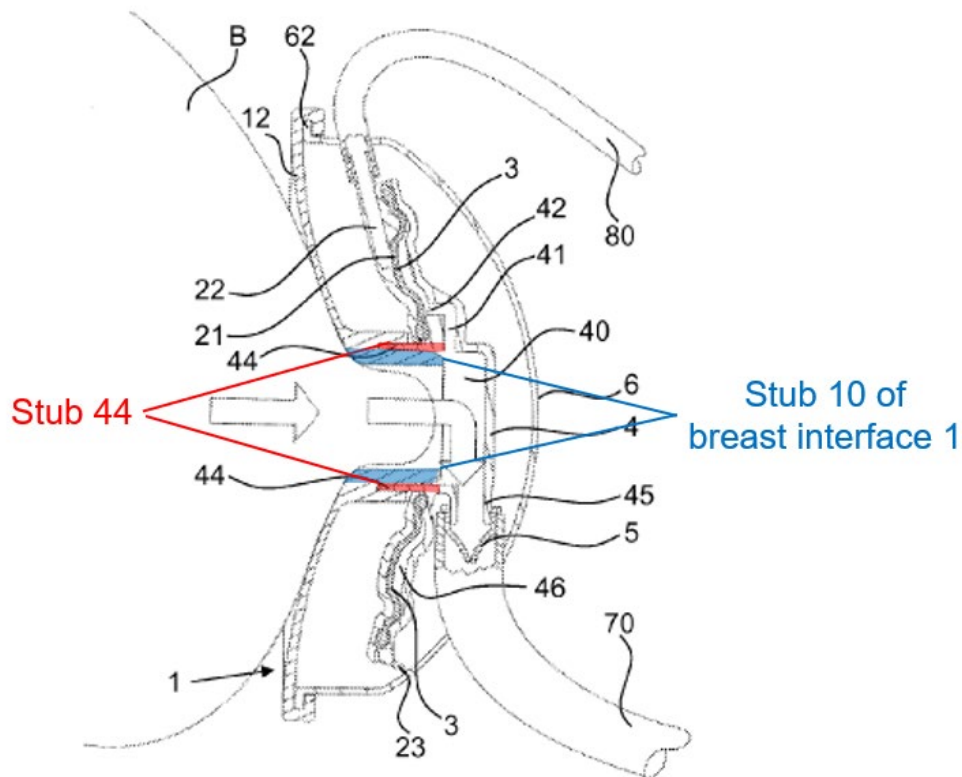


FIG. 5

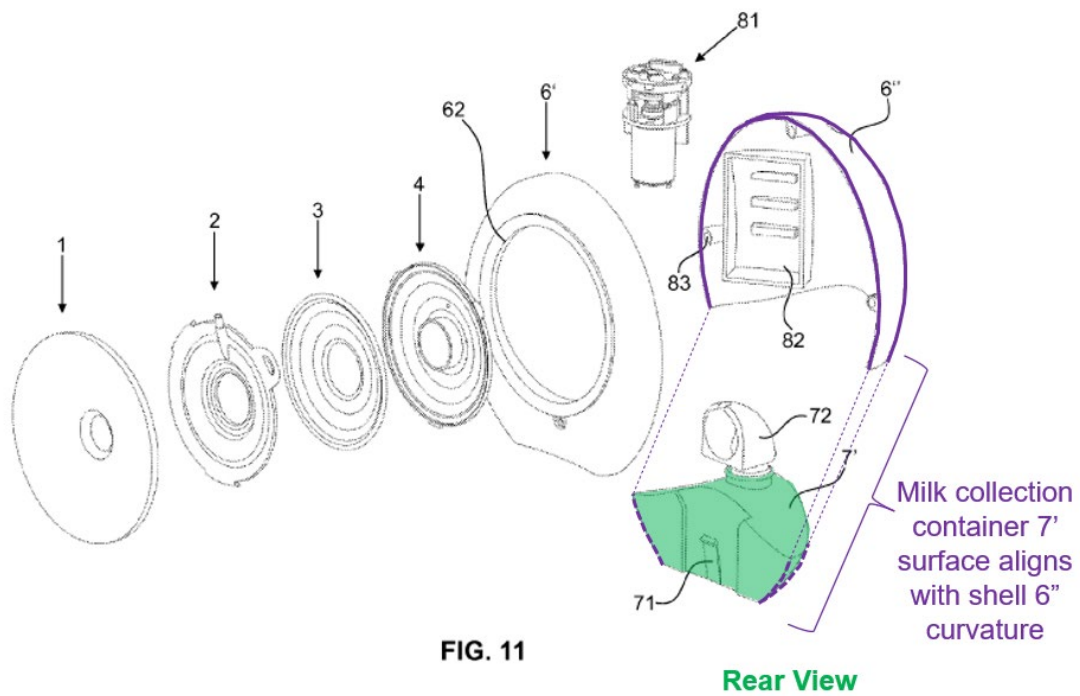
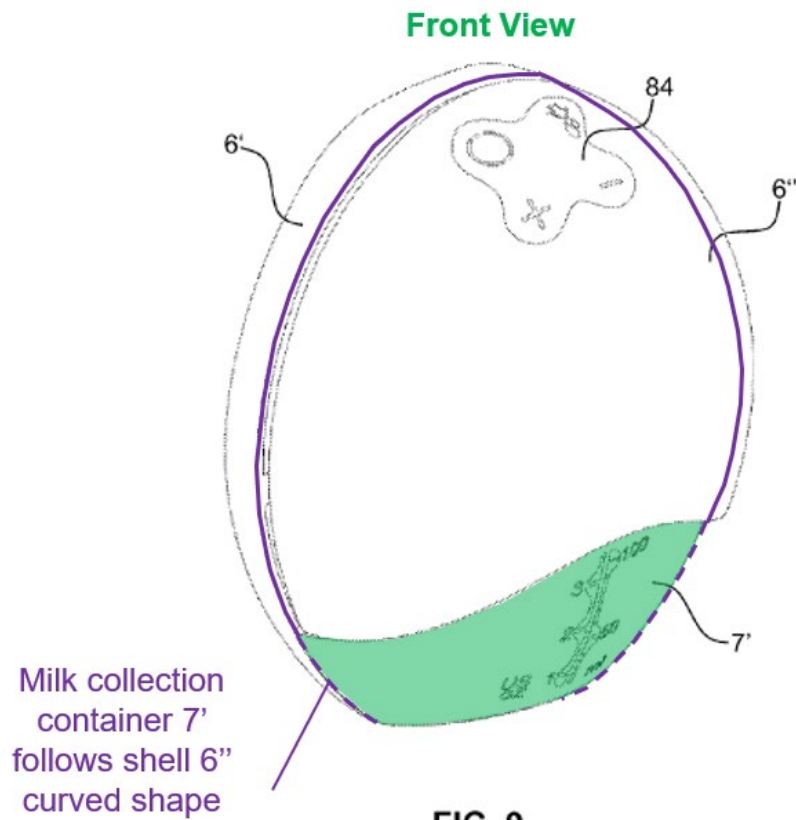
A POSITA would have understood that Khalil’s two circular, connected stubs 10 (of breast interface 1) and 44 push together to hold the 3-piece membrane component together and seal for proper pressure and vacuum operation, but may be pulled apart for cleaning so that breast interface 1 (“breast shield”)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

As discussed above at pages 72-74, a POSITA would have been motivated to use aspects of the diaphragm pump of Khalil in the breast pump of Chang. In such a combination, as described above, 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. *See Bauer*, ¶206-208.

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.

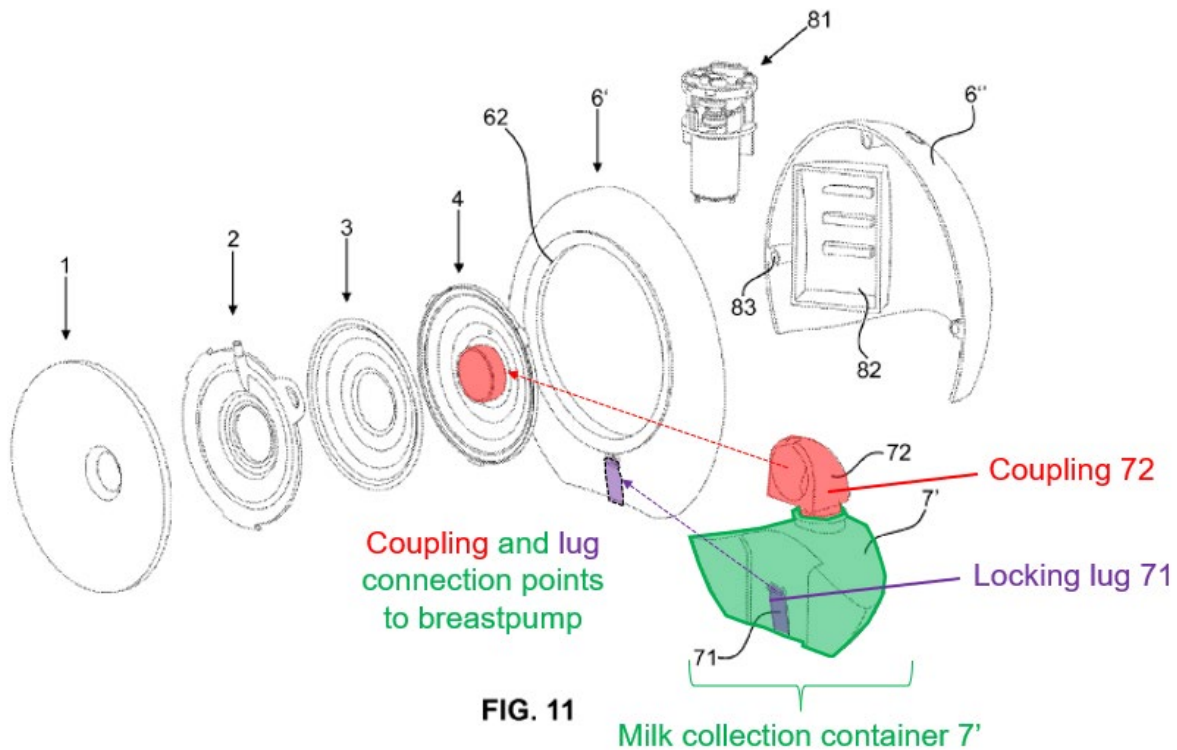
Khalil discloses these limitations. *See Bauer*, ¶209-210. Khalil discloses a breast shield unit (or breast pump) “designed as a *hands-free unit and worn under a bra*” and including a “milk collection container...*integrated in the housing of the unit* or...coupled directly thereto.” *Khalil*, ¶32, 70. To achieve such design goal, the milk container (green) is in a curved shape that continues the curved shape of the pump housing, as shown in annotated Figures 9 and 11 below.



As discussed above at pages 72-74, a POSITA would have been motivated to combine Chang and Khalil to use a rigid milk container that, when connected to the pump housing, has a shape that fits in a bra. *See Bauer*, ¶¶209-210.

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.**

Khalil discloses these limitations. *See Bauer*, ¶¶211-212. Annotated Figure 11 below shows that the milk container releasably attaches to the housing (6' and 6'') by a locking lug (71):



Khalil states:

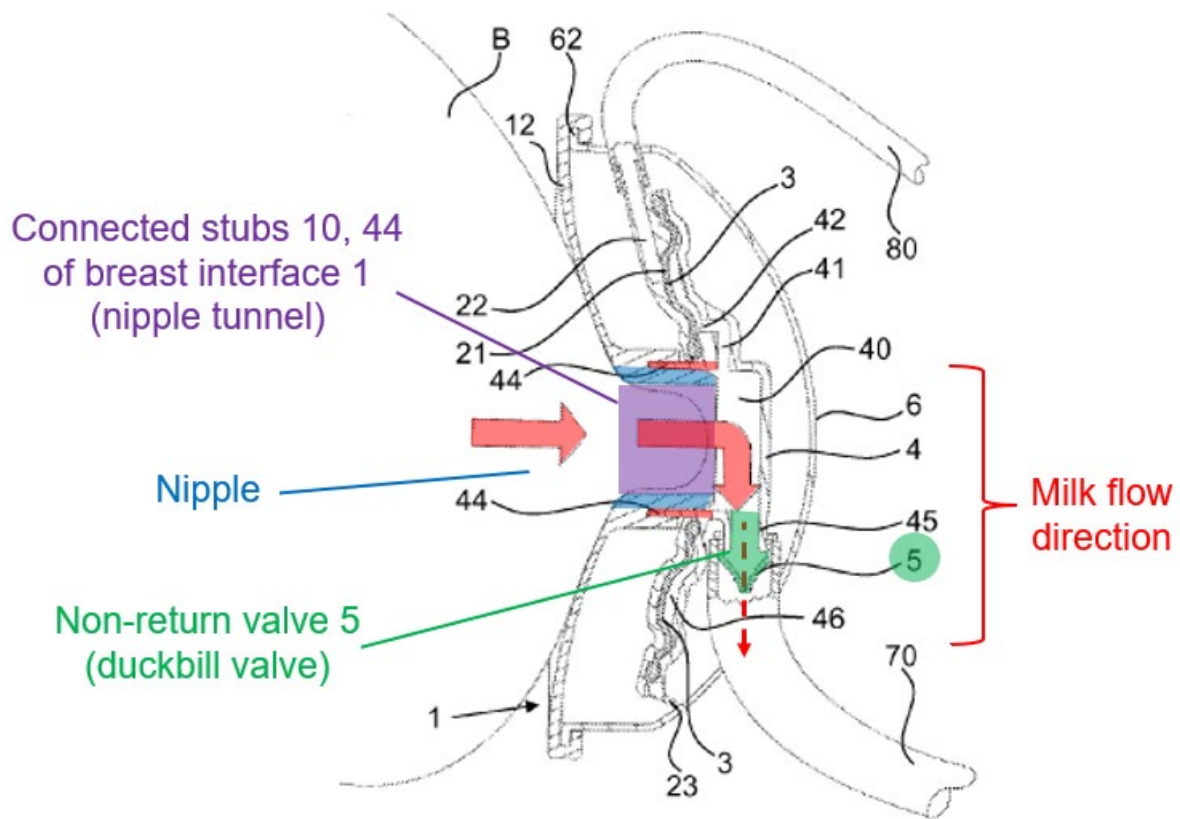
A milk collection container 7' is arranged in the lower area adjoining the cover 6". It is preferably made of plastic like the cover 6". A locking lug 71 is integrally formed on this milk collection container 7' and can engage in a corresponding recess (not shown in the Figures) of the shell ring 6'.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

Khalil, ¶69. Accordingly, 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. *Bauer*, ¶211.

As discussed above at pages 72-74, a POSITA would have been motivated to combine Chang and Khalil to have a breast pump with a rigid milk container located below the pump housing. *See Bauer*, ¶¶211-212.

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.

Khalil discloses these limitations. *See Bauer*, ¶¶213-216. 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 annotated Figure 5 below. *Khalil*, ¶¶61-62.



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 below. *Id.*, ¶¶66, 69.

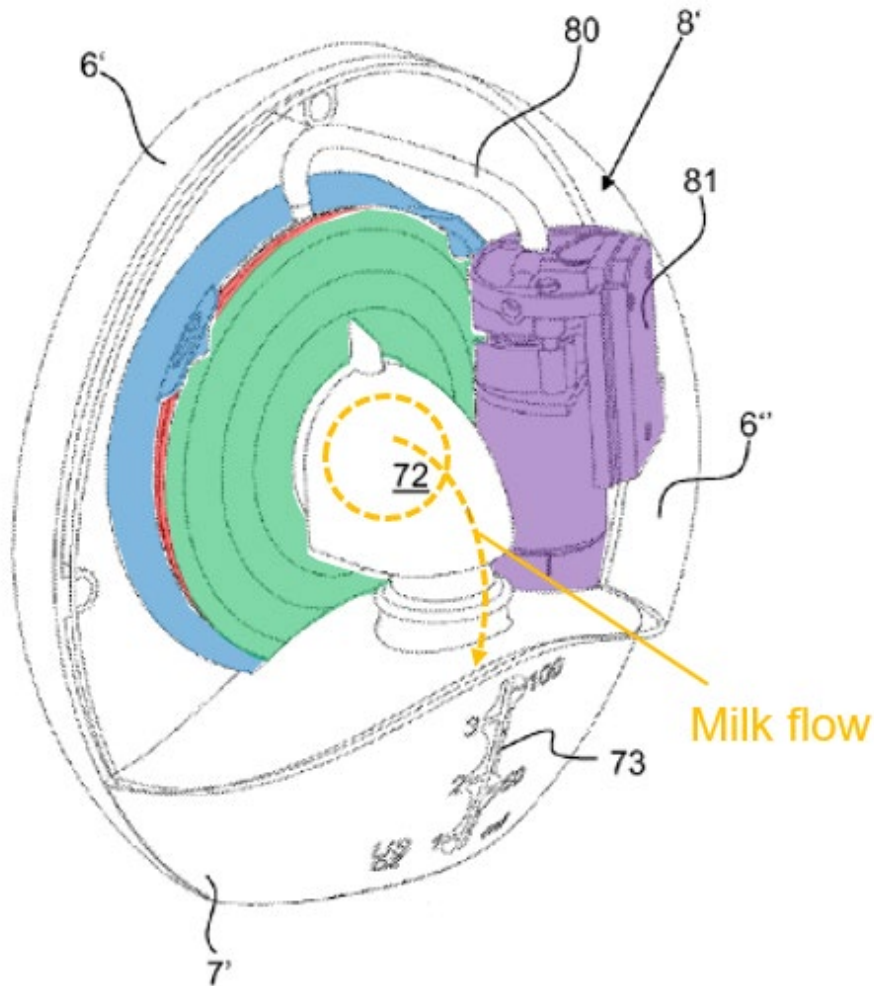


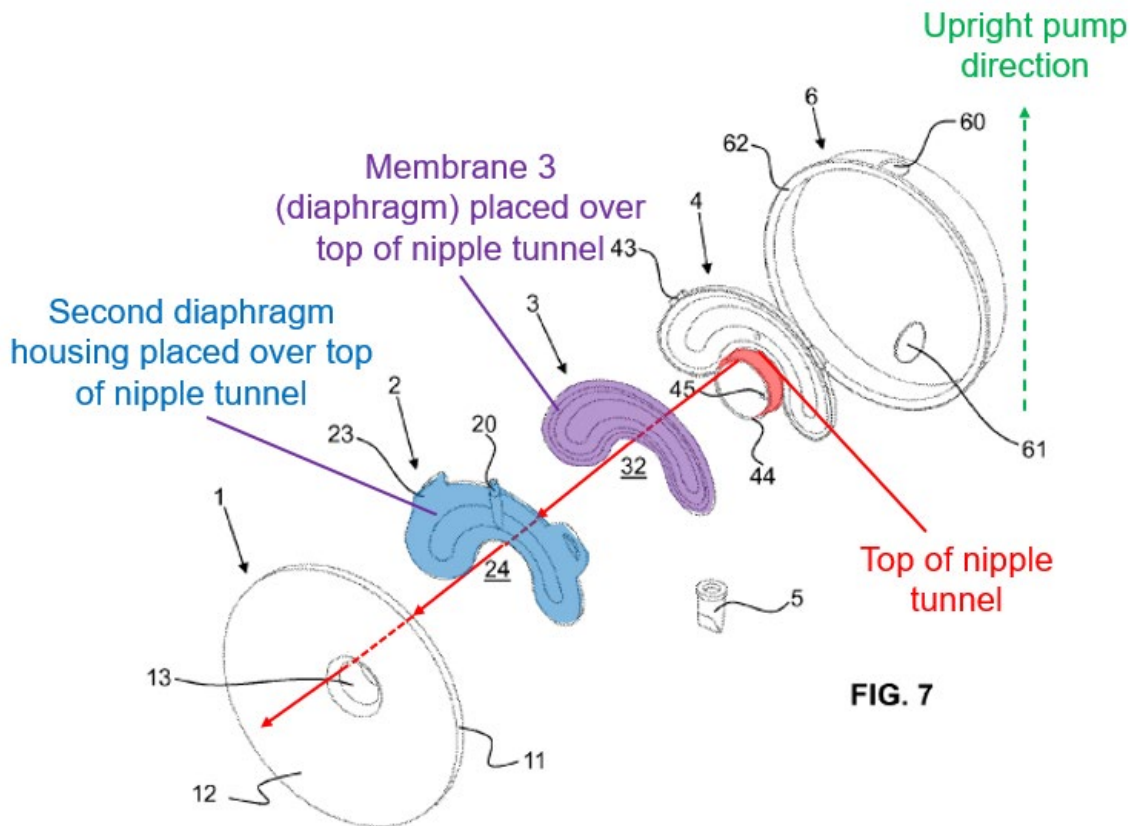
FIG. 10

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. *Bauer*, ¶215.

As discussed above at pages 72-74, a POSITA would have been motivated to combine Chang and Khalil to have a breast pump with a rigid milk container located below the pump housing. *See Bauer*, ¶213-216.

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.

Khalil discloses this limitation. *See Bauer*, ¶217-219. 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 annotated Figure 7 below. *Khalil*, ¶65.



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. *Khalil*, ¶52-55. *Bauer*, ¶217-218.

As discussed above at pages 72-74, a POSITA would have been motivated to combine Chang's breast pump with aspects of Khalil's diaphragm pump, an embodiment of which has the second diaphragm housing positioned over a top surface of the nipple tunnel. *See Bauer*, ¶217-219.

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].**

See discussion of claims 11 and 37 above. *See Bauer*, ¶220.

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.**

Khalil discloses these limitations. *See Bauer*, ¶221-223. As discussed above for claims 12 and 38, the Chang-Khalil combination teaches that expressed milk flows under gravity through an opening in the nipple tunnel into the milk container. Furthermore, Chang itself discloses that “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” (i.e., back to the pump), and the valve can be “a duckbill valve.” *Chang*, ¶21. Khalil similarly 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 below in annotated Figure 3. *Khalil*, ¶53.

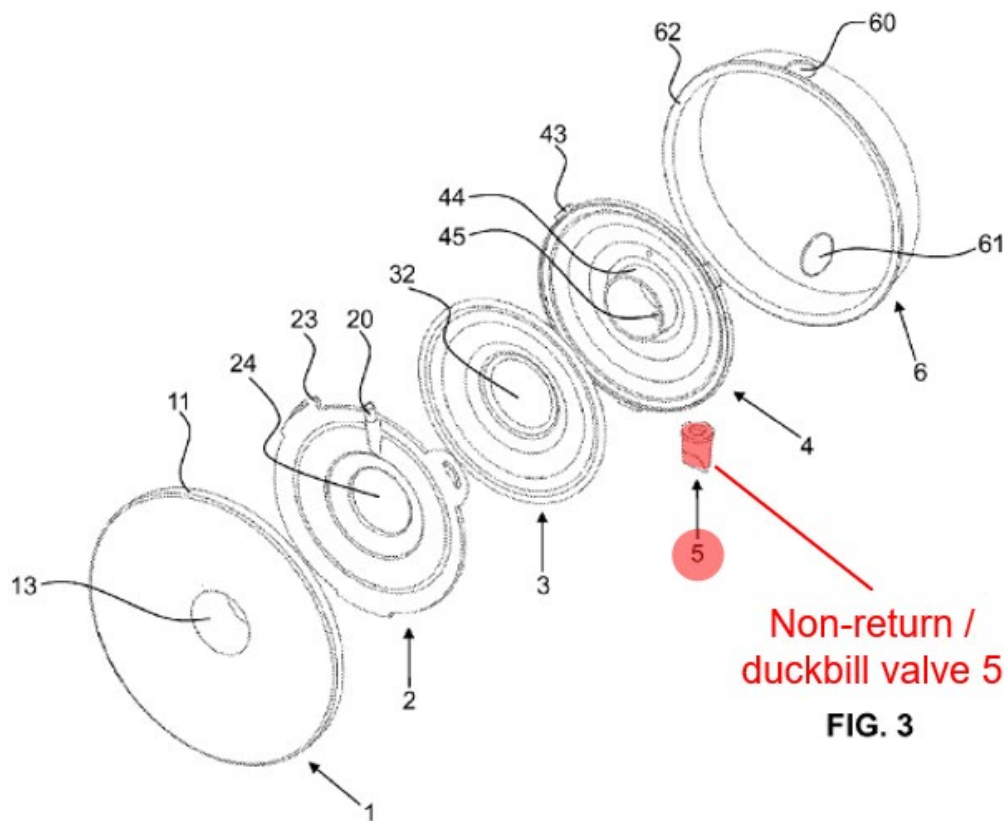


FIG. 3

Duckbill valve 5 is used in Khalil's in-bra embodiment to directly flow 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. *Bauer*, ¶221.

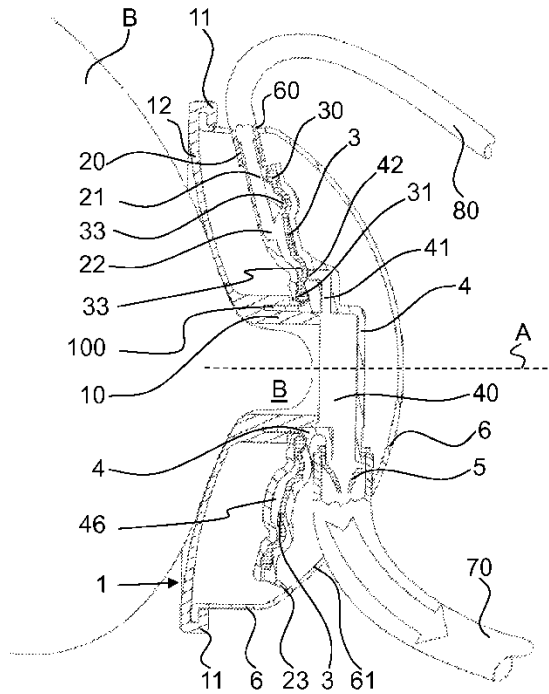


FIG. 4

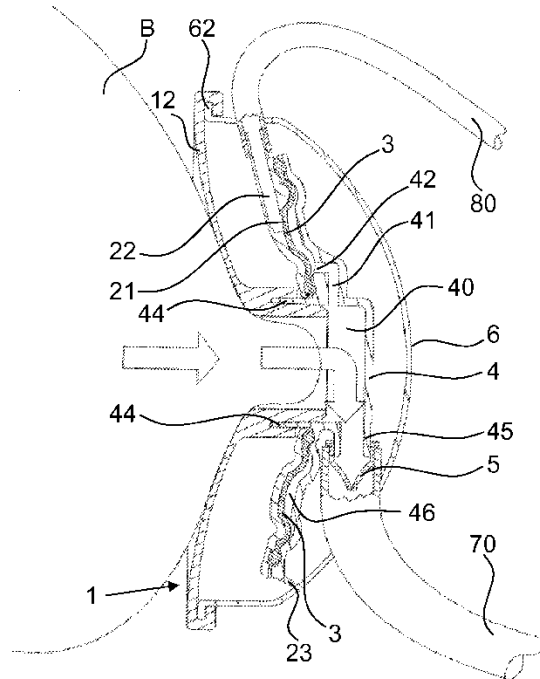


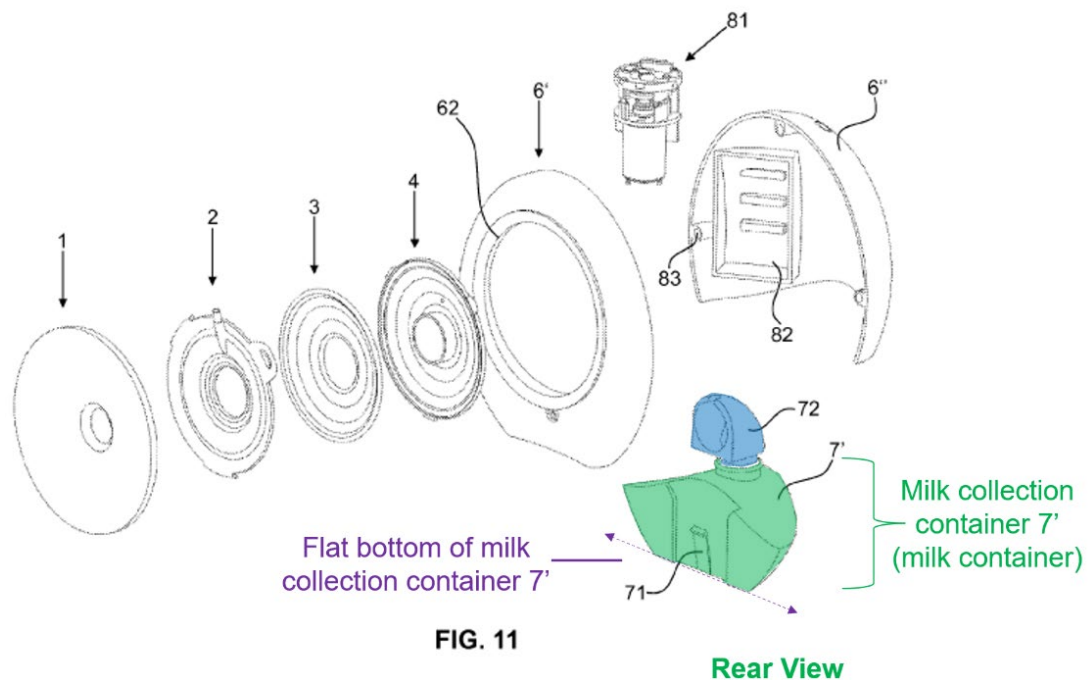
FIG. 5

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

As discussed above at pages 72-74, a POSITA would have been motivated to combine Chang and Khalil to have a breast pump with a rigid milk container located below the pump housing. *See Bauer*, ¶221-223.

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.**

Khalil discloses these limitations. *See Bauer*, ¶224-225. As described for claims 10 and 36, Khalil's milk container has a curved surface. In addition, as shown in annotated Figure 11 below, Khalil's milk container has a flat base.



As discussed above at pages 72-74, a POSITA would have been motivated to combine Chang and Khalil to have a breast pump with a rigid milk container located below the pump housing. *See Bauer*, ¶224-225.

- 10. Claims 28 And 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.**

See discussion of claims 10 and 36 above. *See Bauer*, ¶226.

X. CONCLUSION

Inter Partes Review of the challenged claims is respectfully requested.

XI. DISCRETIONARY FACTORS FAVOR INSTITUTION

A. Section 314(a)

The '380 patent is involved in a lawsuit, *Shenzhen Root Technology Co., Ltd. v. Chiaro Technology, Ltd.*, Case No. 2:23-cv-00631 (W.D. Wash.) (“Lawsuit”). Petitioner filed the complaint in the Lawsuit on April 28, 2023, seeking declaratory judgment of noninfringement and invalidity of one of PO’s patents. EX-1016, Dkt.1. Early in the Lawsuit, on July 5, 2023, the court set the trial date for September 2, 2025. *Id.*, Dkt.62. PO subsequently counterclaimed to allege infringement of two patents—the initial patent and the '380 patent challenged here. *Id.*, Dkt.69. Recently, on May 1, 2024, PO amended its complaint to assert two more patents, one of which is not in the same patent family as the previously asserted patents. *Id.*, Dkt.114. In view of PO’s significant expansion of the scope of the Lawsuit, Petitioner plans to file a motion to amend the schedule, with a proposed trial date in the first half of 2026. Petitioner will advise the Board of any changes to the trial date. Because of these facts, Petitioner expects that *Fintiv* will not apply here.

B. Section 325(d)

The Board should not exercise its discretion under §325(d) to deny institution. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17-18 (Dec. 15, 2017) (precedential); *Advanced Bionics, LLC v. MED-EL Elektro-medizinische Geräte GmbH*, IPR2019-01469, Paper 6, 9-11 (Feb. 13, 2020) (precedential). This Petition's grounds rely on four prior art references. Prosecution of parent '057 application is pending; to date, the Examiner has applied Khalil and Chang in rejections, but PO has attempted to distinguish those references for reasons different from how those references are cited and applied herein to any claim limitations of the '380 patent. EX-1003, 2427-33, 2164-2219, 2094-2106, 1823-66, 1808-19, 1028-68, 959-70, 898-937, 871-82. During prosecution of the grandparent '547 application, the Examiner cited Khalil in rejections, but PO distinguished Khalil for reasons different from how those references are cited and applied herein to any claim limitations of in the '380 patent. EX-1004, 383-410, 362-81, 289-314, 269-85, 219-43, 197-213, 152-59, 128-45, 62-68, 16-20.

XII. MANDATORY NOTICES

A. Real Party in Interest

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

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

Hong Kong Lute Technology Co., Ltd.

Shenzhen Conglin E-Commerce Co., Ltd.

Shenzhen Jinruihang Technology Co, Ltd.

Shenzhen Xitao Network Technology Co., Ltd.

ROOT Technology Ltd.

B. Related Matters

The '380 patent is involved in the Lawsuit identified above.

C. Notice of Counsel and Service Information

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Respectfully submitted,

/ Gene Lee /

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CERTIFICATE OF WORD COUNT UNDER 37 CFR § 42.24(d)

Pursuant to 37 C.F.R. §42.24(a), Petitioners hereby certify that portions of the above-captioned Petition for *Inter Partes* Review of U.S. Patent 11,413,380, in accordance with and reliance on the word count provided by the word-processing system used to prepare this Petition, that the number of words in this paper is 13,594. Pursuant to 37 C.F.R. §42.24(a), this word count is in compliance and excludes the table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, appendix of exhibits, and any claim listing. This word count was prepared using Microsoft Word.

Respectfully submitted,

/ Gene Lee /

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the Petition for *Inter Partes* Review of U.S. Patent No. 11,413,380 and supporting materials (Exhibits and Power of Attorney) were served via overnight delivery on the Patent Owner at the correspondence address of record as listed on PAIR:

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A courtesy copy was also sent via electronic mail to Patent Owner's litigation counsel listed below:

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