

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Jonathan O'Toole et al.
U.S. Patent No.: 11,413,380 Attorney Docket No.: 58498-0003IP2
Issue Date: August 16, 2022
Appl. Serial No.: 17/203,327
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Title: BREAST PUMP SYSTEM

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Central Reexamination Unit
Commissioner for Patents
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DECLARATION OF RYAN BAUER

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

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

Date: August 14, 2024

By: /Ryan Bauer/
Ryan Bauer

TABLE OF CONTENTS

I.	BACKGROUND AND QUALIFICATIONS	1
A.	Educational Background	1
B.	Professional Experience	1
II.	MATERIALS CONSIDERED	2
III.	LEVEL OF ORDINARY SKILL IN THE ART	4
IV.	TECHNOLOGY BACKGROUND.....	5
V.	THE '380 PATENT	17
A.	Specification.....	17
B.	Claims	22
C.	Prosecution History	30
VI.	RELEVANT LEGAL STANDARDS	33
VII.	CLAIM INTERPRETATION	37
VIII.	PRIOR ART.....	37
A.	Chang (EX1007)	37
B.	Fang (EX1009).....	41
C.	Yuen (EX1011).....	43
D.	Khalil (EX1010).....	44
E.	Park (EX1014)	47
F.	Chen (EX1015)	48
IX.	THE CLAIMS OF THE '380 PATENT ARE OBVIOUS.....	50
A.	Ground 1A: Obviousness of Claims 1-8, 11, 13-23, 25, 29-35, 37, 39-41, and 43 Based on Chang, Fang, and Yuen.....	51
1.	Combination of Chang, Fang, and Yuen	51
b.	Motivation to Combine Chang, Fang, and Yuen.....	58
2.	Claim Analysis.....	62
a.	Claim.....	62

TABLE OF CONTENTS
(continued)

	Page
B. Ground 1B: Obviousness of Claims 1-11, 13-23, 25-37, 39-41, and 43-46 Based On The Combination of Chang, Fang, Yuen, and Khalil	106
1. The Combination of Chang, Fang, Yuen, and Khalil	106
2. Claim Analysis	110
C. Ground 1C: Obviousness of Claims 12, 24, 38, and 42 Based On The Combination of Chang, Fang, Yuen, Khalil, and Park	130
1. Combination of Chang, Fang, Yuen, Khalil, and Park	130
2. Claim Analysis	133
D. Ground 1D: Obviousness of Claim 20 Based On The Combination of Chang, Fang, Yuen, Khalil, and Chen	135
1. Combination of Chang, Fang, Yuen, Khalil, and Chen	135
2. Claim Analysis	137

TABLE OF CONTENTS
(continued)

Page

EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent 11,413,380
1002	File History of Application 17/203,327
1004	File History of Application 16/009,547
1005	File History of Application 17/181,057 as of May 29, 2024
1007	U.S. Patent Application Publication 2018/0333523 (“Chang”)
1008	CN Utility Model CN205913571U (“Fang CN”)
1009	Certified English Translation of CN Utility Model CN205913571U (“Fang”)
1010	U.S. Patent Application Publication 2013/0023821 (“Khalil”)
1011	PCT Patent Publication No. WO 2017/190678 (“Yuen”)
1012	AU Patent Application Publication No. 2010300058 (“Weber”)
1013	PCT Publication No. WO 2016/186452 (“Park KR”)
1014	Certified English Translation of PCT Publication No. WO 2016/186452 (“Park”)
1015	U.S. Patent Application Publication US2017/0080135 (“Chen”)
1017	U.S. Application Publication 2015/0217033 (“Pollen”)
1018	U.S. Application Publication 2012/0116299 (“Tack”)
1019	U.S. Patent Application Publication 2016/0082166 (“Guthrie”)
1020	U.S. Application Publication 2015/0157775 (“Hu”)

TABLE OF CONTENTS
(continued)

Page

Exhibit	Reference
1024	PCT Publication WO 2002/102437 (“Myers ’437”)
1025	PCT Publication WO 2008/137678 (“Myers ’678”)

I, Ryan Bauer, hereby declare:

I. BACKGROUND AND QUALIFICATIONS

1. I have been retained by Petitioner Shenzhen Root Technology Co., Ltd. (“Shenzhen” or “Petitioner”) to provide my opinions regarding claims 1-46 of U.S. Patent 11,413,380 (“the ’380 Patent,” EX1001).

2. A copy of my current curriculum vitae is submitted herewith as EX1006, which provides details about my academic and professional background and qualifications.

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

A. Educational Background

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

B. Professional Experience

5. I have extensive experience and training in the specific technical field of the ’380 patent. Based on my education and experience, I was at the time the

earliest priority application leading to the '380 patent was filed, and continue to be, a person of ordinary skill in the relevant art.

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

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

II. MATERIALS CONSIDERED

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

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

10. All of the opinions contained in this declaration are based on the documents I reviewed and my knowledge and professional judgment. My opinions have also been guided by my appreciation of how a person of ordinary skill in the art would have understood the claims and the specification of the '380 patent at the time of the alleged invention, which I have been asked to initially assume is June 15, 2017.

11. Based on my experience and expertise, it is my opinion that certain references disclose and/or suggest, alone or in combination, all the features recited in claims 1-46 ("Challenged Claims") of the '380 patent, as I explain in detail below.

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

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

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

III. LEVEL OF ORDINARY SKILL IN THE ART

15. I understand that patents and prior art references are analyzed from the point of view of a person of ordinary skill in the art (“POSITA”) at the time of the invention of, in this case, the ’380 Patent. I understand that “the time the claimed invention was made” is often referred to as the priority or critical date.

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

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

18. Based on my background and experience, a POSITA as of June 15, 2017, would have at least a bachelor’s degree in mechanical engineering or a similar field and at least two years’ experience designing human breast pump equipment. A

POSITA could potentially have higher extent of education and a lower level of work experience or vice versa.

IV. TECHNOLOGY BACKGROUND

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

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

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

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

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

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

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

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

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

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

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

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

28. As discussed earlier, breast pumps must act upon a localized volume that includes the nipple of a lactating woman. Major components of the pump include the breast shield (often called a funnel) engaging the breast tissue, a pump or actuator to generate negative pressure (i.e., vacuum or suction), and a collection container. Often a one-way valve is used to minimize the size of the localized volume allowing extracted milk to escape between vacuum cycles. Another typical embodiment includes a membrane or diaphragm defining one boundary of the localized volume on one side and is in fluid or mechanical communication with the pump on the other. Such a diaphragm is commonly referred to as a media separation since it keeps milk away from the pump mechanism for cleaning and sanitary purposes.

29. Many diverse types of pumps have been used to generate the negative pressure in breast pumps, such as bellows, diaphragms, piston-cylinder, peristaltic motion, or any kind of mechanical deformation or air removal of the target volume. *See, e.g.*, Pollen (EX1017) [0045] (“The term, “vacuum pump,” refers to any device that provides subatmospheric pressure continuously, cyclically, or at least momentarily. Vacuum pump 16 is schematically illustrated to represent all types of vacuum pumps, examples of which include, but are not limited to, a diaphragm pump, a bellows pump, a piston pump, a reciprocating pump, a peristaltic pump, a positive displacement pump, a gear pump, a lobed rotor pump, a screw compressor, a scroll compressor, and a rotary vane pump.”). Similarly, these technologies or others can be deployed in a multi-cycle (high frequency) capacity during each breast pump cycle such as multi-stroke pistons, diaphragms, and piezo actuators. This is a common approach to miniaturize the pumping mechanism and remove air or liquid directly from the target volume to generate negative pressure.

30. A diaphragm pump was a well-known type of pump used in breast pumps by the Critical Date. *See, e.g.*, Weber (EX1012), 7:24-26 (“The vacuum pump may be a diaphragm pump, wherein the chamber is the vacuum generating pump chamber of the vacuum pump, and the diaphragm is the diaphragm of the pump chamber used for generating the vacuum.”); Khalil (EX-1010) [0067] (“The vacuum pump 81 is preferably a diaphragm vacuum pump of a known type, which is

operated by means of an electric motor.”); Tack (EX1018) [0006] (“To address this concern, in a first aspect of the present invention, a drive mechanism for a breast pump is provided comprising a housing, a motor coupled to a rotatable drive element within the housing, a resilient membrane coupled to the housing, and a flexible strap coupled between the drive element and the membrane, wherein rotation of the drive element causes the flexible strap to pull and resiliently deform the resilient membrane to create the negative pressure in a vacuum chamber of a breast pump.”) and Hu (EX1020) [0009] (“[T]he host unit comprises a miniature diaphragm vacuum pump, a miniature magnetic valve, and an air loop comprising an air inlet and an air outlet; an air inlet of the miniature diaphragm vacuum pump and an air outlet of the miniature magnetic valve communicate with each other and both are connected to the air inlet of the air loop; an air inlet of the magnetic valve and an air outlet of the miniature diaphragm vacuum pump are both connected to the air outlet of the air loop.”).

31. By the time of the '380 patent, it was well-known that breast pumps may be configured in a variety of ways. Of the main components of the pump (pump/actuator, breast shield, and collection container), only the breast shield is required to be at the breast since it forms part of the localized volume for milk extraction. Different pump configurations have combined these components or connected them in various ways, such as through tubing or fittings at various

locations on or off the body. Some common configurations that were known to a POSITA include:

- Separate breast cups, pump, milk container. *See, e.g.*, EX1012, Fig. 1, 14:15-27; U.S. Patent No. 6,379,327 (“Lundy”), Figs. 1, 3, 3:42-46.
- Handheld breast pumps. *See, e.g.*, Tack (EX1018) at Fig. 1, [0024].
- Wearable integrated breast pumps that fit entirely in a bra. *See, e.g.*, EX1007, Fig. 1, [0019] (“[T]he flange or skin contact member, the conduit, the driving mechanism, the external shell and the milk collection container are all contained within a cup of a brassiere.”); EX1010, [0032] (“The breastshield unit according to the invention can be designed as a hands-free unit and worn under a bra. In a preferred embodiment, a milk collection container is integrated in the housing of the unit or can be coupled directly thereto.”).

32. Many other variations also existed at the time, and would have been known to a POSITA, including hands-free breast pumps with breast shields and collection containers connected to or supported by a nursing bra, wearable breast pumps with in-bra breast cups and milk container and separate pump, wearable breast pumps with in-bra breast cups and pump but milk container outside bra, and wearable integrated breast pumps with in-bra breast cups and milk container but pump protruded outside bra, among others. *See, e.g.*, WO 2002/102437 (EX1024)

at Figs. 20A and 20B, [0044]; WO 2008/137678 (EX1025) at Fig. 1, pp. 12-13; and Guthrie (EX1019) at Fig. 1, [0026].

33. As can be seen from the above, POSITAs recognized that components of breast pumps were freely combined or separated in many different configurations depending on the goals of the designers and/or various commercial considerations. A POSITA would have known how to combine or separate components according to these goals. The selected pump technology and configurations is a matter of design choice to meet commercial and clinical requirements. In particular, breast pump technology at the time of the '380 patent involved relatively simple electromechanical technology that was well understood to a POSITA, and a POSITA would have recognized the various tradeoffs for a particular design, such as cleanability, power consumption, compensation for anatomical variation, lifestyle and expense.

34. For this reason, there were (and are) a large variety of breast pump designs on the market and in the prior art. There was (and is) no single design or configuration that is ideal for all purposes and consumers. Take for example tradeoffs in a wearable pump design – which can take many forms. One example shown by Chang is a breast pump that is fully supported by the bra at the breast:

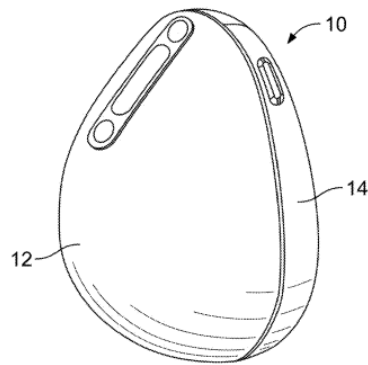


FIG. 1A

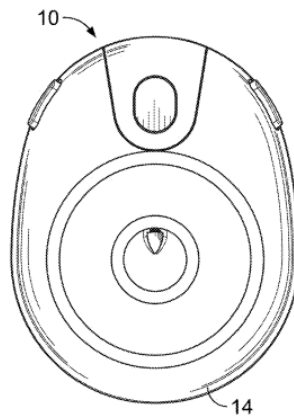


FIG. 1B

EX1007, Figs. 1A, 1B

35. A tradeoff with this configuration is that the full pump weight with electronics, housings, controls, milk container (plus extracted milk), etc. would hang from the front of the user's chest. This may not be comfortable for some women. Also, the bulk of the pump system would protrude even further in the bra, which some women would object to because it alters their appearance and/or is not discrete.

36. Chang clearly recognized the interchangeability of arranging breast pump components into different configurations:

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

EX1007, [0019]. These alternate embodiments are prevalent in the prior art. As one example, a design for a wearable pump is shown in Lundy (U.S. Patent No. 6,379,327), which separated the components of the pump so they could be supported by different parts of the body:

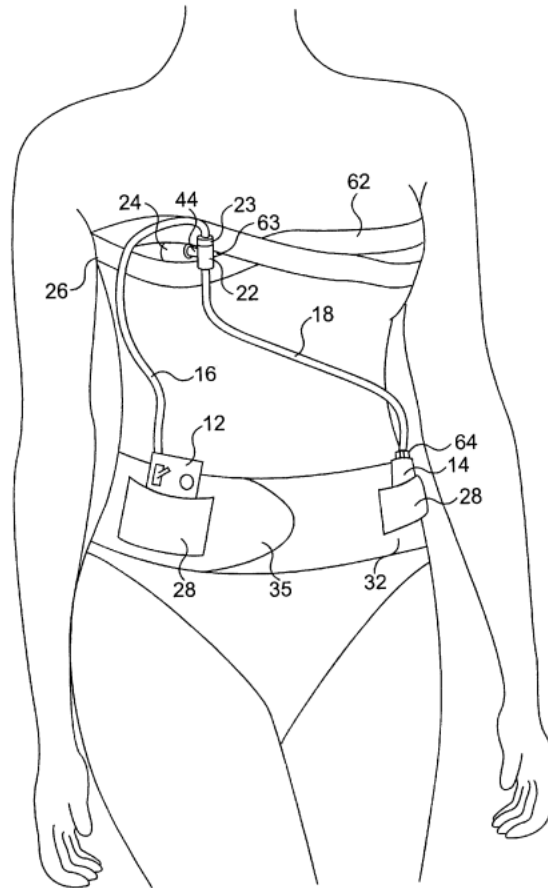


FIG. 3

Fig. 3, 3:42-46.

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

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

V. THE ’380 PATENT

A. Specification

38. The ’380 patent is entitled “Breast Pump System.” It generally discloses a breast pump that is wearable inside a bra. EX1001, 3:57-62. The specification of the ’380 patent begins by acknowledging that fully integrated in-bra breast pumps existed in the prior art, including as disclosed by U.S. Application Publication 2016/0206794 (“Makower”):

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

Id., 2:5-15.

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

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

40. The ’380 patent claims are generally directed to “a self-contained, in-bra wearable” breast pump device with a pump housing, a pump powered by a rechargeable battery, a breast shield, a milk container, and a diaphragm (or membrane) that defines a pumping chamber with a diaphragm housing/external surface of the pump housing and deforms in response to changes in air pressure caused by the pump. EX1001, claims 1 (“a self-contained, in-bra wearable device comprising:”), 29 (same).

41. The ’380 patent specification describes that the breast shield engages with the user’s breast. EX1001, 5:40-47. The shield is also connected to the milk container for collecting milk expressed by the user. *Id.* The housing includes one or more pumps, control electronics, and a rechargeable battery. *Id.*, 5:47-49, 5:58-59. The breast shield and milk container are “directly removable or attachable from the housing.” *E.g., id.*, 5:58-6:3.

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

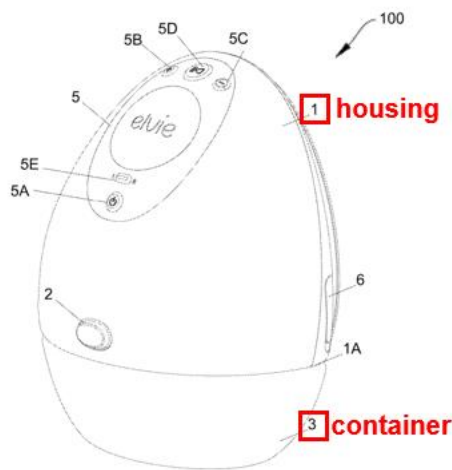


FIGURE 1

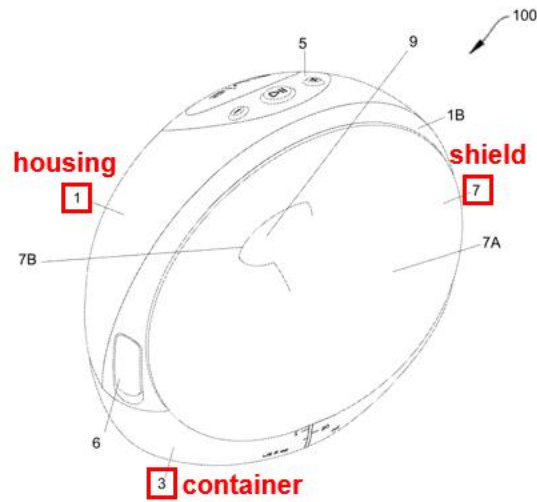


FIGURE 2

EX1001, Figs. 1 2 (annotated), 5:56-6:3, 6:14-21

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

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

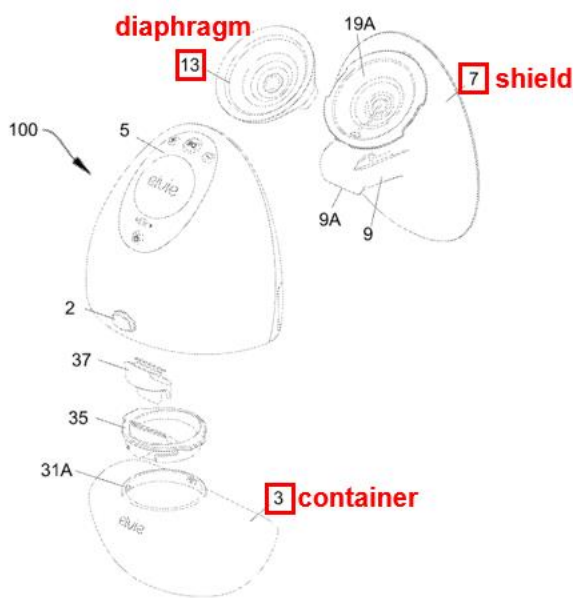


FIGURE 5

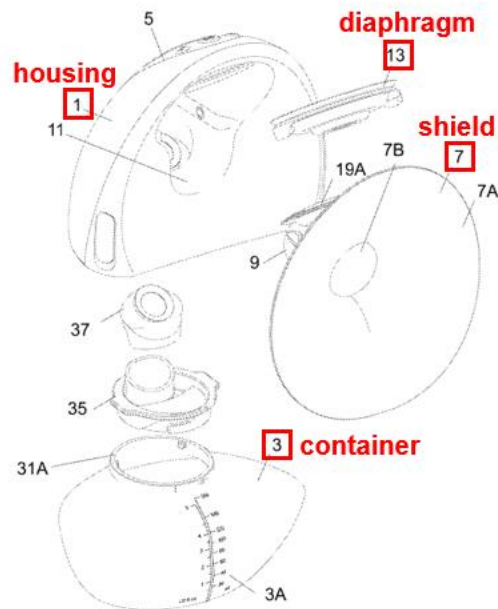


FIGURE 6

EX1001, Figs. 5, 6 (annotated)

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

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

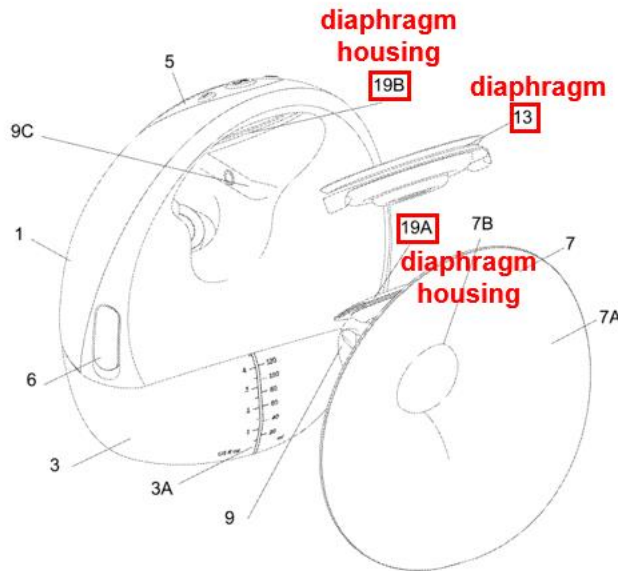


FIGURE 4

EX1001, Fig. 4 (annotated), 11:23-27

46. As set forth in more detail in my analysis herein, wearable breast pumps that utilize a diaphragm pump and that include each feature recited by the claims of the '380 patent were not new. Instead, prior art references such as Chang, Fang, Yuen, Khalil, Park, and Chen demonstrate that the recited breast pump was known. Fang, for example, confirms that use of a diaphragm seated against a diaphragm housing that is fixed to a recessed surface of the pump housing, or that defines a pumping chamber at least in part with an external surface of the housing, were known options for implementing a diaphragm in a breast pump.

B. Claims

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

Element	Claim Limitations
Claim 1	
1[pre]	A breast pump device comprising:
1[a]	a self-contained, in-bra wearable device comprising:
1[b]	a pump housing that includes:
1[b][i]	a rechargeable battery,
1[b][ii]	a power charging circuit for controlling charging of the rechargeable battery,
1[b][iii]	control electronics powered by the rechargeable battery,
1[b][iv]	a pump powered by the rechargeable battery and configured to generate negative air pressure,
1[b][v]	a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery, and
1[b][vi]	a recess or cavity that defines a pumping chamber;
1[c]	a breast shield made up of a breast flange and a nipple tunnel;
1[d]	a milk container that is configured to be attached to and removed from the pump housing; and
1[e]	a diaphragm that is configured to prevent milk from reaching the pump, the diaphragm being seated against a diaphragm housing that is fixed to a recessed surface of the pump housing, and the diaphragm being a membrane that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

Claim 2	
2	The breast pump device of claim 1, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.
Claim 3	
3	The breast pump device of claim 1, wherein the breast shield is a one piece item that in use presents a single continuous surface to a nipple and a breast.
Claim 4	
4	The breast pump device of claim 1, 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.
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	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.
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	The breast pump device of claim 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.
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.

C. Prosecution History

48. The '380 patent issued from Application 17/203,327 ("327 application"; EX1002) filed on March 16, 2021, which is a continuation of Application 17/181,057 ("057 application"; EX1005), which is a continuation of Application 16/009,547 ("547 application"; EX1004).

49. The '380 patent has two similar independent claims, claims 1 and 29. These claims were allowed after amendment to add structural features specifying

how the diaphragm of the pump is held in the device. Independent claim 1 was allowed based on the diaphragm housing being fixed to a recessed surface of the pump housing, and independent 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.

50. The examiner rejected originally-filed independent claim 1 as obvious over Khalil combined with other references. EX1002, 550-552. The Patent Owner 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.*, 520. The Patent Owner also added new independent claim 47, which 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.”

51. During an interview, after an initial round of amendments, the examiner indicated claim 1 would be allowable if amended to “indicat[e] that the diaphragm housing is fixed to a surface of the pump housing.” *Id.*, 499. The Examiner indicated that “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 Patent Owner amended it to “clarify that the surface [of the housing] is an exterior surface of the housing.” *Id.*

52. After subsequent amendments, the Examiner allowed claim 1, stating “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.” EX1002, 24, 304. The Examiner cited to Khalil’s “membrane” (citing Khalil’s Fig. 11, element 3) in support of the reasons for allowance.

53. Based on my review of the prosecution history, the examiner ignored the actual state of the art reflected by the references discussed herein. For example, Fang provides an example of the claimed diaphragm arrangement that the examiner seemed to indicate was absent from the prior art. None of Chang, Park, Fang, or Yuen were applied in any claim rejection in any office action during prosecution of the ’380 patent. Chang was listed among the dozens of references on the face of the ’380 patent, and applied in a rejection against a dependent claim in a parent application of the ’380 patent, subsequent to allowance of the ’380 patent.

VI. RELEVANT LEGAL STANDARDS

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

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

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

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

58. I understand, however, that the words of a claim may be given a meaning other than their plain and ordinary meaning if: (1) a patentee expressly and unambiguously defined a term in a way that is different from its plain meaning; or (2) a patentee “disclaims” the full scope of a claim term’s plain meaning, for

instance, by making clear and unambiguous statements during prosecution that a claim term does or does not encompass certain features.

59. I understand that, after construing the claims, the teachings of the prior art are considered. I also understand that a POSITA is assumed to be aware of all relevant prior art in the field of endeavor covered by the patent-at-issue and all analogous prior art.

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

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

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

63. I understand that there are several rationales for combining prior-art references. For instance, I understand that it is considered obvious to: combine prior-art elements according to known methods to yield predictable results; substitute one known element for another to obtain predictable results; use the prior-art elements in a predictable way according to their established functions; apply a known technique to a known device (method or product) ready for improvement to yield predictable results; choose from a finite number of identified, predictable solutions, with a reasonable expectation of success; or if there is some teaching, suggestion, or motivation in the prior art that would have led a POSITA to modify a prior-art reference or combine prior-art teachings to arrive at the claimed invention. I understand, however, that a POSITA does not need to have the same motivations or reasons to combine the prior art as the inventors, and can arrive at the claimed invention for completely different reasons than the inventors.

64. I also understand that the prior art cannot be modified or combined using “hindsight.” I understand that hindsight refers to situations in which the patent-at-issue is used as a framework to pick and choose pieces from the prior art to arrive at the claims, or adopting rationales identified by the patent-at-issue that those in the art would not have recognized. Instead, I understand that the obviousness inquiry is evaluated from the perspective of a POSITA as of the critical date of the patent-at-issue, with all the prior art before them, to determine whether the POSITA would

have independently arrived at the claimed invention without the benefit of the patent-at-issue for guidance.

65. I understand that “objective indicia” or “secondary considerations” of non-obviousness include whether: (1) there was a long-felt need for the claimed invention; (2) the claimed invention has achieved commercial success; (3) there was copying of the claimed invention by others; (4) there were failed attempts by others to make the alleged invention; (5) there was praise of the invention in the field; and (6) there was skepticism the claimed invention could be achieved, among a few others.

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

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

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

VII. CLAIM INTERPRETATION

69. As previously noted, I understand that the words of a claim are generally given their ordinary and customary meaning as understood by a POSITA in light of the patent specification and prosecution history. During prosecution of the '380 patent's parent application, U.S. Patent Application No. 17/181,057 ("057 application"), 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." EX1005, 2290. The applicant did not dispute the examiner's construction. I apply this understanding in this declaration.

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

VIII. PRIOR ART

A. Chang (EX1007)

71. Chang is a U.S. patent application publication, entitled "Breast Pump Assembly and Methods." See EX1007. Chang was published on November 22, 2018. Chang is a continuation of PCT Application PCT/US17/17112 filed on February 9, 2017, which claims priority to a set of U.S. patent applications filed in 2016., which claims priority to U.S. patent applications filed in 2016 and generally directed to the Willow breast pump which had viral media coverage at the 2017 Consumer Electronics Show.

72. Chang is generally related to a “portable breast pump system.” EX1007, [0001]. Chang discloses an integrated breast pump where all its components fit entirely within in a user’s bra. *See, e.g., id.*, Fig. 6A, [0072], [0080], [0101].

73. Chang discloses a breast pump that is “wearable” (*id.*, [0004]) and “fit[s] comfortably and conveniently into a bra of a user” (*id.*, [0011]). *Id.*, [0019] (the components of the system “are all contained within a cup of a brassiere”). The breast pump includes a “housing or outer shell 12” and “pump chassis 35” that form a pump housing (in blue) and “flange 14” (in purple):

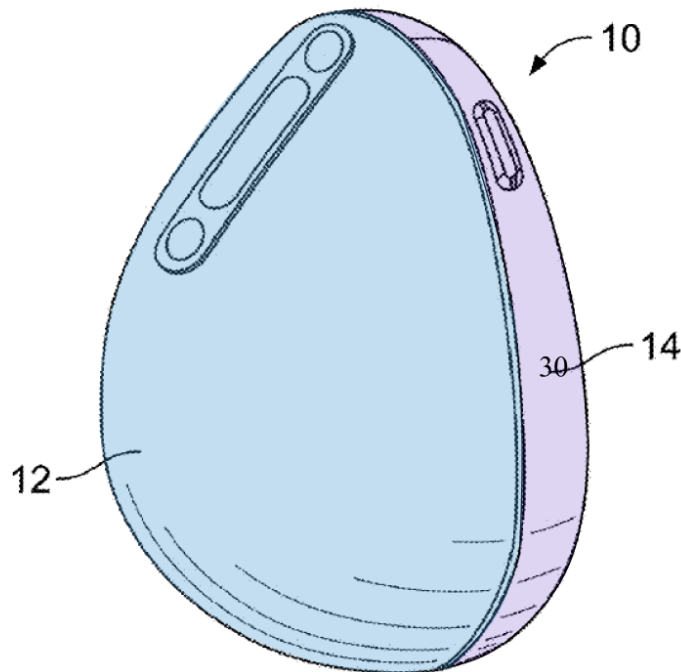
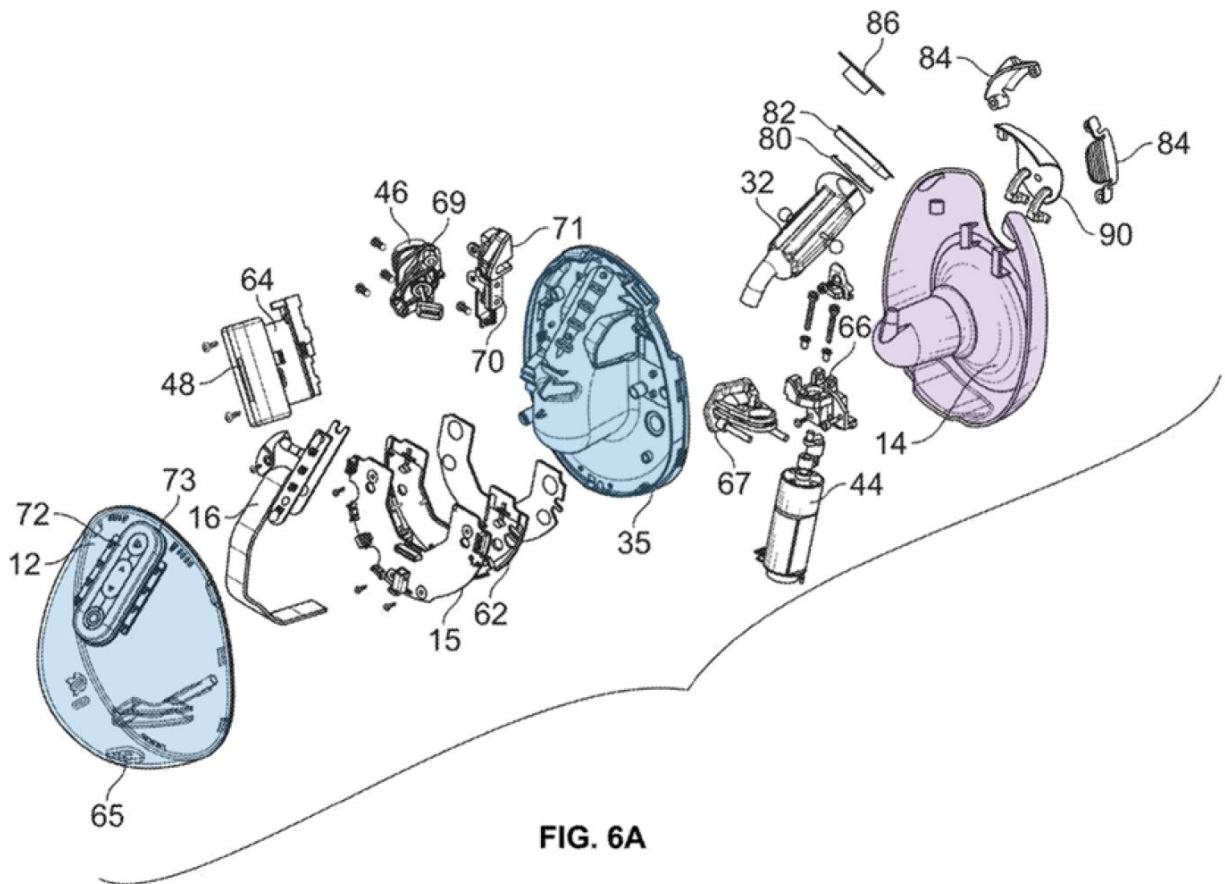


FIG. 1A

EX1007, Fig. 1A (annotated); *see id.*, [0071]

74. The flange, which is “sized and shaped to engage a breast of a user” (*id.*, [0071]), includes “a nipple receiving portion...contoured to more closely match the natural shape of the nipple.” *Id.* [0090]. The shape of the flange 14 is apparent in Chang’s Figure 6A:

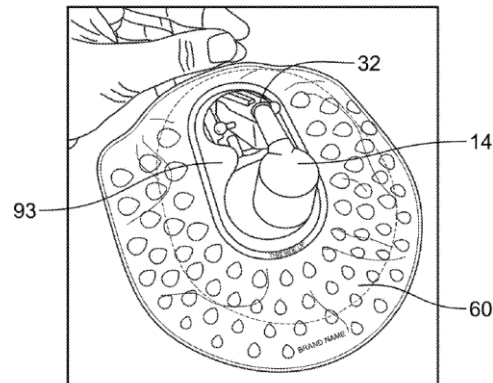
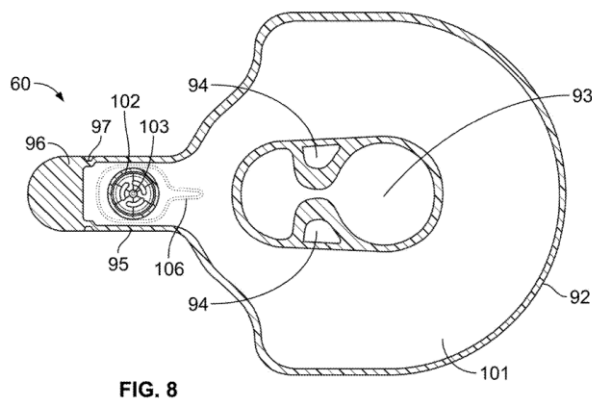


EX1007, Fig. 6A (annotated); *see also, e.g., id.* Figs. 1, 2, 4; *id.* [0071], [0072],

[0080]

The “shell 12” and “pump chassis 35” provide a pump housing that accommodate pump components (e.g., “motor 46”), and the “pump chassis 35” includes a recessed surface (e.g., that accommodates portions of the “flex tube”). *Id.*; FIG. 6A.

75. The breast pump includes a “milk collection container.” *Id.*, FIGS. 8, 11B.



EX1007, FIGS. 8, 11B; *see id.*, [0081], [0086], [0099]-[0101], [0105], [0106]

76. Chang describes the following in relation to the configuration of its “milk collection container”:

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

or other valve. Moreover, in one or more embodiments, the container can be flexible or rigid, or disposable or reusable.

Id., [0021].

77. Chang discloses that its breast pump also includes a “rechargeable battery” that power powers its system, including a “system controller” circuit board and a pump (e.g., “motors 44, 46 are further provided and controlled electronically by the system to effect manipulation of actuators (described below) operating on a conduit or flex-tube 32”). *Id.*, [0072]. Chang discloses that its “pump” can be “one or more pumps and equivalents thereof known to those skilled in the art.” *Id.*, [0068]. Chang also discloses that its breast pump may include sensors to control “the pumping cycles.” *Id.*, [0096]. All of these components are contained under the housing, between a body (including housing 12 and chassis 35) and the flange 14. EX1007, Fig. 6A, [0072], [0080].

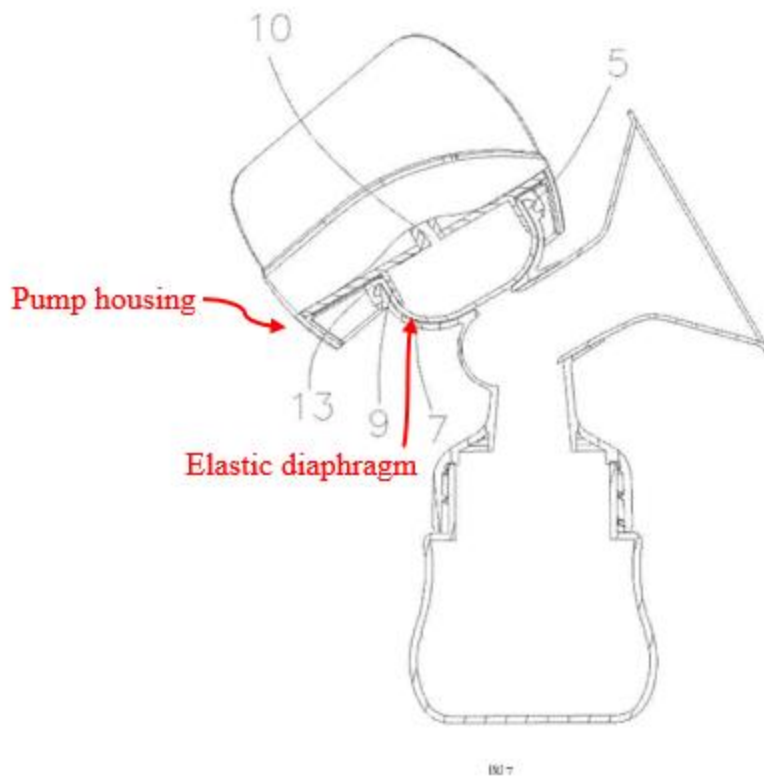
B. Fang (EX1009)

78. Fang is a Chinese utility model patent, entitled “Electric Breast Pump Convenient for Both Separate and Combined Configurations.” See EX1008 (original Chinese publication); EX1009 (certified translation of EX1008). Fang was published on February 1, 2017 from application (App. No. 201620663091.1) filed on June 29, 2016.

79. Fang describes a “breast pump” having an “air pump main unit” and that utilizes an “elastic diaphragm” to transmit negative pressure. EX1009, Abstract.

The “elastic diaphragm” also “prevent[s] the milk from flowing into the main body of the pump.” *Id.* Notably, Fang describes that the “air pump main unit” includes features that allow the “elastic diaphragm” and the diaphragm housing it is seated in to be connectable directly with features on the exterior surface of the “air pump main unit.”

80. The “elastic diaphragm 7” has “a circular wrapping 13” that is “sleeved on the annular edge 5.” EX1009, [0020]. The “air pump main unit” includes a “flange 9” and adjacent features, that serve as a first diaphragm housing. The “flange 9” of the pump housing the “presses the wrapping edge 13 of the elastic diaphragm 7 against the annular edge 5.” *Id.* Fang thus provides an example in which a diaphragm is seated against a diaphragm housing that is fixed to a recessed surface of the pump housing, and that defines a pumping chamber at least in part between an external surface of the housing and the elastic diaphragm.



EX1009, FIG. 7 (annotated)

C. Yuen (EX1011)

81. Yuen describes a battery-powered electronic device used in the collection/measurement of breast milk. See EX1011, 1, 8-11. The battery is “charged by a power supply through a charging port 1110 e.g. a micro USB port located on the upper housing 112.” *Id.*, 14:14-20. Yuen describes that the device includes “circuitry” to “monitor the charging current and the overall progress.” *Id.* “For instance, the circuitry 900 may provide a signal associated with the charging status of the apparatus 100 to the indicator 500 for presenting a visual indication to the user.” *Id.*

D. Khalil (EX1010)

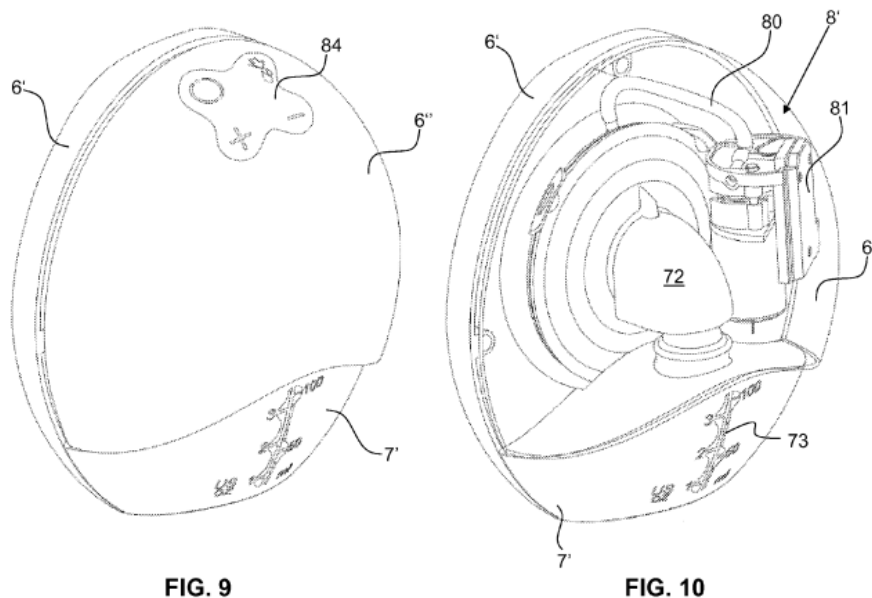
82. Khalil is a U.S. patent application publication, entitled “Breastshield Unit.” See EX1010. Khalil was published on January 24, 2013.

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

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

Id., [0032]; see also *id.*, [0070] (“The breastshield unit is small and easy to clean and is particularly suitable for use as a hands-free breastpump unit that can be worn in the bra.”).

84. An embodiment of Khalil’s breastshield unit is illustrated below:



Id., Figs. 9-10; *see also id.* Fig. 11, Abstract, [0066].

85. As can be seen from above, Khalil discloses that its breastshield unit has a shell, which include cover 6” and shell ring 6’, a milk container 7’ and an integrated pump unit 8’ with vacuum pump 81. *Id.* [0066]-[0067].

86. Khalil discloses that its pump can include any “known” type of electric “diaphragm pump.” *Id.*, [0067] (“The vacuum pump 81 is preferably a diaphragm vacuum pump of a known type, which is operated by means of an electric motor.”). The power source for the pump may also be integrated into the housing. *Id.* (“A pump seat 82, in which a vacuum pump 81 is held, is formed integrally in this cover 6”. A power source is preferably integrated in this vacuum pump 81.”).

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

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

Id., [0069]; *see also id.* Figs. 4, 9, 10.

88. Khalil also discloses a funnel-shaped flange, referred to as a “breast interface,” “for placing on a human mother's breast.” *Id.*, [0048] (“The breastshield unit 9 has a breast interface 1 for placing on a human mother's breast and a shell 6 on which the breast interface 1 is secured releasably.”); *id.*, [0060] (“As can be seen here, the breast interface 1 preferably has a base part 12 with a slightly funnel-shaped configuration and the stub 10 formed integrally thereon.”). The breast interface has a stub 10 which is where the user’s “nipple B protrudes into”:

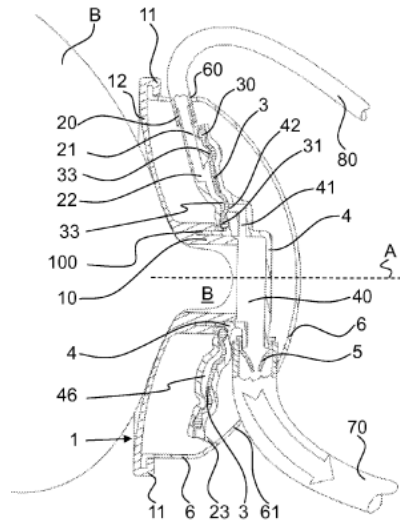


FIG. 4

EX1010, Fig. 4; *see id.*, [0060]

89. Khalil’s breastshield may include “membrane 3,” as shown in Figure 11:

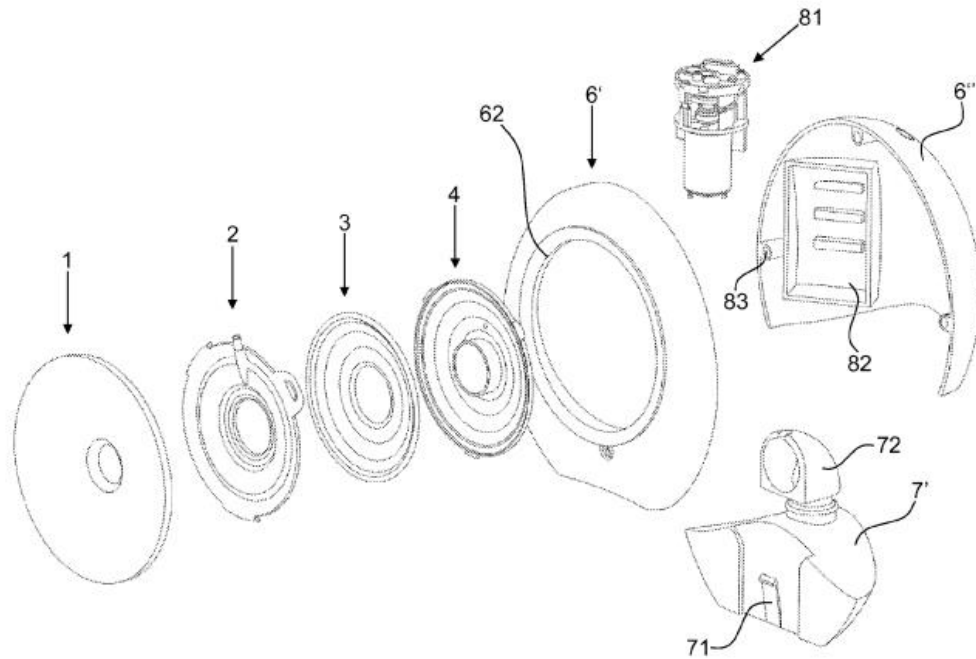


FIG. 11

EX1010, FIG. 11; *see id.*, [0066]-[0067], [0053]-[0058]

90. As shown above, membrane 3 located between “membrane housing parts 2, 4,” which are attached to the shell via cover ring 6’. The membrane 3 is “preferably made of a plastic material, in particular of silicone.” *Id.*, [0054].

E. Park (EX1014)

91. Park is International Patent Publication No. WO 2016/186452. *See* EX1013 (original Korean publication); EX1014 (certified translation). Park was published on November 11, 2016 based on a PCT application (PCT/KR2016/005271) filed on May 18, 2016.

92. Park describes a wearable breast pump having a diaphragm components and integrated container. EX1014, [1], [8], [10], [37]-[62]. Expressed milk passes

through the nipple tunnel and into a container via an opening in a lower surface of the nipple tunnel. *Id.*, [37]-[38]. The diaphragm (e.g., “flow separation membrane”) has a contoured shape that includes a central raised portion and a concentric raised portion. *Id.*, [39], [54]-[56], FIGS. 5, 7-8. The diaphragm (“flow separation membrane 500”) and opening on the lower surface of the nipple tunnel (“milk discharging hole 120”) are annotated in FIG. 5 below:

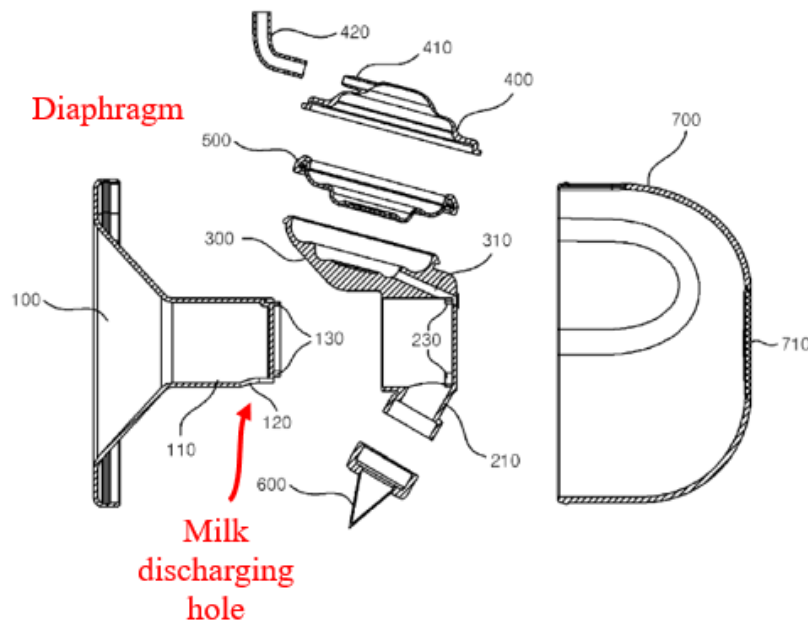
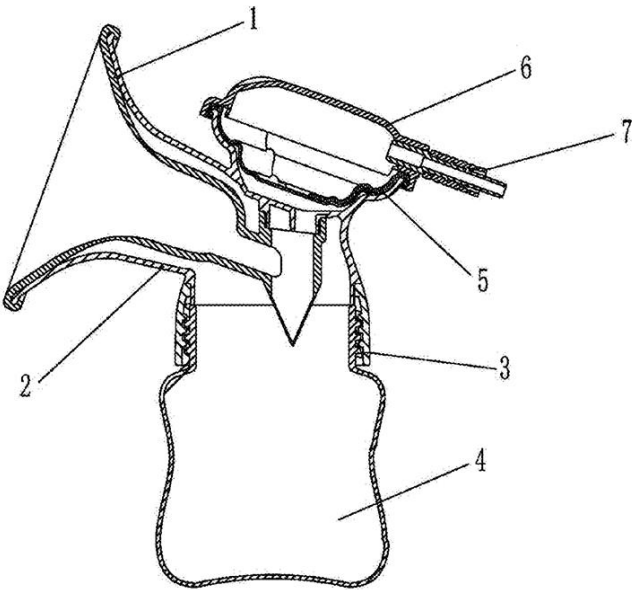


FIG. 5

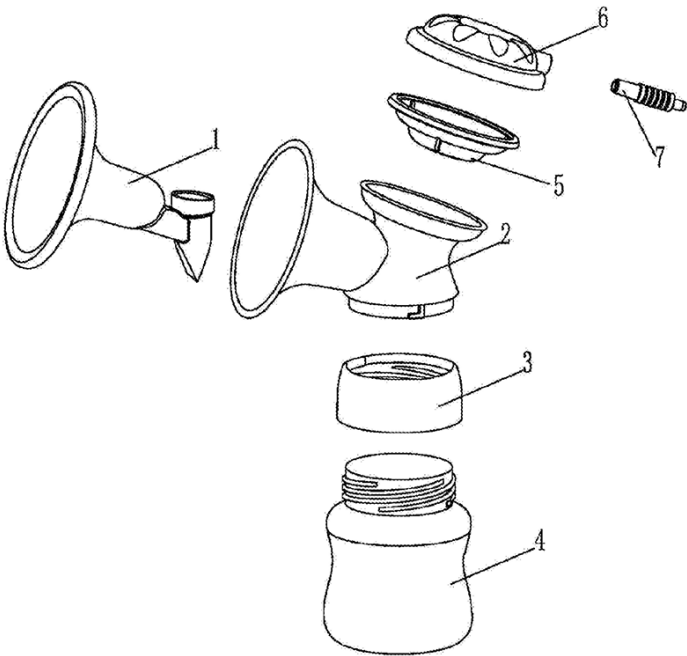
EX1014, FIG. 5 (annotated)

F. Chen (EX1015)

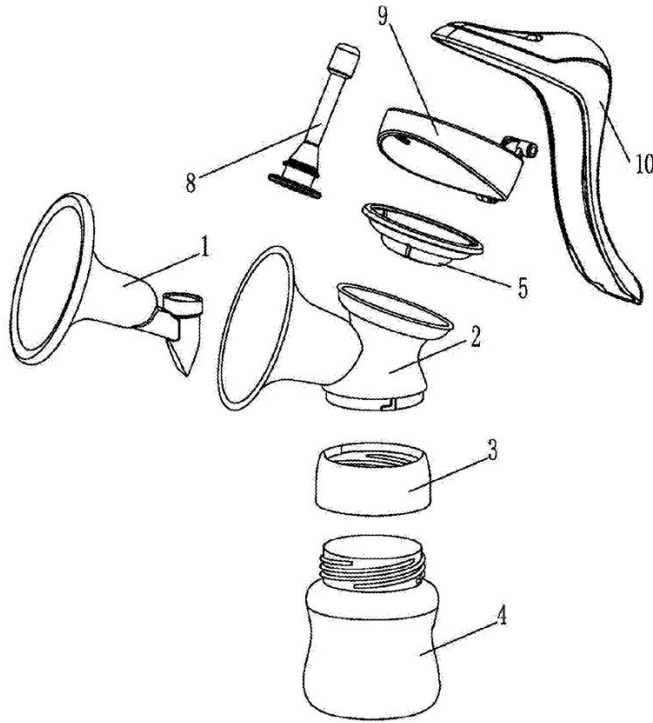
93. Chen describes a breast pump that includes a diaphragm housing attached to a breast shield. EX1015, FIGS. 2-4. Components of Chen’s breast pump are shown in Figures 2-4:



EX1015, FIG. 2



EX1015, FIG. 2



EX1015, FIG. 4

94. Chen describes that the breast shield and diaphragm housing are “integrally molded to make disassembly and assembly more convenient.” EX1015, [0015]. This configuration also addresses a disadvantage of prior art breast pump systems discussed in Chen, which is that “too many joints may cause improper[] assembly.” *Id.*, [0003].

IX. THE CLAIMS OF THE '380 PATENT ARE OBVIOUS

95. It is my opinion that all the claims of the '380 patent are obvious in view of Chang combined with other prior art references as discussed below. In particular, claims 1-8, 11, 13-23, 25, 29-35, 37, 39-41, and 43 are obvious over the combination of Chang, Fang, and Yuen. Claims 1-11, 13-23, 25-37, 39-41, and 43-

46 are obvious over the combination of Chang, Fang, Yuen, and Khalil. Claims 12, 24, 38, and 42 are obvious over the combination of Chang, Fang, Yuen, Khalil, and Park, and claim 20 is obvious over the combination of Chang, Fang, Yuen, Khalil, and Chen.

A. Ground 1A: Obviousness of Claims 1-8, 11, 13-23, 25, 29-35, 37, 39-41, and 43 Based on Chang, Fang, and Yuen

96. As discussed below, Chang, Fang, and Yuen provide each element of claims 1-8, 11, 13-23, 25, 29-35, 37, 39-41, and 43 .

1. Combination of Chang, Fang, and Yuen

a. Motivation To Combine Chang and Fang

97. A POSITA would have been motivated to combine Chang and Fang for the reasons discussed below. In particular, a POSITA would have been motivated to implement Chang’s breast pump device using a diaphragm to transmit negative pressure, as suggested by Fang. As I discussed above, Chang describes a pump that generates suction by cyclical compression and decompression of a conduit or flex-tube, and expressly notes that other configurations were known and suitable. *E.g.*, EX1007, [0022], [0025], [0028], [0068] (“one or more pumps and equivalents thereof known to those skilled in the art....”); *see also id.*, [0079] (“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”); [0084]-[0086]. Fang provides a known breast pump that uses a diaphragm pump

including a diaphragm housing component formed in a wall of the pump housing. EX1009, [0024]-[0025], FIG. 7.

98. A POSITA would have combined Chang and Fang to provide a breast pump device that includes a diaphragm pump and that has first and second diaphragm housing components and an elastic diaphragm, as suggested by Fang. EX1009, [0019] -[0025] (“flaring 4,” “ring rim 5,” “elastic diaphragm 7,” “flange 9”), FIGS. 4-5, 7. In more detail, Chang describes a recessed wall of a pump housing (“chassis 35” that accommodates Chang’s “flex tube 32.” See EX1007, FIG. 7A. Like Fang suggests, a first diaphragm housing (e.g., as suggested by Fang’s flange 9 and adjacent surfaces) would have been formed in this recessed pump housing wall. *Id.*; EX1019, [0020]-[0025], FIG. 7. The elastic diaphragm and second diaphragm housing (e.g., as suggested by Fang’s “flaring 4” and “ring rim 5”) would have been attached with the breast shield such in a complementary mating position, in accordance with Fang. The overall form factor of the device would thus remain generally like Chang, and would have been enhanced with an improved pump chamber defined between a recessed wall of the pump housing and the elastic diaphragm, based on the configuration suggested by Fang. In the resulting system based on Chang and Fang, a perimeter of the first diaphragm housing surface would have been fixed with the remainder of the pump housing wall such that the diaphragm housing surface defines part of the external surface of the pump housing,

and the elastic diaphragm sealingly engages when the device is assembled. I note that the diaphragm arrangement suggested by Fang would have enhanced the Chang device, as I discuss in more detail below, and provides a milk flow path to the container along a milk-side of the diaphragm.

99. In my opinion, based on Chang and Fang, a POSITA would have included vacuum pump components to generate a vacuum and drive the diaphragm. As I noted previously, the use of a diaphragm pump in breast pump devices was not new and was widely known prior to the '380 patent. This included the use of diaphragm pumps in devices having an “in-bra” form factor. Moreover, I note that a POSITA would have readily implemented such pump components withing the pump housing (e.g., at the locations of Chang’s “motor” and “actuators,” and/or associated components), based on Chang and Fang’s suggestions.

100. Based on my knowledge and experience in the field, and my review of Chang and Fang, the selecting and sizing of pump components, including for “in-bra” devices, was common and predictable for engineers in the field before June 2017. This is corroborated by, for example, Khalil, which described “a manually controlled or a motor-driven vacuum pump can be integrated in the housing.” EX1010, [0032]. Khalil confirms that “[d]evices for expressing human breastmilk are well known[,]” which included “[m]annually or electrically operated vacuum pumps [which] are connected directly

or via vacuum lines to a breastshield, which is used to receive a part of the mother's breast including the nipple." EX1010, [0003].

101. The pumps discussed above provided effective, compact, and quiet solutions for generating the necessary suction to extract milk while being worn discreetly inside a bra. The flexible diaphragm in these pumps created a vacuum by moving back and forth in response to pressure changes, which mimicked the natural suckling action. This technology allowed in-bra breast pumps to be more portable, comfortable, and convenient for users, as it reduced the bulk and noise associated with traditional pump mechanisms, making it easier for mothers to pump milk discreetly while on the go. The selection and sizing of pump components for "in-bra" devices was a common and predictable task for engineers in the field before June 2017. Engineers in this domain were commonly engaged in this task, as it involved standard engineering principles and well-established methodologies that had been in use for a significant period. The knowledge and techniques required for this work were widely known and regularly applied, making it a common practice in the industry at the time.

102. A POSITA would have been prompted to implement a diaphragm pump in Chang's breast pump device (in accordance with Fang's suggestions) for various reasons. One reason was to facilitate cleaning and maintenance based on Fang's description of an elastic diaphragm that isolates a milk side from the pump side,

preventing flow of milk to the pump components. EX1009, [0019] (“elastic diaphragm 7 is used to prevent the milk from flowing into the pump main body 8”). From this description, a POSITA would have recognized that diaphragm components would benefit from being readily accessed for cleaning. The ability to disassemble the diaphragm ensures that all milk contact surfaces can be thoroughly cleaned and sterilized. This maintains the hygiene and functionality of the breast pump system over time. Detachable diaphragms are practically significant in that they play roles in both the performance and maintenance of breast pump systems (such as the types of systems described in Chang).

103. The cleaning and maintenance benefits of diaphragm pump components were also known to a POSITA. Park, for example, corroborates the significance and known benefits of components that are easily cleaned. *See, e.g.*, EX1014, [0008] (“easily cleaned and maintained”), [0023] (“convenience in use due to easy cleaning and maintenance”), [0037] (“flow separation member 500”), [0040] (“inner space of the funnel connector 300 is sealed by the flow separation membrane 500, and thus, the breast milk is not allowed to flow backward”). As expressly recognized in Fang, diaphragm pump components serve as a critical barrier between the milk and the pump’s mechanical parts. EX1009, [0019]. Additionally, because the diaphragm is detachable, it can be easily removed, cleaned, and sterilized, further enhancing the overall hygiene and longevity of the breast pump system. These

features made diaphragm pumps a preferred choice in breast pump designs, where hygiene and ease of maintenance are essential considerations.

104. A POSITA would have also implemented the first diaphragm housing on a surface of the pump housing, according to Fang's express suggestion, to further enhance cleanability. Doing so would have reduced the number of parts to be assembled/disassembled, and associated interfacing surfaces or small crevices. Relatedly, a POSITA would have been motivated to utilize diaphragm components to reduce the use of tubing and the length of tubing to be cleaned. Tubing was known to be difficult to clean. Reducing tubing would alleviate this concern, and also reduce the likelihood of mold and mildew growth over time exacerbated by tubing that was difficult to dry.

105. Another reason a POSITA would have been prompted to implement diaphragm pump components in Chang according to Fang's suggestions was to facilitate more rapid and intuitive assembly and disassembly by the user. For example, a POSITA would have recognized the benefit of diaphragm components that are readily slid into and out of engagement, as suggested by Fang, and would have been motivated to impart such benefits in Chang's device. I note that, based on Chang and Fang's suggestions, a POSITA would have further recognized that the first diaphragm housing surface be positioned as part of the pump housing wall (e.g., "pump chassis 35" of Chang), in order to reduce additional attachment features that

would need to be manipulated and connected (e.g., during original manufacture and/or assembly/disassembly the user). Relatedly, such a construction would have further reduced interfaces between separate parts.

106. As an additional reason, a POSITA would have been prompted to combine Chang and Fang since the POSITA would have found Fang's diaphragm pump components to be an effective and suitable option to generate negative pressure that had been used effectively in breast pump devices. As I discussed above, Chang expressly invites the use of other pump components in the breast pump device, such as instead of the "flex tube 32." Fang provides suitable diaphragm pump features that a POSITA would have been recognized as readily implemented in Chang's device.

107. Additionally, I note that a POSITA would have been motivated to combine Chang and Fang because Fang suggested known diaphragm pump components for generating negative pressure in a breast pump, including a pump chamber defined in part between an external surface of a pump housing and elastic diaphragm, which a POSITA would have readily implemented to Chang's known breast pump device that generates negative pressure and has a recessed external pump housing that was ready for improvement and would have achieved the benefits I noted above. Ultimately, a POSITA would have found the modifications to be a simple substitution of one known pump configuration for another.

108. A POSITA would have had a reasonable expectation of success in making the modification. Both Chang and Fang describe similar breast pump device features and configurations and both include flexible pump components. The use of such diaphragm pump components in similar breast pump devices was widely known, including implementing a first diaphragm housing on an external surface of the pump housing and a second diaphragm housing with the breast shield. One example of such a configuration was described by Weber (EX1012), which described a “diaphragm 14” that was “arranged in a recess 112 of the housing 10, which forms part of a pump chamber.” EX1012, 15:1-15; EX1001, 5:5-7 (“breast shield[]connected directly to the first port of the chamber.”). Other examples that were well-known before the Critical Date were described in Khalil (EX1010), Tack (EX1018), and Hu (EX1020)). Diaphragm pumps were also used in “wearable” in-bra devices, as demonstrated by Khalil and Weber. *See* EX1012, [0006], [0047], [0090].

b. Motivation to Combine Chang, Fang, and Yuen

109. A POSITA would have been motivated to combine Chang, Fang, and Yuen for reasons I discuss in more detail below. For example, a POSITA would have been motivated to use a power charging circuit and a Universal Serial Bus socket on the Chang-Fang device. I note that Chang already describes its breast pump includes a rechargeable battery and “is configured to be plugged into a power

source for charging,” and also describes a socket for receiving a charging cable. EX1007, [0072]. Yuen describes a suitable example of a portable electronic device, in the same field, that includes a known power charging circuit for controlling charging of a rechargeable battery, and a USB socket that receives a USB connector of a power charging cable that can be plugged into an external power source. *See* EX1011, 14:14-20.

110. To a POSITA in the timeframe leading up to the '380 patent, the combination of Chang, Fang, and Yuen would have been predictable. In the combined device, a power charging circuit would have been included within the device, based on Yuen's suggestions, for controlling charging of the rechargeable battery. EX1011, 14:14-20. Additionally, the combine device would have included a micro USB socket that receives a USB connector of a charging cable. *Id.* The micro USB socket would have been readily included, either in addition or as an alternative to the existing “power cord connector” of “cover jack 65” (e.g., providing multiple form factors for the power cord connector).

111. In my opinion, a POSITA would have been led to implement a power charging circuit and USB socket, based on Yuen's suggestions, in the Chang-Fang device for several reasons. This configuration would have improved the Chang-Fang device in a way that supports the functionality of the breast pump systems described in Chang and Fang.

112. One reason a POSITA would have combined Chang and Fang with Yuen is to use charging techniques that were known by the relevant time frame to facilitate controlled charging and charging status feedback in similar portable electronic devices. As I noted above, Chang already describes rechargeable battery and a connector to charge the rechargeable battery within the device. EX1007, [0072], [0080], [0111]. Yuen provides further details of a power charging circuit that a POSITA would have recognized as enhancing performance of the device by “monitor[ing] the charging current and the overall progress,” and “provid[ing] a signal associated with the charging status.” EX1011, 14:17-20.

113. A POSITA would have also combined Chang, Fang and Yuen to facilitate charging in the device using a known USB port. USB ports were widely used in the timeframe before the '380 patent, especially on portable electronic devices. A POSITA would have recognized from Yuen's suggestions that using a micro-USB port on the Chang-Fang device would have allowed for charging using a connector type that was familiar to many users. Moreover, because it was a conventional connector type, such a port would have been widely available and interchangeable, such that an alternative cable could be located and used to charge the device in the even a user misplaced the original cable.

114. In my opinion, a POSITA would have been motivated to implement the power charging circuit to facilitate control of battery charging in a breast pump

device from an external power supply. A POSITA would have recognized from Chang and Yuen that the breast pump device operates using electrical power having characteristics different than the raw supply of electricity from a typical outlet. For example, household electricity in the U.S. is alternating current and 120 volts. Rechargeable batteries for devices such as breast pumps operated using direct current and low voltages (e.g., 3 volts). Therefore, household electricity is converted and/or altered using electrical components such as a rectifier (to convert AC to DC) and a transformer (to step down voltage) to work with the rechargeable battery. Such electrical components are often contained in a “transformer brick” or block-shaped plug that have been ubiquitous for electrically-powered consumer devices for decades, but such components can be located in the devices themselves instead.

115. 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. A POSITA would have found it obvious based on Chang and Yuen’s description that these modifications are carried out by a power charging circuit that is embodied by electrical components on one or more printed circuit boards inside the device. Doing so would have promoted effective charging and avoided damage to the battery.

116. As an additional reason, I note that combining the teachings of Chang and Fang with Yuen would have merely involved combining prior art elements according to known methods to yield predictable results. Yuen, like Chang, describes a rechargeable battery within the device, and a port on the device to receive a charging cable. A POSITA would have readily implemented such features, with a reasonable expectation of success, to facilitate charging and further Chang's express objective of charging the rechargeable battery, without significantly altering or hindering operation of the Chang-Fang device. Each of the references are directed to similar portable devices, and would have been implemented as a matter of routine skill.

2. Claim Analysis

117. As I note in detail below, the Chang-Fang-Yuen device, when combined for at least the reasons described above, provides all elements of claims 1-8, 11, 13-23, 25, 29-35, 37, 39-41, and 43.

a. Claim 1

(i) 1[pre]: A breast pump device comprising:

118. The Chang-Fang-Yuen device is an example of a breast pump device. For example, Chang describes "portable breast pump systems and methods for collecting milk from a breast of a nursing mother." EX1007, [0001], Abstract, FIGS. 1-21.

(ii) 1[a]: a self-contained, in-bra wearable device comprising:

119. The Chang-Fang-Yuen is an example of a self-contained, in-bra wearable device. For example, Chang expressly describes “a small, portable, self-powered, energy efficient, wearable breast pump system.” EX1007, [0004]. The device “is contemplated to fit comfortably and conveniently into a bra of a user” such that all of the components of the device are “all contained within a cup of a brassiere.” *Id.*, [0011], [0019]. I note that the Chang-Fang-Yuen device, combined for the reasons noted above, provides a device that is “complete, or having all that is needed, in itself” and is capable of being worn in a bra.” See Section IX.A.1 (Chang-Fang-Yuen); Section VII. (Claim Construction); *see also* Analysis of 1[b]-1[e] in Ground 1A. For example, a POSITA would have readily implemented the device using diaphragm pump components to maintain the compact, in-bra configuration of the breast pump device, with a reasonable expectation of success.

(iii) 1[b]: a pump housing that includes:

120. The Chang-Fang-Yuen device provides a pump housing. For example, Chang describes a “housing or outer shell 12 of” the breast pump device (annotated in blue below), and a recessed “pump chassis 35”. EX1007, [0071], [0073], FIGS. 1A, 6A. Pump components of the device are positioned in the space within the “outer shell” and “pump chassis,” such that these components together form a pump housing. *Id.*

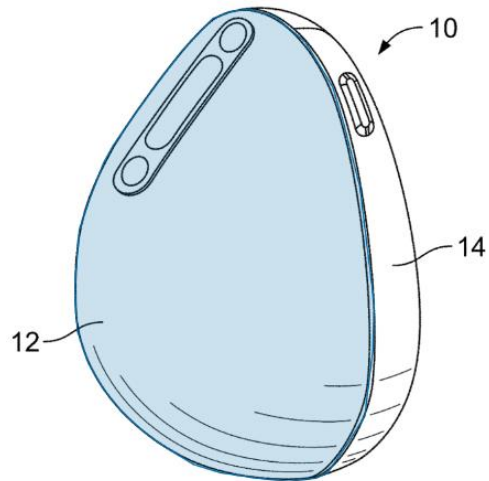


FIG. 1A

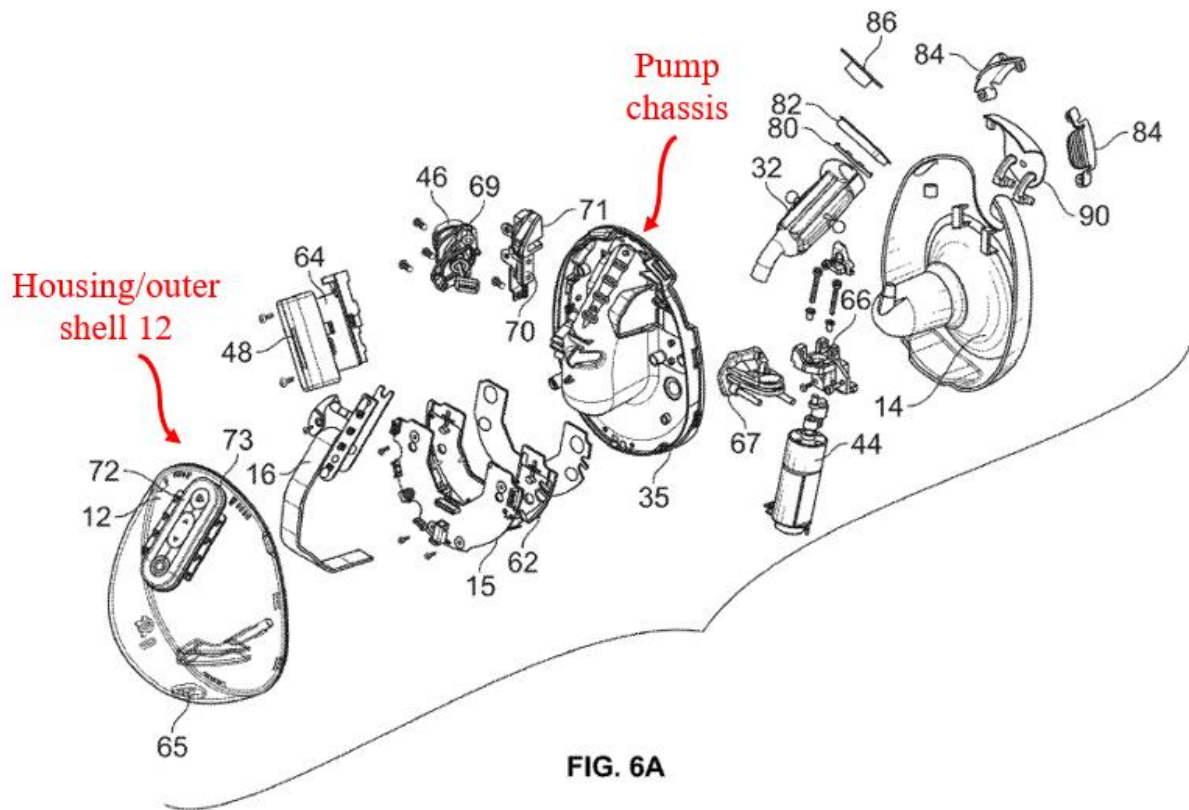


FIG. 6A

EX1007, FIGS. 1A, 6A (annotated)

(iv) **1[b][i]: a rechargeable battery,**

121. The Chang-Fang-Yuen device includes a rechargeable battery. Chang describes a rechargeable battery used to power the pump device: “A **battery** 48 is included to provide a **rechargeable** power source and is configured to be plugged into a power source for charging.” EX1007, [0072]. Chang additionally describes the device is “battery powered” and that the battery is “received in the compartment of the external shell.” *Id.*, [0020]; *see also* [0080] (“A battery bracket 64A” within the chassis inside housing 12 is “sized and shaped to receive a **rechargeable battery** 48 assembly that powers the system”); Fig. 6A.

(v) **1[b][ii]: a power charging circuit for controlling charging of the rechargeable battery,**

122. As I discussed above (refer to the Chang-Fang-Yuen device), the Chang-Fang-Yuen device includes a power charging circuit for controlling charging of the rechargeable battery. For example, Chang describes the breast pump device is “configured to be plugged into a power source for charging” to charge the rechargeable battery within the device. EX1007, [0004], [0020], [0072]. Based on my knowledge, a POSITA would have understood, and found it obvious, from Chang’s description, that the device include a power charging circuit for controlling charging of the battery in order to achieve Chang’s express objective of battery charging via an external power source. *Id.*, [0108]. I note that a POSITA recognized a power charging circuit as a conventional feature of rechargeable breast pumps and

other portable electronic devices. A POSITA would have predictably implemented the Chang, Fang, Yuen device to include power charging circuitry electrically between the “power connector” and the “rechargeable battery” to carry out the expressly stated objective of Chang of charging the battery while it is within the device via power from the external power source. EX1007, [0080], [0111].

123. A power charging circuit as recited by 1[b][ii] was obvious based on Chang’s description. But even if Chang did not provide a power charging circuit for controlling charging of the rechargeable battery, this was a conventional feature and would have been included in the combined Chang, Fang, Yuen device based on Yuen’s suggestions. *See* Section IX.A.1 (Chang-Fang-Yuen). As I noted above, Yuen expressly describes “circuitry” to “monitor the charging current and the overall progress” and to provide “feedback” to a user on the status of charging. EX1011, 14:14-20. Based on my knowledge and experience in the field and my review of Chang, Fang, and Yuen, a POSITA would have recognized and found obvious from Chang and Yuen’s description that the circuit in the combined system monitors the incoming “charging current.” In doing so, the circuit ensures proper current for safe and effective charging, furthering Chang’s stated objective of charging the rechargeable battery within the device.

124. Furthermore, a POSITA would have utilized a power charging circuit within the device to account for electricity of potentially varying characteristics

being supplied to the device so that power of suitable characteristics (e.g., appropriate “charging current”) is supplied to the battery. A POSITA would have recognized the benefit of such a circuit to facilitate safe and consistent control of charging the battery. Moreover, doing so would have allowed a range of power supplies (e.g., of varying characteristics) to charge the rechargeable battery within the device, further enhancing flexibility, portability, and overall user experience. I note that the teachings of Chang and Yuen provide more detail regarding the power charging circuit than the '380 patent itself. The '380 patent mentions “a power charging means within the control circuitry 71 for charging the battery 81,” but does not provide further explanation or implementation details. EX1001, 13:29-30. Based on Chang and Yuen’s description, a POSITA would have readily implemented a power charging circuit for controlling charging of the rechargeable battery.

(vi) 1[b][iii]: control electronics powered by the rechargeable battery,

125. The Chang-Fang-Yuen device includes control electronics powered by the rechargeable battery. For example, Chang describes the system is “battery powered,” and control electronics including, for example, “control panel 17,” “flex-circuit 16,” and/or “controller”/“circuit board 15” such that a user can “power the system on and off as well as[] alter functioning.” EX1007, [0072]. “A battery 48 is included to provide a rechargeable power source and is configured to be plugged

into a power source for charging,” further confirming the control electronics powered by rechargeable battery 48. *Id.* Referring to Figure 6A (annotated in red and yellow below), Chang describes “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.*, [0080].

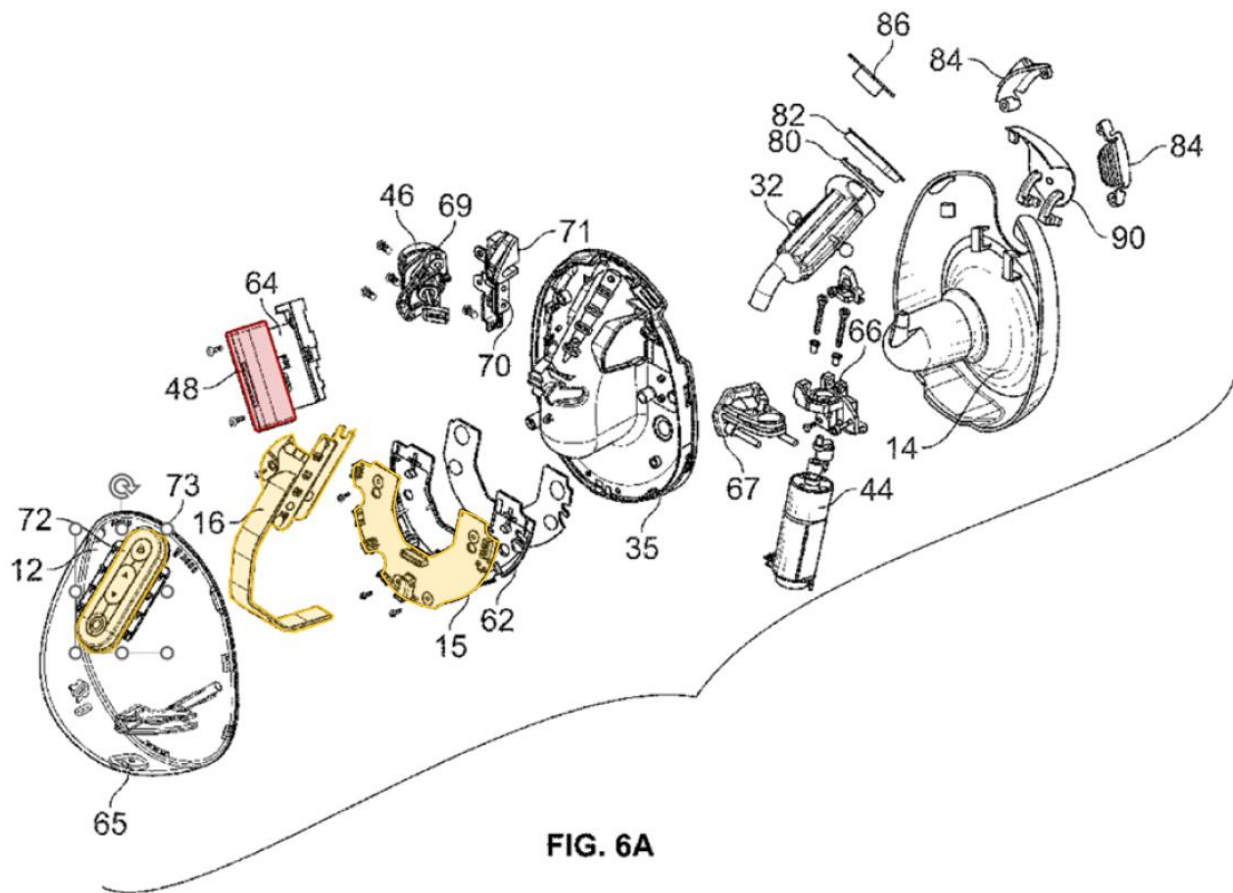


FIG. 6A

EX1007, FIG. 6A (annotated)

126. Control electronics powered by the rechargeable battery as recited by 1[b][iii] would have been provided in the combined device based on Chang’s express

description. But even if Chang did not provide these features expressly, a POSITA would have been prompted to include these conventional features in the combined Chang, Fang, Yuen device based on Chang's description. In particular, Chang expressly describes the "system is battery powered" via a battery "received in the compartment of the external shell." EX1007, [0020], [0072]. A POSITA would have found it obvious, from Chang's description, that the control electronics are powered by the rechargeable battery. A POSITA would have powered the control electronics via the "battery" to utilize an existing battery (e.g., rather than an additional power source distinct from the battery), and to achieve the express functionality of the control electronics that Chang describes.

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

127. The Chang-Fang-Yuen device includes a pump powered by the rechargeable battery and configured to generate negative air pressure. As I discussed above (in combining Chang and Fang, and Chang-Fang and Yuen), the combined system includes a diaphragm pump that generates negative air pressure. For example, Fang describes an "air pump" in pneumatic connection with the diaphragm that serves to generate negative air pressure. EX1009, [0019], [0024], FIG. 7. In the combined system, the location of the pump components would remain generally at the locations Chang describes (e.g., its motor). The "air pump" components of

the combined device would thus likewise be positioned within the pump housing, within the “shell” and “chassis,” for example. EX1007, [0072] (motor 46), [0080], FIG. 6A.

128. I note that, in the combined system, the air pump is powered by the rechargeable battery. For example, Chang describes the “rechargeable battery 48 assembly that powers the system 10” and “the system motor which is powered by the battery”. EX1007, [0072], [0080].

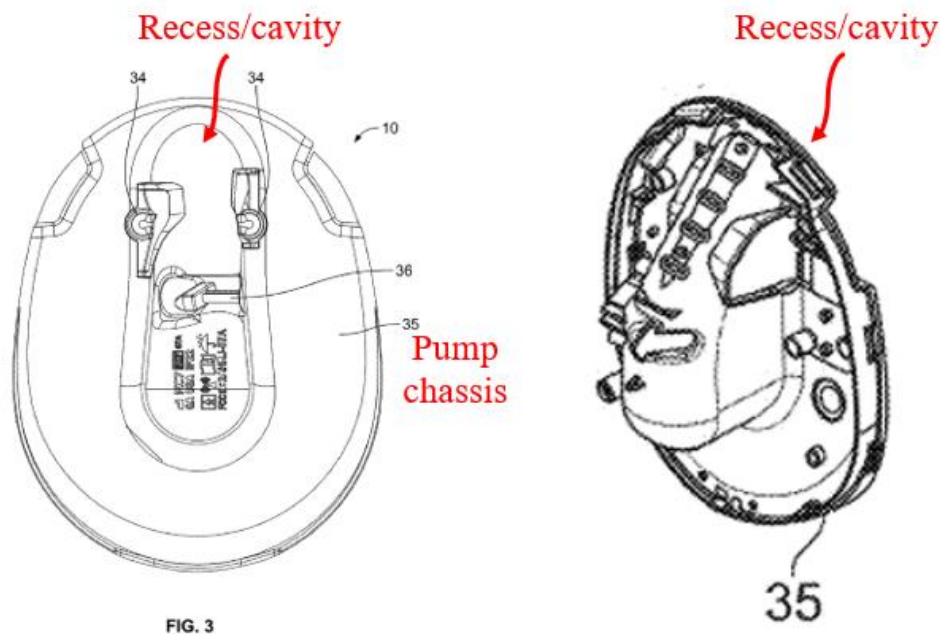
(viii) 1[b][v]: a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery, and

129. The Chang-Fang-Yuen device includes a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery. Chang describes its breast pump includes a “cover jack...for accepting a power cord connector” for charging the rechargeable battery. EX1007, [0080]. In the combined device (*see* Section IX.A.1 (Chang-Fang-Yuen)), the power cord connector is implemented as a “micro USB” charging socket, according to Yuen’s suggestions. Consistent with Chang and Fang’s description, the “micro USB” socket receives a complementary micro USB plug of a charging cable. When plugged into a power source, the socket serves to transfer power to the power charging circuit and the rechargeable battery. In doing so, charging of the

rechargeable battery within the device is carried out in accordance with the express objectives of Chang and Yuen.

(ix) 1[b][vi]: a recess or cavity that defines a pumping chamber;

130. The Chang-Fang-Yuen device includes a recess or cavity that defines a pumping chamber. As I discussed above in Section IX.A.1 (Chang-Fang-Yuen), a recess or cavity is defined between a pump housing wall (e.g., Chang’s “pump chassis 35”) and the flexible diaphragm. EX1007, FIGS. 3, 6A; EX1008, FIG. 7 (illustrating recessed wall of pump housing that defines cavity with “elastic diaphragm”); see Section IX.A.1 (Chang-Fang combination). Chang illustrates an example recess/cavity in the pump housing wall in FIGS. 3 and 6A.



EX1007, FIGS. 3, 6A (annotated).

Chang already describes a recess/cavity in the pump housing wall. *Id.* In the combined system, the recess or cavity is configured in accordance with Fang's suggestions, and such that the recess or cavity between the pump housing wall and flexible diaphragm defines a pump chamber on the air-side of the diaphragm.

(x) 1[c]: a breast shield made up of a breast flange and a nipple tunnel;

131. The Chang-Fang-Yuen device includes a breast shield made up of a breast flange and a nipple tunnel. For example, the combined device includes a breast shield made up of a breast flange and nipple tunnel in accordance with Chang's nipple receiving portion and breast contact portion. EX1007, [0071], [0090]. As Chang describes, the breast shield is "sized and shaped to engage a breast of a user." EX1007, [0071]. The breast shield is also "contoured to comfortably fit against a wide range of user's bodies and to provide structure for sealingly engaging with breast tissue." *Id.* A POSITA would have recognized from Chang's description that the breast shield has two portions including a "nipple receiving portion...contoured to more closely match the natural shape of the nipple" (*id.*, [0090]), 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.*, [0071]). "The nipple receiving portion can be cylindrical in the portion adjoining the breast contact portion." *Id.*, [0090]. Figure 4 of Chang

illustrates a flange comprising the nipple receiving portion (green) and breast-contact portion (blue).

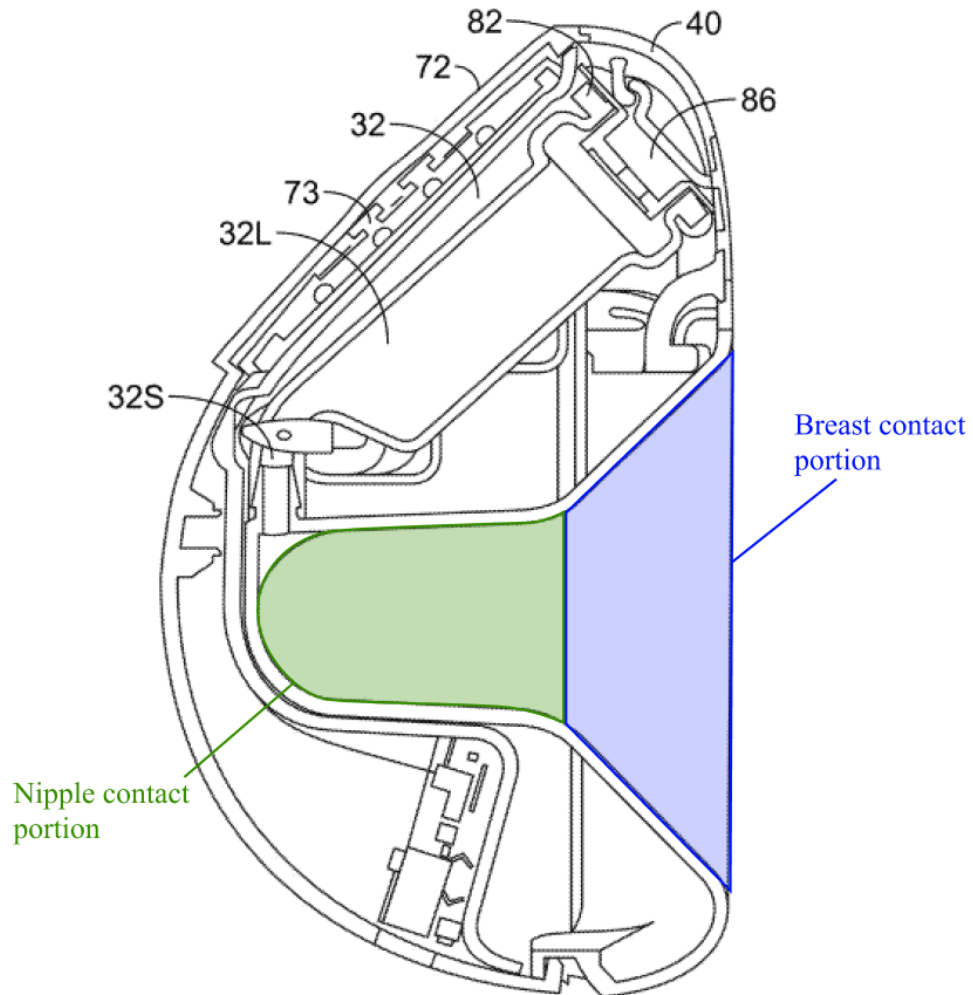
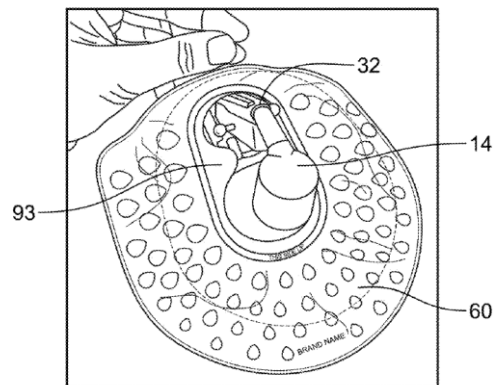
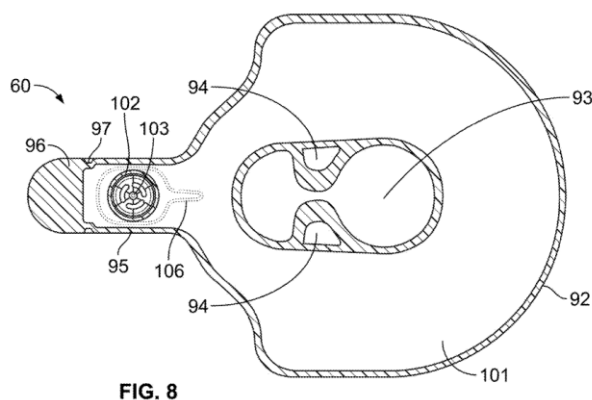


FIG. 4

EX1007, FIG. 4 (annotated)

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

132. The Chang-Fang-Yuen device includes a milk container that is configured to be attached to and removed from the pump housing. For example, Chang describes a milk container that is located within the device and configured to be attached to and removed from the pump housing. EX1007, [0008], [0010], [0019], [0021], [0023], [0081], [0086], [0092], [0099], [0100] (“positioning of collection or container assembly 60 within a pump system 10.”), [0101] (“the system is configured to pump into a sealed collection or container assembly 60” and “inside or outside of the pump housing”). Notably, the milk container is configured to be attached to and removed from the pump housing as part of the wearable, in-bra form factor. *Id.*, [0019] (“the milk collection container are all contained within a cup of a brassiere”); [0106]-[0107]; FIGS. 11A-11E.



EX1007, FIGS. 8, 11B; *see id.*, [0099]-[0101], FIGS. 11A, 11C-11E

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

133. The Chang-Fang-Yuen device includes a flexible diaphragm configured to prevent milk from reaching the pump. For example, Fang expressly describes an “elastic diaphragm” and first and second diaphragm housing components that engage with the “elastic diaphragm.” EX1009, [0019], FIG. 7; see Section IX.A.1 (Chang-Fang-Yuen combination). “The elastic diaphragm 7 is used to prevent the milk from flowing into the air pump main unit 8.” *Id.*

134. In the combined device, the diaphragm is seated against a diaphragm housing that is fixed to a recessed surface of the pump housing. Fang provides an express example of this known configuration. Fang describes a diaphragm housing that is fixed to a recessed surface of the pump housing. EX1009, FIG. 7. For example, diaphragm housing features are fixed to a recessed surface of the pump housing wall (e.g., Chang’s “chassis 35”). See Section IX.A.1 (Chang-Fang-Yuen). I note that this configuration, in which the diaphragm housing is fixed to a recessed surface of the pump housing, was known in the timeframe before the ’380 patent, and would have been readily implemented by a POSITA in the combined device. As an example corroborating and confirming this knowledge of the POSITA, the

Weber reference describes a diaphragm 14 “arranged in a recess 112 of the housing 10, which forms part of a pump chamber.” See, EX1012, 12:3-5. Furthermore, I note that the suggestions of Fang and the prior art, and the Chang-Fang-Yuen device, are just like the ’380 patent’s example embodiment. EX1001, FIG. 4.

135. 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. For example, Fang describes an “elastic” diaphragm. EX1009, [0019], [0020]-[0025]. When a vacuum is created on the pumping chamber, the “elastic diaphragm” deforms away from the nipple tunnel, creating negative air pressure in the nipple tunnel.

b. Claim 29

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

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

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

(ii) 29[a]: a self-contained, in-bra wearable device comprising:

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

(iii) 29[b]: a housing that includes:

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

(iv) 29 [b][i]: a rechargeable battery,

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

(v) 29 [b][ii]: a power charging circuit for controlling charging of the rechargeable battery,

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

(vi) 29 [b][iii]: control electronics powered by the rechargeable battery,

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

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

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

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

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

(ix) 29 [c]: a breast shield made up of a breast flange and a nipple tunnel;

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

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

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

- (xi) **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.**

147. Element 29[e] corresponds to elements 1[b][vi] and 1[e]. Element 1[e] recites “a diaphragm housing that is fixed to a recessed surface of the pump housing.” Element 29[e] recites “a pumping chamber at least in part with an external surface of the housing.” The prior art discloses this element of claim 29 for similar reasons discussed above, as set forth in my analysis of elements 1[b][vi] and 1[e]. For example, a membrane (e.g., “elastic diaphragm”) is configured to define a pumping chamber at least in part with an external surface of the pump housing (e.g., “chassis 35”), in accordance with Fang’s suggestions, as I discussed above (*see* Chang-Fang combination). To be clear, I note that the recessed surface of “chassis 35” that defines the pumping chamber with the diaphragm is an external surface. It is exposed when the “flange 14”/breast shield is removed, for example, and houses pump components internally. EX1007, FIGS. 3, 6A; *see also* EX1009, [0024], FIG. 7.

148. A POSITA would have understood that “diaphragm” as I discussed with respect to claim 1 provides the claimed “membrane” of claim 29. Based on the ’380 patent specification, both terms describe a flexible, thin barrier that helps create a vacuum by moving in response to air pressure changes. This movement

facilitates the suction needed to extract milk from the breast. While the terminology is different, the function and material are identical, making the terms interchangeable in this context.

c. Other Claims

- (i) 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.**

149. As I discussed above (refer to Analysis of 1[c]), in the Chang-Fang-Yuen device, the breast shield includes a nipple receiving portion and breast contact portion, such as described by Chang. EX1007, [0071], [0090]. A POSITA would have understood, and found obvious from Chang's description, the flange ("breast shield") is symmetrical about the cylindrical nipple receiving portion and has an operating position. Chang indicates the breast shield is "symmetrical about the nipple receiving portion," which is "cylindrical," and that the device is configured to be "disabled when the flange ["breast shield"] is not placed in an operating position." EX1007, [0017]. A POSITA would have found it obvious, based on Chang's description, that 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.

(ii) 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.

150. In the Chang-Fang-Yuen device, the breast shield is a one piece item such that, in use, it presents a single continuous surface to a nipple and a breast, in accordance with Chang. For example, Chang describes a breast shield including a nipple receiving portion and breast contact portion that is a “skin contact member” and “configured to form a seal with the breast.” EX1007, [0008], [0071].

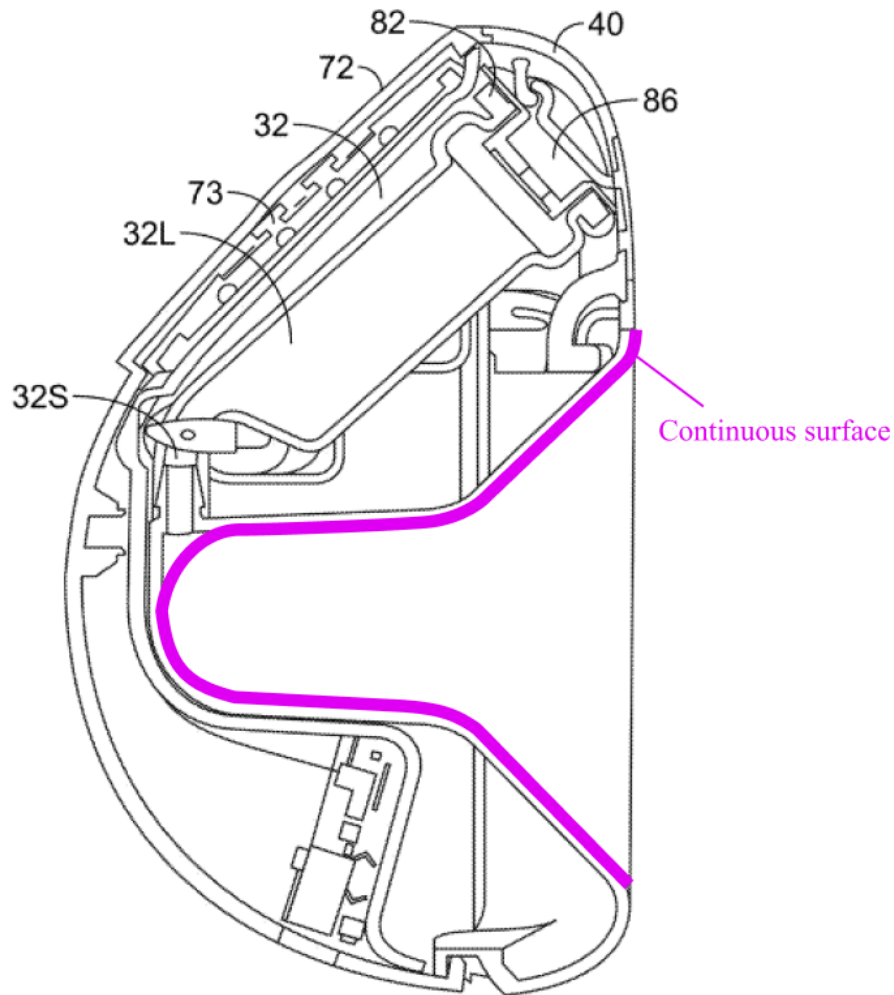


FIG. 4

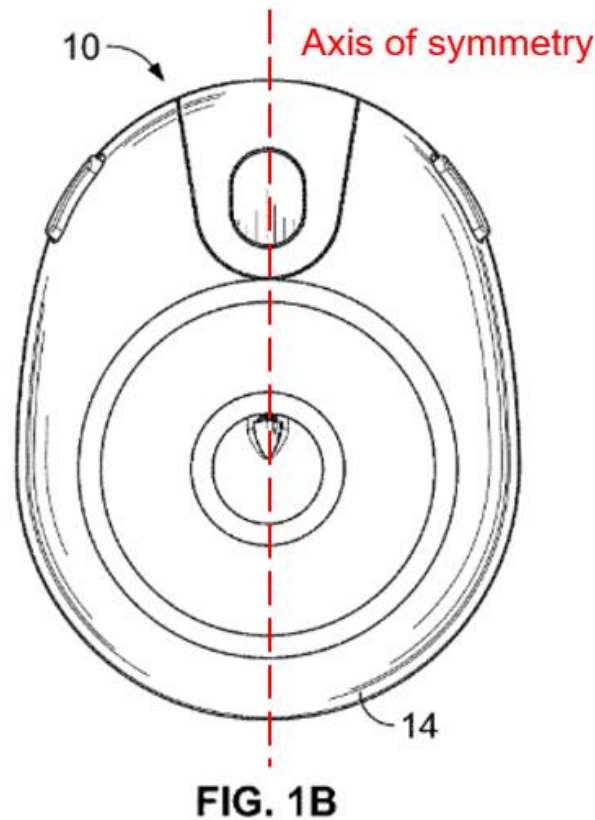
EX1007, FIG. 4 (annotated)

151. Chang additionally describes that 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.” EX1007, [0071], [0090]. The one piece structure is further illustrated by Chang in Figures 4, 5, and 6A, for example. Based on these teachings,

a POSITA would have also recognized and found obvious that the breast shield would have presented a single continuous surface to a nipple and breast to “form a seal with the breast.” EX1007, [0022]. Moreover, the single continuous surface would have avoided edges or interfaces that could create discomfort when sealingly engaged with the breast during use.

(iii) 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.

152. In the Chang-Fang-Yuen device, 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. For example, Figure 1B shows a back view of Chang’s breast pump, the side facing the user’s breast and includes the breast shield (and its nipple receiving portion and breast contact portion). EX1007, [0071]. Figure 1B shows Chang’s breast pump in an upright orientation when it engages the breast for normal use. *Id.* 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:

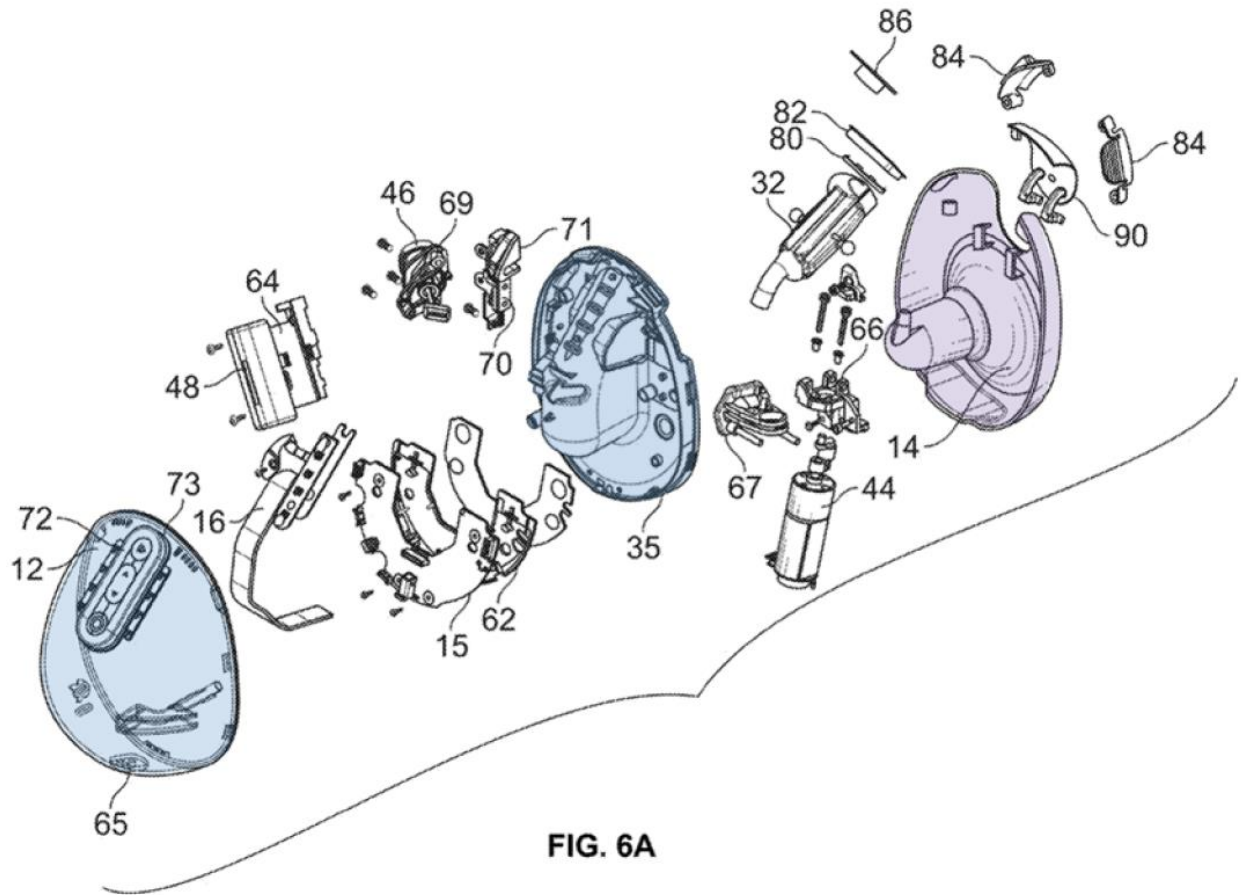


EX1007, FIG. 1B (annotated)

- (iv) **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.**

153. In the Chang-Fang-Yuen device, the breast shield and pump housing (e.g., Chang’s “outer shell 12” and/or “chassis 35”) are arranged based on Chang’s teachings, and the flexible diaphragm (e.g. “elastic diaphragm 7”) and second diaphragm housing (e.g., that the “elastic diaphragm 7” is seated in) are attached with the breast shield. Section IX.A.1(a) (Chang-Fang); EX1007, [0071], [0073], FIGS. 1A, 6A; EX1009, [0019], FIG. 7.; As shown in the annotated figure below,

in the combined device, the breast shield and the pump housing would be arranged like Chang's outer shell 12 and chassis 35(blue) and the breast shield (purple), with the breast shield configured to slide in and out when assembled/disassembled:



EX1007, FIG. 6A (annotated)

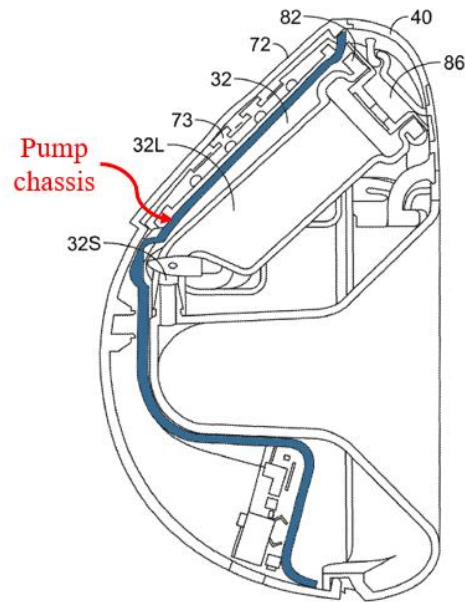


FIG. 4

EX1007, FIG. 4 (annotated); [0105]

154. In the combined device, the flexible diaphragm and second diaphragm housing are attached with the breast shield. EX1009, [0019], FIG. 7. The flexible diaphragm therefore moves together with the breast shield such that both are configured to slide in and out from the pump housing. To be clear, sliding the breast shield in and out from the pump housing would have predictably facilitated cleaning, allowing for the breast shield to be removed and cleaned and providing access to diaphragm components. The diaphragm is received with a second diaphragm housing attached to the nipple tunnel such that it slides from the pump housing together with the breast shield.

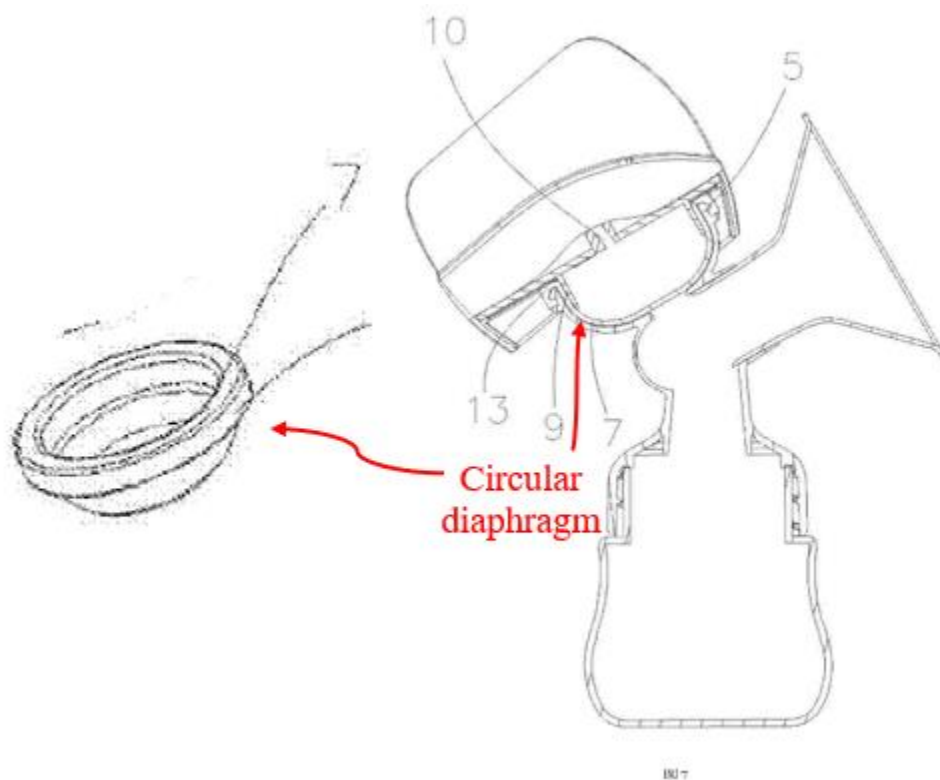
- (v) **Claims 6, 33: The breast pump device of claim [1/29], wherein the breast pump device includes only the breast shield and the milk container that are directly removable from the [pump housing/housing] in normal use or normal disassembly.**

155. In the Chang-Fang-Yuen device, only the breast shield and the milk container are directly removable from the pump housing/housing in normal use or normal disassembly. For example, Chang describes the breast shield and container are each removable from the remainder of the breast pump device. EX1007, [0105] (“removed from engagement with the remainder of the” breast pump device), [0021], [0023], [0081], [0086], [0092], [0099]-[0100]; see Analysis of 1[d] in Ground 1A. A POSITA would have recognized from Chang’s description that, in normal use or disassembly, only the breast shield and milk container are directly removable from the pump housing. See EX1001, 6:61-67. For example, in normal use or disassembly to empty the milk container or clean the milk flowpath, the breast shield would be “removed from engagement with the remainder” of the breast pump device, and the container likewise removed to extract the collected milk. That is, the breast shield and milk container are directly removable to provide access to empty the milk container and clean the diaphragm components, for example, without requiring further disassembly of the breast pump device. *Id.*

(vi) **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.

156. In the Chang-Fang-Yuen device, the diaphragm/membrane is substantially circular. For example, Fang shows elastic diaphragm 7 to have a substantially circular shape:



EX1009, Fig. 5 (partial), FIG. 7 (annotated)); *see also* EX1009, [0020]

157. Complementing the circular shape of the diaphragm, the diaphragm housing (e.g., including flange 9 and associated features) is likewise substantially

circular, facilitating engagement with the circular elastic diaphragm 7. EX1009, [0020]-[0025] (The elastic diaphragm 7 has “a circular wrapping 13”); FIG. 7.

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

158. The Chang-Fang-Yuen device includes a milk container (e.g., Chang’s milk container). See EX1007, [0008], [0010], [0019], [0021], [0023], [0081], [0086], [0092], [0099], [0100], [0101]; see Analysis of 1[d]. Chang describes that its milk container may be “flexible or *rigid*, or disposable or reusable.” EX1007, [0021]. Additionally, the use of rigid milk containers in breast pump devices were well-known by the Critical Date. For example, Khalil describes a milk container “made of plastic.” EX1010, [0069] (“like the cover 6”); [0050] (“the shell 6 is . . . rigid, and usually made of plastic”). A POSITA would have recognized that implementing Chang’s milk container as a rigid material provides a structurally stable outer contour of the breast pump device, and prevent compression of the volume of the milk container that could otherwise affect filling. See EX1007, [0021].

(viii) 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.

159. The Chang-Fang-Yuen device includes a milk container (e.g., Chang’s milk container) 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/housing] with a single push action. *See* EX1007, [0008], [0010], [0019], [0021], [0023], [0081], [0086], [0092], [0099], [0100], [0101]; *see* Analysis of 1[d] in Ground 1A. For example, Chang describes that its milk container includes “a rigid or flexible sealing component, such as a ring or gasket into which [a] pump or container valve is **pushed** or twisted and sealed.” *Id.*, [0101]. Based on my review of Chang, a POSITA would have recognized that the “sealing component” provides a mechanical mechanism that attaches to the pump housing (e.g., at the pump valve) via a single push action (e.g., a single push to secure the sealing component to the container valve). *Id.*; *see also*, EX1007, [0108] (describing magnets that facilitate determination that shield and housing are properly attached). The attachment secures the milk container with the pump housing, and allows the milk container to be released (e.g., after a pump session). Such a configuration can allow the user to attach the milk container to the pump housing

with one straightforward motion. The sealing component, such as a ring or gasket, aligns with the pump valve, for example, so that when the container is pushed into place, it automatically engages and forms a secure seal. This mechanism can provide a simplified attachment process, making it quick and user-friendly, requiring only a single push to securely connect the milk container to the pump.

(ix) 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].

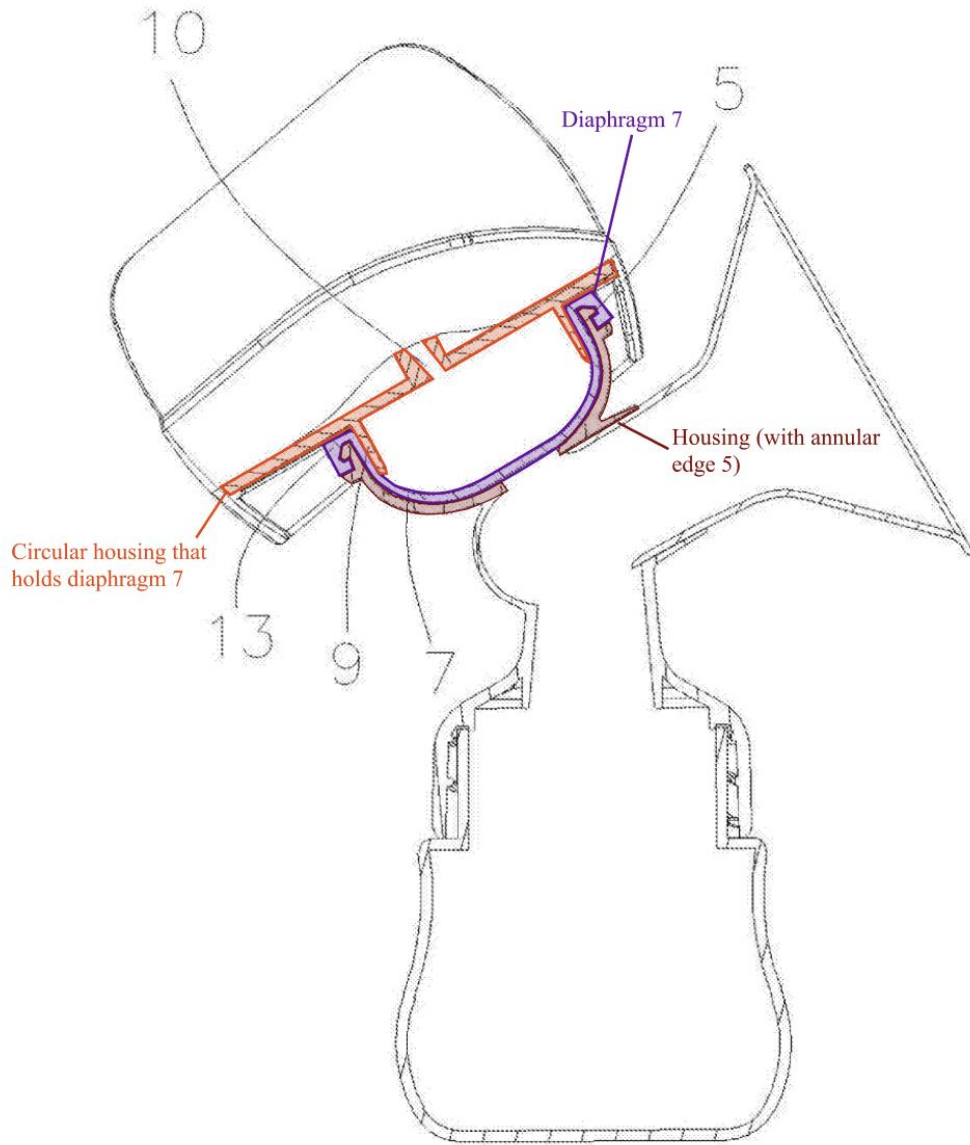
160. In the Chang-Fang-Yuen device, the [diaphragm/membrane] defines a milk-flow side chamber on one side of the [diaphragm/membrane] and an air-side chamber on the other side of the [diaphragm/membrane]. *See* Analysis of 1[e] in Ground 1A; *see* Section IX.A.1 (Chang-Fang-Yuen). To be clear, an air-side chamber is defined between the first diaphragm housing (e.g., on “chassis 35”) and the diaphragm, and a milk-flow side chamber is defined between a second diaphragm housing (e.g., attached with the breast shield) and the diaphragm.

- (x) **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].**

161. In the Chang-Fang-Yuen device, the flexible diaphragm (e.g., Fang’s elastic diaphragm 7) is configured to self-seal under negative pressure around its outer edge (e.g., without adhesive or moisture). *See* EX1009, [0019]-[0025], FIG. 7; *see also* Analysis of 1[e] in Ground 1A ; EX1001, 6:25-28 (“Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture”. A POSITA would have understood, and found obvious, to configure the flexible diaphragm of the Chang-Fang-Yuen device to self-seal under negative pressure to form a watertight and airtight seal around the recess or cavity in the pump housing (e.g., flange 9). Doing so would have predictably prevented passage of milk and provided for generating the clinically required negative pressure. *Id.*, [0020]; *see id.*, [0025] (“secure installation”); *see also id.*, [0010]; FIG. 7.

162. As shown in the annotated Figure 7 of Fang below, based on the placement of the elastic diaphragm 7 within Fang’s device, a POSITA would have recognized that, in the Chang-Fang-Yuen device, a watertight and/or airtight seal is achieved around the recess or cavity. A POSITA would have recognized that an airtight and/or watertight seal in Fang’s device helps ensure that the vacuum pressure

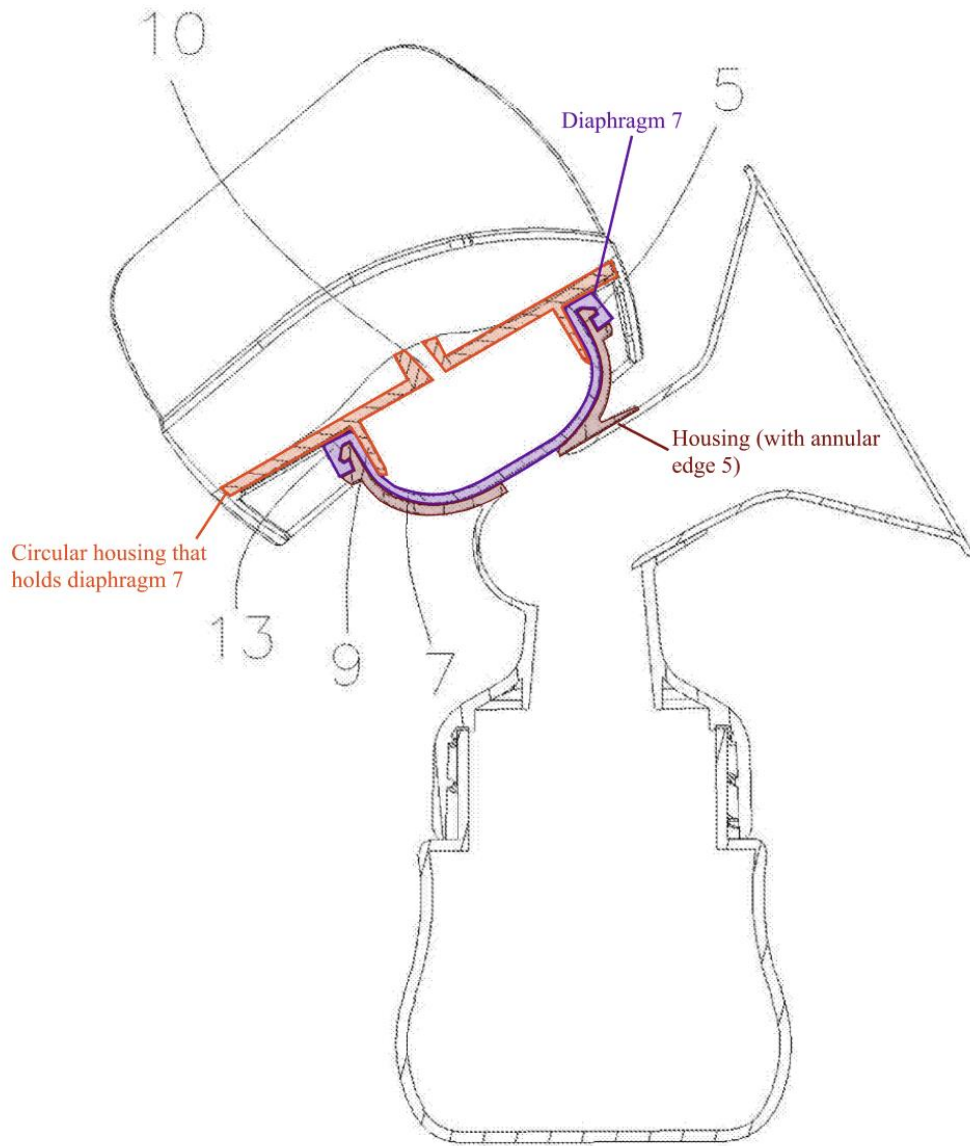
generated by the pump is effectively transmitted to the breast, which is important for efficient milk expression. An airtight or watertight seal prevents the loss of suction, which could lead to reduced milk flow and require longer pumping sessions.



EX1009, Fig. 7 (annotated); *see id.*, [0020]

- (xi) **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.**

163. As discussed for 1[e], in the Chang-Fang-Yuen device, a flexible diaphragm (e.g., Fang's elastic diaphragm 7) is seated against a diaphragm housing (e.g., protruding flange 9 and related features) that is fixed to a recessed surface of the pump housing, in accordance with Fang's suggestions. EX1009, Fig. 7, [0019]-[0025]. For example, as shown in the annotated figure below, Fang describes an elastic diaphragm 7 positioned between the first diaphragm housing on the pump housing, highlighted in orange) and the second diaphragm housing (e.g. flaring 4, alone or together with annular edge 5 highlighted in maroon). *Id.*; *see also* FIG. 5 (labeling flaring 4). In the combination, the second diaphragm housing is attached to the nipple tunnel such that the diaphragm components are in an upper, central location, consistent with Chang and Fang's suggestions (e.g., near the original locations of Chang's "flex tube" and Fang's elastic diaphragm and housing). *Id.*

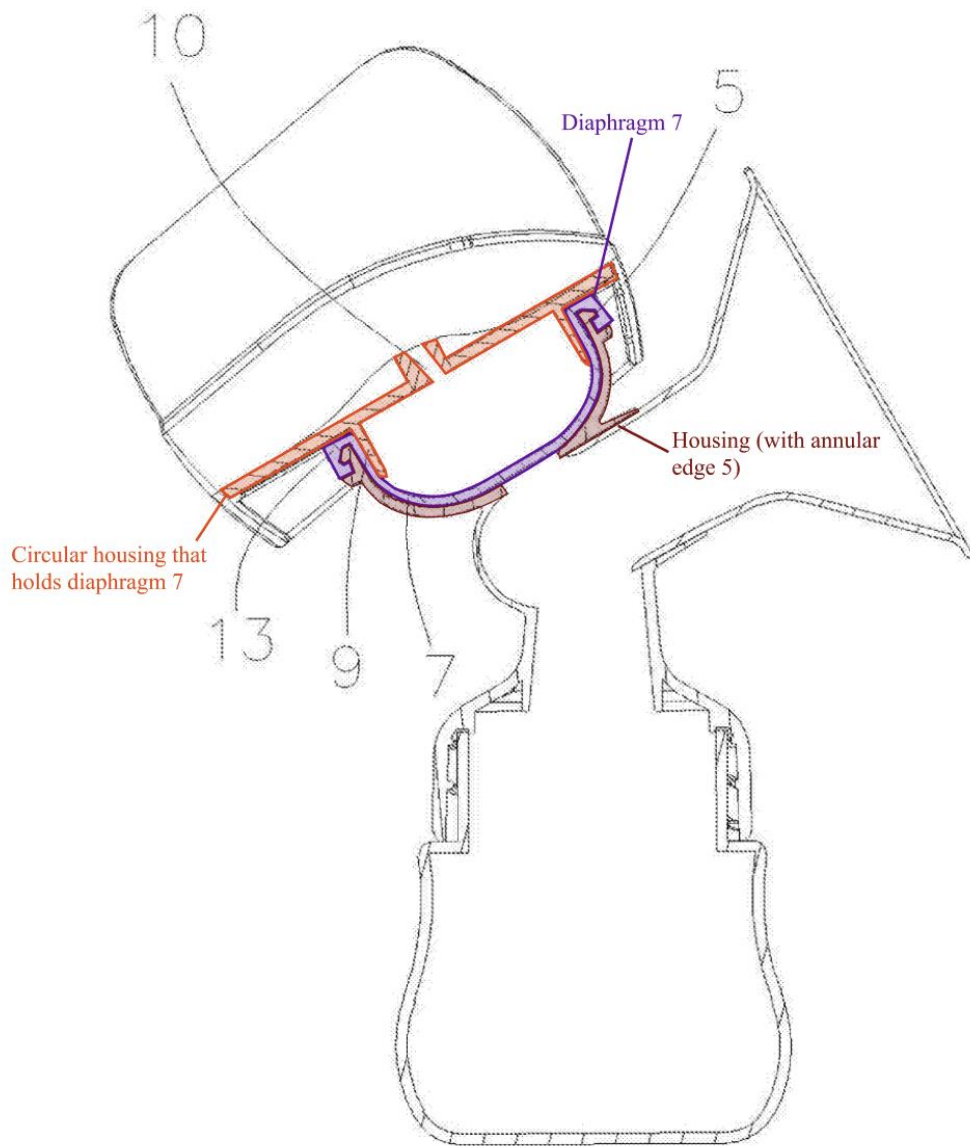


EX1009, Fig. 7 (annotated)

164. The second diaphragm housing is configured to define a milk-flow side chamber with the diaphragm. For example, a milk-flow side chamber is defined between the diaphragm and “flaring 4” (e.g., alone or together with annular edge 5).

- (xii) 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.**

165. In the Chang-Fang-Yuen device, a flexible diaphragm (e.g., Fang's elastic diaphragm 7) is releasably secured around an edge of the second diaphragm housing, which is attached to the nipple tunnel. EX1009, Fig. 7, [0019]-[0025]. For example, Fang illustrates the elastic diaphragm releasably secured around an edge (e.g., annular edge 5) of the second diaphragm housing. *Id.* This is shown in Fang's Figure 7 below.



EX1009, Fig. 7 (annotated)

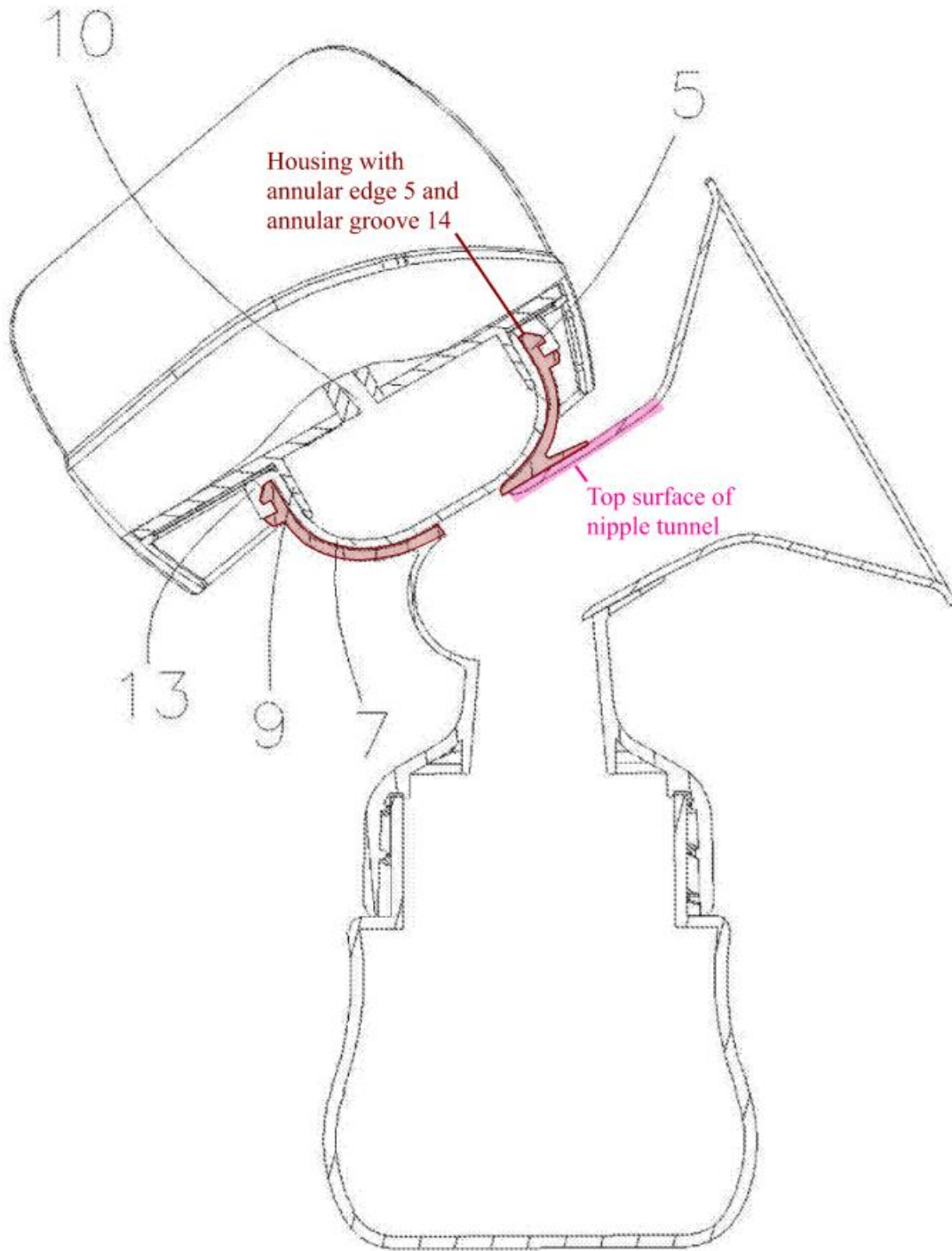
166. The features of claim 16 are expressly described by Fang (for the above reasons). But even if not, a POSITA would have found them obvious based on Fang’s description. A POSITA would have recognized that the elastic diaphragm 7 is “releasably secured,” e.g., to facilitate disassembly for cleaning/sterilization. See EX1009, [0004]. Moreover, a POSITA would have understood from Fang’s

description of the attachment of the “elastic diaphragm” that is its releasably attached via engagement between the “wrapping 13” of the diaphragm and the annular edge 5 of the second diaphragm housing. The releasable assembly allows the diaphragm to be easily removed and reattached, facilitating disassembly. This design enables users to remove the diaphragm for cleaning and sanitization, ensuring that all components can be thoroughly cleaned without difficulty, and then securely reassembled for continued use.

167. Use of detachable (i.e., releasably secured) diaphragms in breast pump systems were well-known by the Critical Date. For example, Weber corroborates the known configuration of a breast pump system that includes a “cover 13 that is detachably connectable to the housing 10 secures the diaphragm 14 in its position.” EX1012, 15:1-15; *see id.*, [0097], [0099], Fig. 12. Such detachable diaphragms offered a practical solution for maintaining hygiene and ensuring effective cleaning of the pump components. The ability to remove and sterilize the diaphragm was known to be important in preventing bacterial buildup and contamination, which is particularly important in devices that come into contact with milk. Additionally, detachable diaphragms contributed to the modularity of breast pump designs, allowing for easy replacement and maintenance, which enhanced the overall durability and usability of the systems. These benefits made detachable diaphragms a common feature in breast pump systems well before the Critical Date.

(xiii) 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.

168. As discussed for claim 15, in the Chang-Fang-Yuen device, a flexible diaphragm (e.g., Fang's elastic diaphragm 7) is positioned according to the teachings of Fang, e.g., between the first diaphragm housing (e.g., including protruding flange and adjacent surfaces) and the second diaphragm housing (e.g., including "flaring 4"). EX1009, Figs. 5, 7; *see id.*, [0019]-[0025]. As shown in the annotated figure below, in this arrangement, the second diaphragm housing (highlighted in maroon) is over a top surface of a nipple tunnel (highlighted in pink).



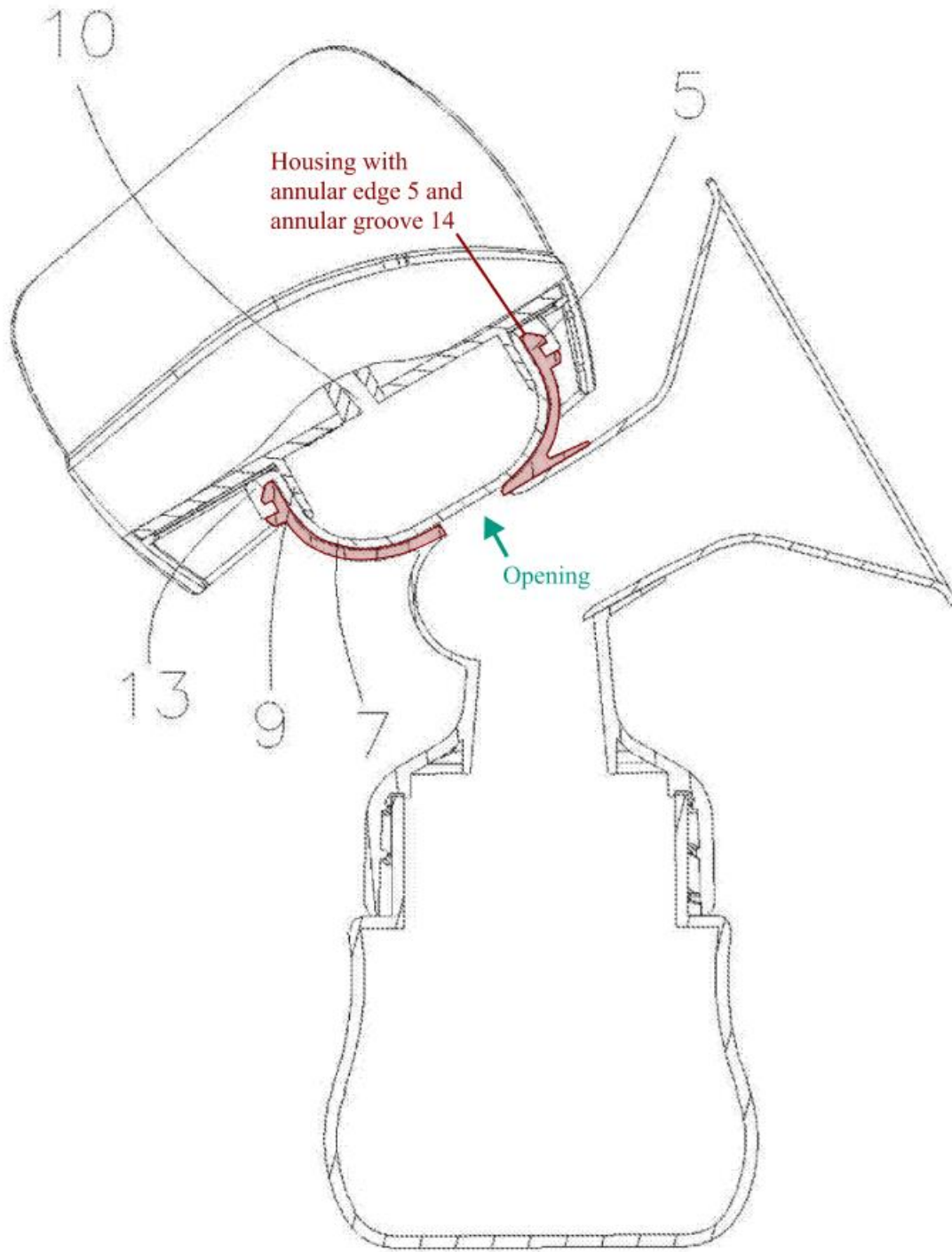
EX1009, Fig. 7 (annotated)

169. In the Chang-Fang-Yuen device, the flexible diaphragm is positioned in a similar manner according to Fang's suggestions (and consistent with the upper,

central location of Chang's "flex tube") such that the structure securing the flexible diaphragm (e.g., second diaphragm housing) is over a top surface of the nipple tunnel of the breast shield (Chang's nipple receiving portion) (e.g., "a top surface of the nipple tunnel") when the combined device is upright.

(xiv) 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.

170. In the Chang-Fang-Yuen device, the second diaphragm housing includes an air hole to transfer negative air pressure to the nipple tunnel, based on Fang's suggestion. Fang provides an air hole of the second diaphragm housing (e.g., including flaring 4). EX1009, Figs 5, 7; *see id.*, [0019]-[0025]. The air hole allows transfer of negative pressure to the nipple tunnel. This is shown in FIG. 7 below:



EX1009, Fig. 7 (annotated)

171. In the Chang-Fang-Yuen device, the flexible diaphragm is positioned in a similar manner according to Fang's teachings such that the structure securing

the flexible diaphragm (e.g., “second diaphragm housing”) has an opening (e.g., “air hole”) to transfer negative air pressure to a portion of the breast shield (Chang’s nipple receiving portion) (e.g., “the nipple tunnel”).

(xv) 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.

172. In the Chang-Fang-Yuen device, the diaphragm is a flexible and generally circular diaphragm. See Analysis of claims 1[e], 7, and 34 in Ground 1A. The second diaphragm housing (e.g., including “flaring 4”) has a corresponding generally circular shape to accommodate the circular diaphragm. EX1009, FIGS. 5, 7; see also *id.*, Abstract (“circular”), [0004], [0005], [0019]-[0025].

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

173. In the Chang-Fang-Yuen device, the second diaphragm housing is connected with the breast shield forming an integral structure when assembled. To be clear, based on my knowledge and experience in the field, a POSITA would have found it obvious, in view of Chang and Fang’s description, to form the second diaphragm housing as an integral part of the breast shield. Fang expressly provides the second diaphragm housing as an integral part of an adjacent structure below the second diaphragm housing. EX1009, FIG. 7. In particular, the adjacent structure

below the second diaphragm housing forms part of the nipple tunnel and is connected with the breast flange. *Id.* In the combined system, a POSITA would have been prompted to likewise integrally form the second diaphragm housing with the adjacent structure below the second diaphragm housing—Chang’s nipple tunnel/breast shield. Indeed, doing so would have reduced the number of separate parts, facilitating assembly/disassembly by the user, and reducing associated interfaces to be cleaned.

174. A POSITA would have also found such modification obvious to try. There was a known market demand for easy to assemble and clean devices prior to the timeframe leading to the ’380 patent. I note also that a POSITA would have recognized a finite number of solutions for attachment of the second diaphragm housing and the breast shield (e.g., integrally or non-integrally) in the location/form factor suggested by Chang and Fang. The need for convenience in consumer products has driven innovation toward solutions that simplify the user experience, especially in products like breast pumps where hygiene and ease of use are critical. Given this context, and considering the limited number of viable methods for attaching the second diaphragm housing to the breast shield—whether integrally or non-integrally—the proposed modification would have been a logical and straightforward choice for someone skilled in the field, aiming to meet both user expectations and market needs.

(xvii) 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.

175. The Chang-Fang-Yuen device provides the elements of Claim 21. *See* Analysis of Claim 16.

(xviii) 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.

176. The Chang-Fang-Yuen device provides the elements of Claim 22. *See* Analysis of Claims 14 and 40. Additionally, the diaphragm is configured to interference fit seal against the first diaphragm housing. For example, a POSITA would have recognized from Fang that the diaphragm engages with protruding flange 9 via an interference fit. EX1009, FIG. 7.

(xix) Claims 23, 41: The breast pump device of claim 1, wherein the diaphragm is a flexible and generally circular diaphragm.

177. The Chang-Fang-Yuen device provides the elements of Claim 23 and 41. *See* Analysis of Claims 1[e], 7, and 34.

(xx) 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].

178. The Chang-Fang-Yuen device provides the elements of Claims 25, 43. *See* Analysis of Claims 11 and 37.

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

179. The Chang-Fang-Yuen device provides the elements of Claim 41. See Analysis of Claims 1[e], 7, and 34.

B. Ground 1B: Obviousness of Claims 1-11, 13-23, 25-37, 39-41, and 43-46 Based On The Combination of Chang, Fang, Yuen, and Khalil

180. Claims 1-11, 13-23, 25-37, 39-41, and 43-46 are obvious over the combination of Chang, Fang, Yuen, and Khalil.

1. The Combination of Chang, Fang, Yuen, and Khalil

a. Motivation To Combine Chang, Fang, Yuen, and Khalil

181. A POSITA would have been motivated to combine Chang, Fang, Yuen, and Khalil for the reasons discussed below. In particular, a POSITA would have been motivated to implement Khalil's approach with devices described by Chang, Fang, and Yuen, to utilize a rigid container at a lower portion of the device, facilitating the downward flow of milk to the container. Chang describes that its device can be implemented to have a "rigid" milk container that can be provided in "alternative locations." EX1007, [0021], [0105]. Khalil offers a clear suggestion for incorporating a rigid container in a wearable, in-bra device. EX1010, [0032] ("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 *id.*, [0069] ("[The milk collection

container] is preferably made of plastic like the cover 6.”), [0050] (“The shell 6 is preferably in one piece and rigid, and usually made of a plastic”), [0067]. These teachings are complementary with one another and would have led a POSITA to create a more efficient and user-friendly breast pump device. For example, by combining the teachings of Chang, Fang, Yuen, and Khalil, a POSITA could design a device that integrates the benefits of rigidity for stability and hygiene, effective sealing for performance, and wearability for user comfort and convenience, ultimately leading to an improved and more desirable product.

182. In the resulting combination, the breast pump device would have included an integrated milk container at a lower location of the device, based on Khalil’s suggestion. Similar to Khalil’s suggestions, the milk container would have a contoured shape to complement the shape of other portions of the device (e.g., “outer shell 12”). Such a shape would have contributed to its wearable, in-bra configuration, furthering an objective of both Chang and Khalil. *Id.* Milk would flow through the nipple tunnel and then downward through a one-way valve into the container. EX1010, [0053] (“non-return valve 5”/“duckbill valve”), [0069]. The container would have included a removable attachment with the pump housing (e.g., “chassis 35” and/or “outer shell 12”), and fluidic connection with the nipple tunnel. EX1010, [0069] (“locking lug” and “corresponding recess” and “expressed milk can

flow from the under pressure chamber 40 into the interior of the milk collection container”).

183. Based on my knowledge and experience in the field and my reviewer of Chang, Fang, Yuen, and Khalil, there were multiple reasons that would have prompted a POSITA to implement the Chang-Fang-Yuen device to have a rigid container at a lower portion of the device, as suggested by Khalil. As a first reason, a POSITA would have combined Khalil with Chang, Fang, and Yuen to further enhance cleanability and assembly/disassembly in a wearable device having a diaphragm to transfer negative pressure. Khalil notes advantages of a configuration that is “small and easy to clean” and “that can be worn in the bra.” EX1010, [0070]. These are benefits that a POSITA would have likewise been motivated to implement in the Chang-Fang-Yuen device by positioning the milk container at a lower portion that can be readily assembled and disassembled with the remainder of the device, as suggested by Khalil. For example, Khalil describes attachment between the container and pump housing, and fluidic connection with the milk flow passage through the nipple tunnel, facilitating assembly/disassembly. EX1010, [0069]. Moreover, in doing so, a POSITA would have recognized the benefits of a downward flow of milk in which the milk flow path remains below the diaphragm components, consistent with Fang and Khalil’s suggestions. A POSITA would have

recognized this configuration as further isolating pump components from milk flow.
Id.

184. As another reason, a POSITA would have recognized that combining Chang-Fang-Yuen with Khalil enhances the user experience during pump removal from the breast at the conclusion of a pumping session. The diaphragm arrangement and downward flow of milk to a lower container (e.g., in which the milk is evacuated into the container during each pump stroke) facilitates removal without requiring the user to lean forward or otherwise adjust the orientation of their body to avoid spilling milk captured within the device. This design not only simplifies the process but also reduces the risk of discomfort or inconvenience, making the pumping experience more user-friendly. It also ensures that the milk is securely collected, minimizing the potential for loss or contamination during the transfer process.

185. As a third reason, a POSITA would have been prompted to use a rigid milk container at a lower portion of the device as a suitable option for collecting expressed milk within the Chang-Fang-Yuen device. As I noted previously, Chang indicates that its container can be “rigid” and positioned in various locations. EX1007, [0021], [0101]. A POSITA would have recognized Khalil as providing a suitable example to implement a rigid container at a lower portion of the device in an integrated manner.

186. A POSITA would have also recognized that combining the teachings of Khalil with Chang, Fang, and Yuen would have merely involved combining prior art elements according to known methods to yield predictable results. Khalil describes the known technique of a milk container at a lower portion of an integrated wearable diaphragm breast pump, and the Chang-Fang-Yuen provides such an integrated wearable breast pump. A POSITA would have readily implemented such features, with a reasonable expectation of success, and without significantly altering or hindering operation of the Chang-Fang-Yuen breast pump. Moreover, I note that any associated modifications to the geometry and connections, for example, would have been readily implemented as a matter of routine skill.

2. Claim Analysis

b. Claim 1

(i) 1[pre]: A breast pump device comprising:

187. The Chang-Fang-Yuen-Khalil combination makes this limitation obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of 1[pre] in Ground 1A.

(ii) 1[a]: a self-contained, in-bra wearable device comprising:

188. The Chang-Fang-Yuen-Khalil combination makes this limitation obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of 1[a] in Ground 1A. As discussed in §IX.B.1, the

combination would have provided a wearable breast pump device that utilizes a rigid container at a lower portion of the device, facilitating the downward flow of milk to the container.

(iii) 1[b]: a pump housing that includes:

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

189. The Chang-Fang-Yuen-Khalil combination makes this limitation obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of 1[b] and 1[c] in Ground 1A.

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

190. The Chang-Fang-Yuen-Khalil combination provides this limitation. In the resulting combination, as I discussed above (Chang-Fang-Yuen-Khalil combination) the breast pump device would have included an integrated milk container at a lower location of the device, in accordance with Khalil's suggestion. For example, Khalil describes a rigid "milk collection container...integrated in the housing of the unit or coupled directly thereto." *Id.*; *see also*, [0069] ("[The milk collection container] is preferably made of plastic like the cover 6."), [0050] ("The shell 6 is preferably in one piece and rigid, and usually made of a plastic"), [0067]. The container is configured to be attached to and removed from the pump housing. Khalil expressly describes complementary features that allow the milk container to

be attached to and removed from a pump housing. EX1010, [0069] (“locking lug” and “corresponding recess” and “expressed milk can flow from the underpressure chamber 40 into the interior of the milk collection container”); *see also* Analysis of Claim 9 in Ground 1B.

- (v) **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.**

191. The Chang-Fang-Yuen-Khalil combination makes this limitation obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of 1[e] in Ground 1A.

c. Claim 29

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

192. The Chang-Fang-Yuen-Khalil combination makes this limitation obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of 29[pre] in Ground 1A.

(ii) 29[a]: a self-contained, in-bra wearable device comprising:

29[b]: a housing...

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

193. The Chang-Fang-Yuen-Khalil combination makes this limitation obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of 29[a]-29[c] in Ground 1A.

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

194. The Chang-Fang-Yuen-Khalil combination makes this limitation obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of 29[d] in Ground 1A.

(iv) 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.

195. The Chang-Fang-Yuen-Khalil combination makes this limitation obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of 29[e] in Ground 1A.

- d. 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.**

196. The Chang-Fang-Yuen-Khalil combination makes these claims obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claims 2 and 30 in Ground 1A.

- e. 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.**

197. The Chang-Fang-Yuen-Khalil combination makes these claims obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claims 3 and 31 in Ground 1A.

- f. 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.**

198. The Chang-Fang-Yuen-Khalil combination makes these claims obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claims 4 and 32 in Ground 1A.

- g. 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.**

199. The Chang-Fang-Yuen-Khalil combination makes these claims obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claim 5 in Ground 1A.

- h. 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.**

200. In the Chang-Fang-Yuen-Khalil combination, only the breast shield and the milk container are directly removable from the pump housing/housing in normal use or normal disassembly. For example, Chang describes the breast shield can be “removed from engagement with the remainder of the” breast pump device. EX1007, [0105]; *see also* analysis of Claims 6 and 33 in Ground 1A. In the Chang-Fang-Yuen-Khalil combination, the milk container is also removable via complementary engagement with the pump housing (e.g., and fluid connection with the nipple tunnel), based on Khalil’s suggestions. EX1010, [0069]; *see* Section IX.B.1 (Chang-Fang-Yuen-Khalil combination). In normal use or disassembly, only the breast shield and milk container are directly removable from the pump housing. For example, in normal use or disassembly to empty the milk container or clean the milk flowpath, the breast shield would be “removed from engagement with the

remainder” of the breast pump device, and the container likewise removed to extract the collected milk. Here again, the resulting configuration in which the breast shield and milk container are directly removable provides access to empty the milk container and clean the diaphragm components, for example, without requiring further disassembly. *Id.*

- i. **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.

201. The Chang-Fang-Yuen-Khalil combination makes these claims obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claims 7 and 34 in Ground 1A.

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

202. The Chang-Fang-Yuen-Khalil provides a milk container that is substantially rigid. *See* Section IX.B.1 (Chang-Fang-Yuen-Khalil combination). For example, Khalil describes a milk container “made of plastic.” EX1010, [0069] (“like the cover 6”); [0050] (“the shell 6 is . . . rigid, and usually made of plastic”). Like the rigid shell components that are made of plastic, the milk container is made of plastic and likewise “rigid.” *Id.*; *see also*, EX1007, [0021] (“rigid”). A POSITA would have recognized, and found it obvious, from Khalil’s description, to

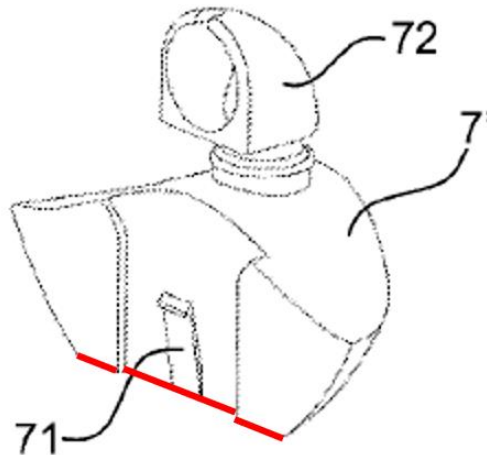
implement the milk container as a rigid material in order to provide a structurally stable outer contour of the breast pump device, and prevent compression of the volume of the milk container that could otherwise affect filling. *See also* EX1007, [0021].

k. 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.

203. In the Chang-Fang-Yuen-Khalil combination, the milk container is configured to attach to a lower part of the pump housing (e.g., “chassis 35”), in accordance with Khalil’s suggestions, as I discussed above (Section IX.B.1 (Chang-Fang-Yuen-Khalil combination)). For example, Khalil describes complementary mating features between the milk container and the pump housing. EX1010, [0069]. The milk container is releasably attachable with a lower part of the pump housing via these complementary mating features. *Id.* Specifically, Khalil describes that “[a] locking lug 71 is integrally formed on this milk collection container 7” and can engage in a corresponding recess of the shell ring 6’. *Id.* In this way, the milk collection container 7 is connected releasably to the shell ring 6’.

204. The container forms a flat bottomed base for the device, consistent with Khalil’s suggestion. EX1010, FIGS. 10-11. A POSITA would have recognized from Khalil’s description, that when the milk container forms a base of the device, a flat

bottom promotes stability and beneficially facilitates an upright orientation of the container (e.g., preventing spillage when disassembled).

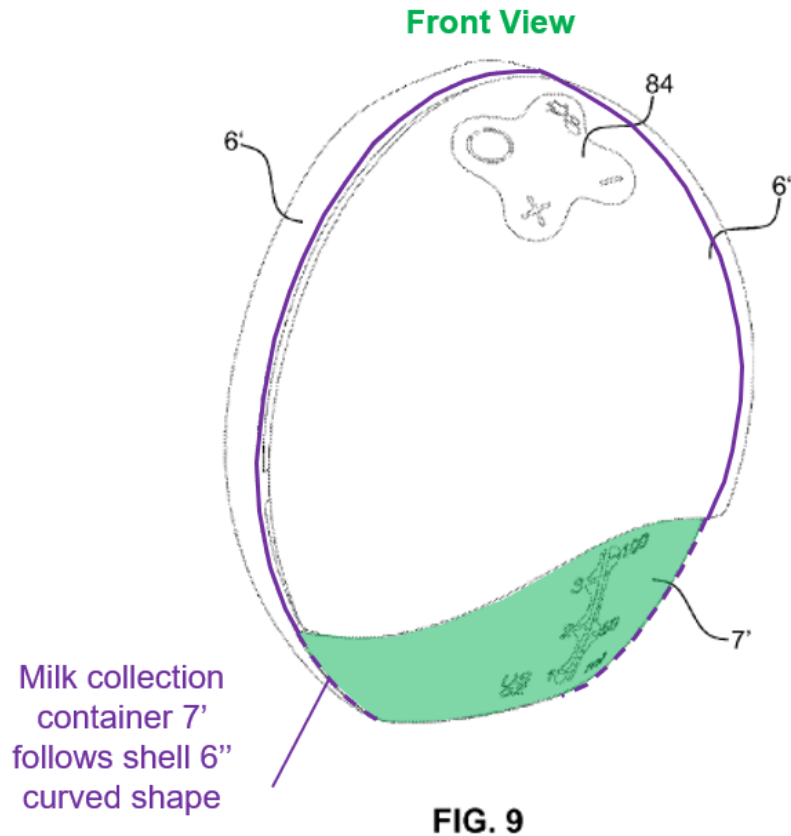


EX1010, FIG. 11 (partial, annotated)

- I. **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.**

205. The Chang-Fang-Yuen-Khalil device system provides the features of claims 10 and 36. For example, the outer surface of the milk container is shaped to continue a curved shape of the pump housing (e.g., “shell 12”) so that the breast pump device can be held comfortably inside a bra, consistent with the configurations described by Chang and Khalil and furthering their express objectives of a wearable, in-bra device. Khalil describes 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.”

EX1010, [0032], [0070]; EX1007, [0004], [0011], [0019], [0071]. To achieve such design goal, Khalil describes a milk container (green) in a curved shape that continues the curved shape of the pump housing.



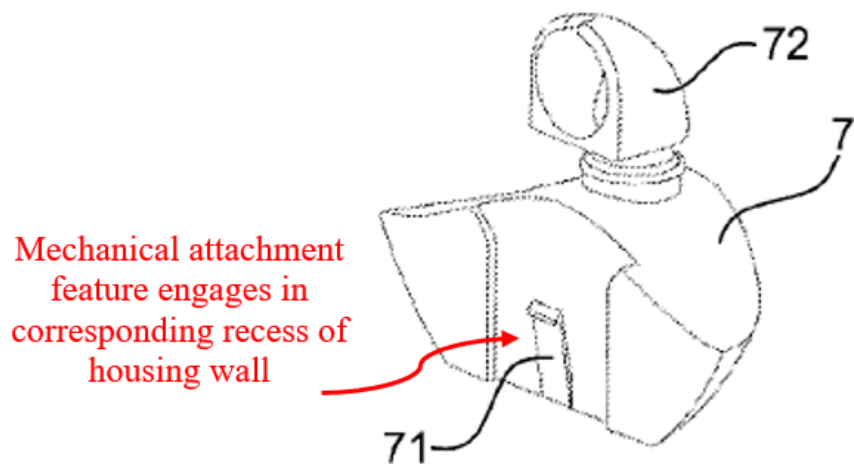
EX1010, FIG. 9 (annotated).

- m. **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.**

206. In the Chang-Fang-Yuen-Khalil combination, the milk container is attachable to the pump housing/housing (e.g., “chassis 35”) with a mechanical or

magnetic mechanism that releasably attaches or latches, as I discussed above regarding Claim 9 in Ground 1B. For example, Khalil describes a locking lug of the milk container that engages in a corresponding recess of the pump housing. *See*, EX1010, [0069]. Khalil also describes that “[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” *Id.* In this way, the milk collection container 7 is connected releasably to the shell ring 6.’

207. I note that a POSITA would have recognized, and found obvious from Khalil, that the milk container releasably attaches with a single push action into engagement with the housing (e.g., “chassis 35”), predictably facilitating assembly by the user, based on the attachment suggested by Khalil. *Id.* Such a mechanism would have facilitated attachment with a single push action to bring the complementary features into engagement.



EX1010, FIG. 11 (partial, annotated)

- n. 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].**

208. The Chang-Fang-Yuen-Khalil combination makes these claims obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claims 13 and 39 in Ground 1A. I note further, in the predictable Chang-Fang-Yuen-Khalil combination, the diaphragm likewise prevents passage of milk into the pump, and thus defines a milk-flow side chamber on one side of the diaphragm (e.g., below the diaphragm) and an air-side chamber on the other side of the diaphragm (e.g., above the diaphragm). EX1009, [0004]; *see* Section IX.B.1 (Chang-Fang-Yuen-Khalil combination).

- o. 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].**

209. In the combined system, the diaphragm/membrane (e.g., “elastic diaphragm”) is configured to self-seal under negative pressure around its outer edge (e.g., without adhesive or moisture), for reasons similar to those discussed above regarding the Chang-Fang-Yuen device for Claims 14 and 40. EX1009, [0004], FIG. 7; EX1001, 6:25-28. The Chang-Fang-Yuen-Khalil device would have likewise

enabled self-sealing between edge of diaphragm and flange of recess in the pump housing, as suggested by Fang's Figure 7 (below).

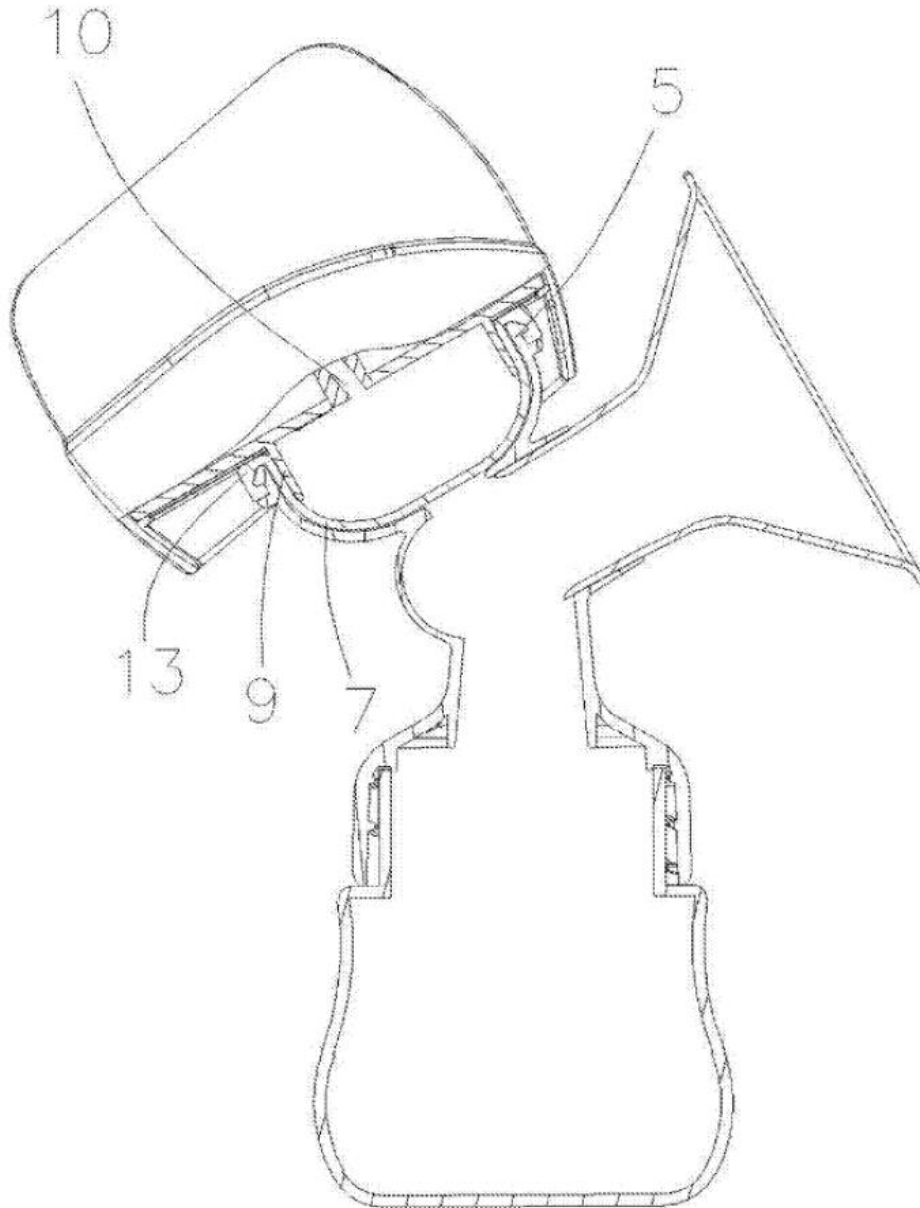


FIG. 7

EX1009, FIG. 7

As suggested in Fang's Figure 7 above, suction created during pumping causes the elastic diaphragm 7 to be pulled more tightly against the diaphragm housing elements. This increased pressure enhances the friction between the diaphragm and the housing, establishing sealing any potential gaps and preventing air or fluid from leaking, thereby maintaining the necessary vacuum for efficient milk expression. Such sealing forms a watertight and airtight seal around the recess or cavity in the pump housing, thereby preventing passage of milk and providing for generating of negative pressure.

- p. **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.**

210. The Chang-Fang-Yuen-Khalil combination renders claim 15 obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claim 15 in Ground 1A; *see also* Analysis of Claims 13 and 39 in Ground 1B.

- q. 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.**

211. The Chang-Fang-Yuen-Khalil combination renders claim 16 obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. See Analysis of Claim 16 in Ground 1A.

- r. 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.**

212. The Chang-Fang-Yuen-Khalil combination renders claim 15 obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. See Analysis of Claim 17 in Ground 1A.

- s. 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.**

213. The Chang-Fang-Yuen-Khalil combination renders claim 18 obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen.

- t. 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.**

214. The Chang-Fang-Yuen-Khalil combination renders claim 19 obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. See Analysis of Claim 19 in Ground 1A.

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

215. The Chang-Fang-Yuen-Khalil combination renders claim 20 obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claim 20 in Ground 1A. To be clear, in the combined Chang-Fang-Yuen-Khalil system, the second diaphragm housing is connected to the breast shield (e.g., above the nipple tunnel). Here again, a POSITA would have found it obvious to integrally connect the second diaphragm housing with the breast shield components as a matter of design choice. Indeed, there were a finite number of options for connecting the second diaphragm housing with the breast shield (i.e., integral or non-integral), and a known design need addressed by integral connection. For example, a POSITA would have readily recognized that forming the second diaphragm housing as an integral part of the breast shield would have promoted cleaning and facilitated assembly/disassembly by reducing part count and an associated connection.

v. 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.

216. The Chang-Fang-Yuen-Khalil combination renders claim 21 obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claim 21 in Ground 1A.

- w. **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.**

217. The Chang-Fang-Yuen-Khalil combination renders claim 22 obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. See Analysis of Claim 22 in Ground 1A.

- x. **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.

218. The Chang-Fang-Yuen-Khalil combination renders these claims obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. See Analysis of Claims 23 and 41 in Ground 1A.

- y. **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].**

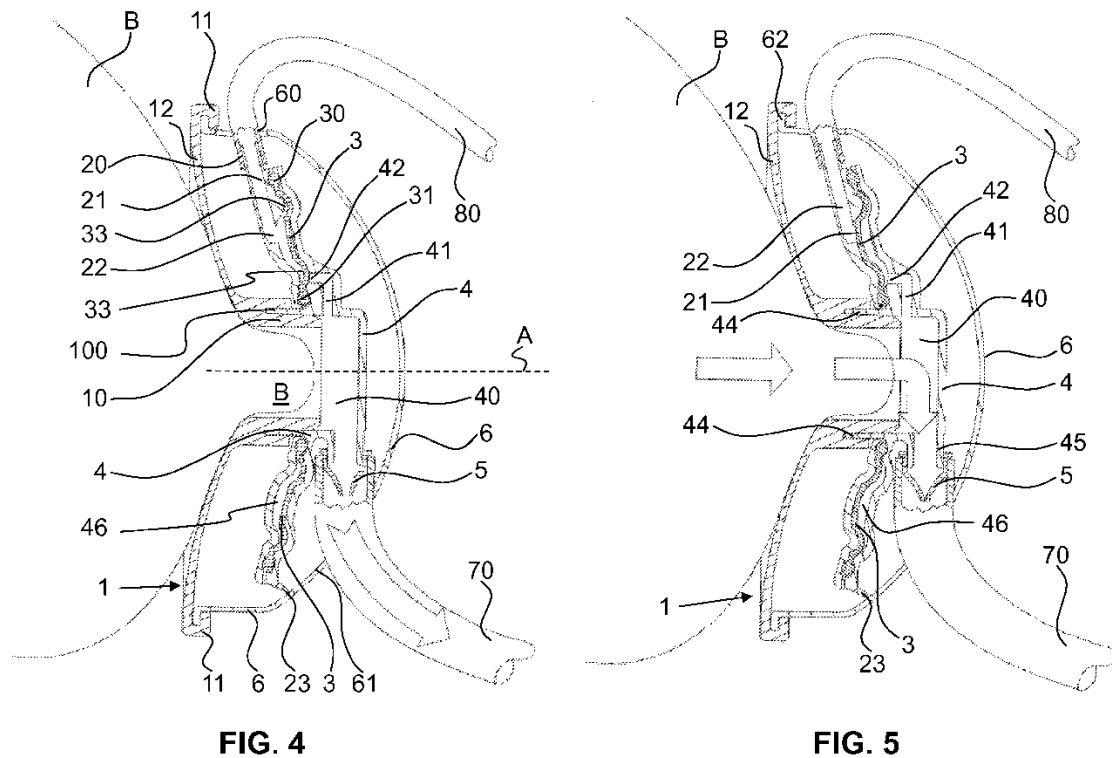
219. The Chang-Fang-Yuen-Khalil combination renders these claims obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. See Analysis of Claims 11 and 37 in Ground 1A.

- z. 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.**

220. In the resulting combination, the breast pump device includes an integrated milk container at a lower location of the device such that expressed milk flows under gravity through an opening in the nipple tunnel and into the milk container, in accordance with Fang and Khalil's suggestions. In particular, in accordance with Khalil's suggestion, milk flows into the container through a one-way "duckbill valve." EX1010, [0053] ("non-return valve 5"/"duckbill valve"), [0069].

221. The "duckbill valve" 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. During pumping, an overpressure is generated that opens the

“duckbill” valve and facilitates milk flow into the container. EX1010, FIGS. 4-5.



EX1010, FIGS. 4, 5

As shown above, the “duckbill” valve is closed when subjected to under pressure, sealing off the milk collection container. Khalil describes this configuration in [0058]:

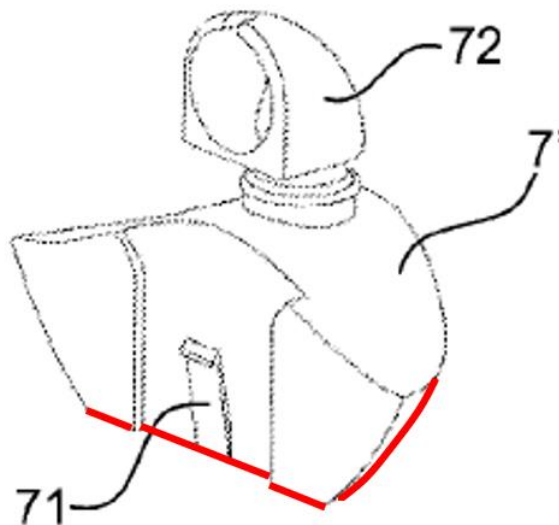
The pump-side opening 22 leads to the vacuum line 80 via a vacuum channel 21, which ends in a port 20. The breast-side opening 42 leads to an underpressure chamber 40 via a connecting channel 41. This underpressure chamber 40 is limited by the membrane housing part 4 facing away from the breast and is open in the direction of the breast interface 1. The underpressure chamber 40 has a milk port 45, which is preferably arranged at that end of the underpressure chamber

40 remote from the connecting channel 41. The non-return valve 5 is arranged in this milk port 45. When there is an overpressure in the vacuum chamber 40 relative to the atmospheric pressure, the non-return valve 5 opens and establishes a connection to the milk line 70. When there is an underpressure in the vacuum chamber 40, the non-return valve 5 closes and thus interrupts the connection to the milk line 70. The non-return valve 5 can be fixedly connected to the milk port 45 or to the milk line 70.

EX1010, [0058].

aa. 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.

222. As I discussed above (Analysis of Claim 10 in Ground 1B), the milk container in the Chang-Fang-Yuen-Khalil combination has a curved surface. The curved surface includes a flat area that serves as a base for the milk container. *See also*, Analysis of Claim 9 in Ground 1B. This configuration is shown in FIG. 11 of Khalil, for example.



EX1010, FIG. 11 (partial, annotated)

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

223. The Chang-Fang-Yuen-Khalil combination renders these claims obvious for the same reasons discussed above for the combination of Chang, Fang, and Yuen. *See* Analysis of Claims 10 and 36.

C. Ground 1C: Obviousness of Claims 12, 24, 38, and 42 Based On The Combination of Chang, Fang, Yuen, Khalil, and Park

1. Combination of Chang, Fang, Yuen, Khalil, and Park

224. A POSITA would have been motivated to combine Chang, Fang, Yuen, and Park for the reasons discussed below. As I discussed above, Fang and Khalil describe known pump configurations that utilize a flexible diaphragm and a milk flow path through a nipple tunnel and into a container below via gravity. Park provides suggestions for diaphragm shape and positioning a milk outlet on a lower surface of a nipple tunnel, which complements these teachings in Fang and Khalil, to achieve known advantages. For example, a POSITA would have recognized that the teachings of Park would have helped prevent milk backflow and ensure efficient milk collection. Based on Park's suggestions, expressed milk flows naturally downward into the collection container via gravity. Such a design can improve milk flow efficiency and reduces the risk of milk backflow into the pump mechanism,

which could lead to contamination or reduced performance. Based on these advantages, a POSITA would have been motivated to incorporate the teachings of Park into the Chang-Fang-Yuen-Khalil device.

225. In the resulting system, a diaphragm/membrane has a contoured shape having a central raised portion and a concentric raised portion, and the nipple tunnel includes an opening on a lower surface for milk to pass through via gravity, in accordance with Park's suggestions. This shape would have enhanced suction through use of the central raised portion to create a more focused area of suction. The shape also allows for better movement of the diaphragm during the pumping cycle. Beyond these advantages, a POSITA would have also looked to incorporate Park's suggestions when implementing the Chang-Fang-Yuen-Khalil device for various reasons.

226. One reason is that Park's suggestions would have provided a mechanism for achieving predictable and controlled flexing of the diaphragm (e.g., Fang's elastic diaphragm"). Park further provides an example of a diaphragm having, in a relaxed state inner and outer raised areas. A POSITA would have recognized from Park that the diaphragm provides a springy and structurally stiff diaphragm. Such characteristics promote quick return to a neutral or relaxed state when pressure is released, which drives out milk and air during each cycle. A diaphragm according to Park's suggestions would have thus been recognized as

enhancing overall system performance and efficiency in the Chang-Fang-Yuen-Khalil device.

227. Another reason a POSITA would have looked to combine Park with the Chang-Fang-Yuen-Khalil combination is to include an opening in the lower surface of the nipple tunnel for the milk flow path. The milk path already flows downward via gravity into a container positioned below the pump housing, as I discussed regarding the Chang-Fang-Yuen-Khalil device. A POSITA would have recognized that a lower opening on the nipple tunnel provides a path for the milk to flow into the container in a known configuration that promotes assembly/disassembly and cleaning, as expressly suggested by Park. EX1014, [8] (“is capable of preventing breast milk from flowing backward, and is easily cleaned and maintained.”). A POSITA would have additionally recognized advantages of facilitating a horizontally compact design by positioning an opening on the lower surface (e.g., versus an extended space to accommodate passage at a lateral end of the nipple tunnel).

228. As a further reason, I note that a POSITA would have also been motivated to combine Park and Chang-Fang-Yuen-Khalil because the combination would have involved a known technique—Park’s diaphragm shape and lower nipple tunnel opening—with known systems having downward milkflow to a lower container. The combination would have provided predictable results, including the

improvements and advantages discussed above in association with the diaphragm shape suggested by Park. The modifications would have represented a simple modification to use known diaphragm and nipple tunnel features. A POSITA would have had a reasonable expectation of success in making the proposed modifications based on the similarity of the devices and because the modifications would have been implemented largely through straightforward mechanical modifications that do not significantly alter the underlying device.

2. Claim Analysis

- a. **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.**

229. In the resulting system, 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, in accordance with Park's suggestions. See Section IX.C.1 (Chang-Fang-Yuen-Khalil-Park combination); EX1014, [37]-[38].

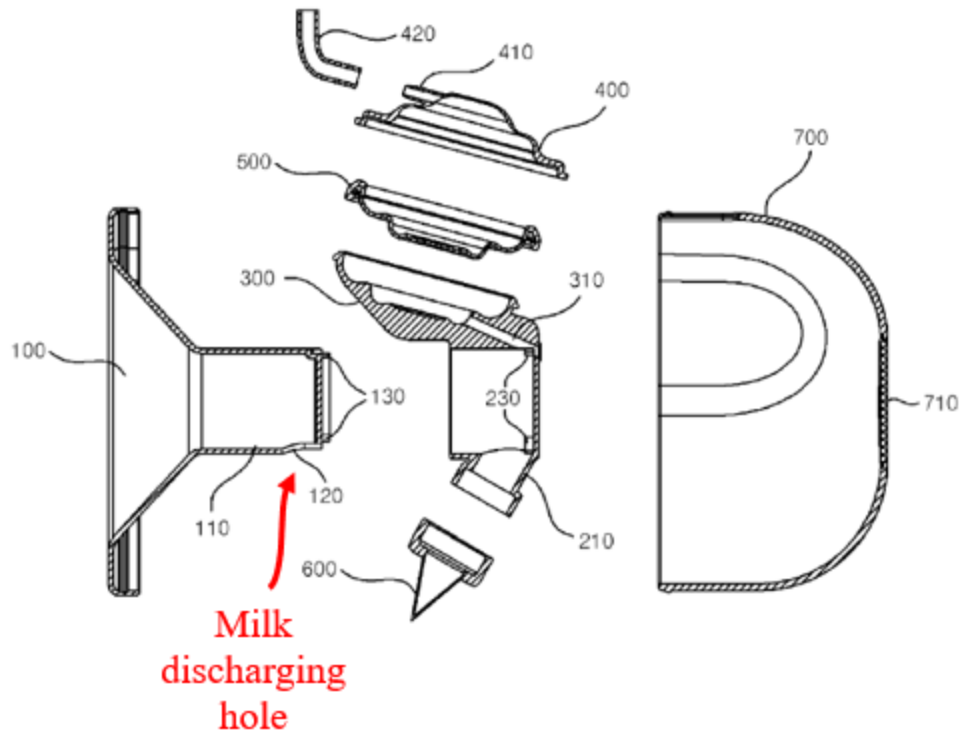
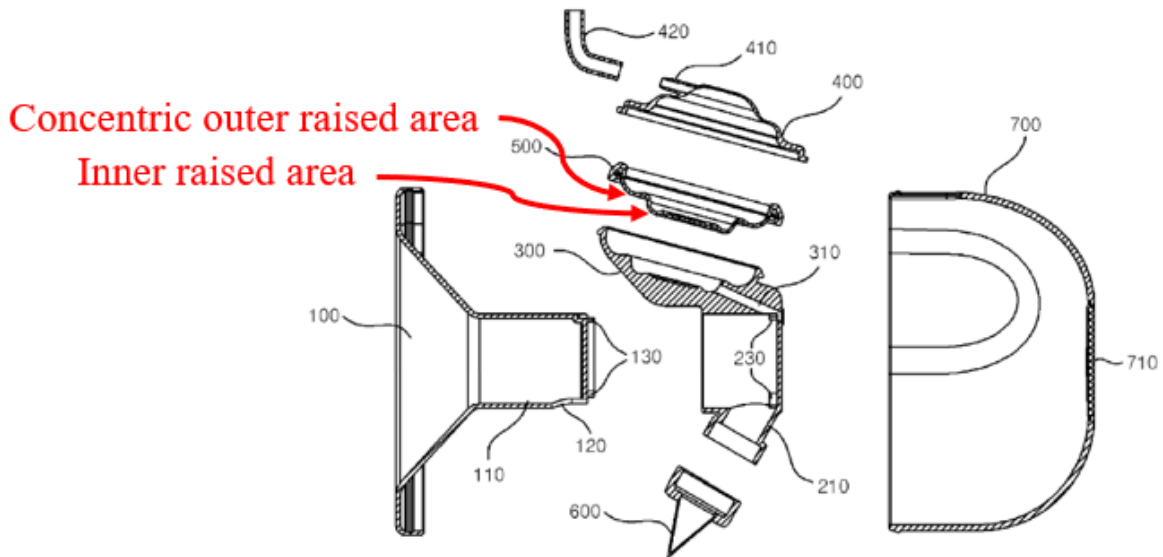


FIG. 5

EX1014, FIG. 5 (annotated)

- b. **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.**

230. The resulting combination includes a diaphragm/membrane that is flexible and generally circular. See Analysis of Claims 24, 42 in Ground 1A. In a relaxed state, the diaphragm includes an inner raised area and a concentric outer raised area, in accordance with Park's suggestions. See Section IX.C.1 (Chang-Fang-Yuen-Khalil-Park combination).



EX1014, FIG. 5 (annotated)

D. Ground 1D: Obviousness of Claim 20 Based On The Combination of Chang, Fang, Yuen, Khalil, and Chen

1. Combination of Chang, Fang, Yuen, Khalil, and Chen

231. A POSITA would have been motivated to combine Chang, Fang, Yuen, Khalil, and Chen for the reasons discussed below. As I discussed above, Chen describes a breast pump device where the diaphragm housing is integrally molded with a breast shield component. EX1015, [0015] (“integrally molded to make disassembly and assembly more convenient.”); FIGS. 2-4 (“2-support”). Based on this suggestion, a POSITA would have implemented the breast shield and second diaphragm housing in the Chang-Fang-Yuen-Khalil device to be integral parts. As

discussed in §IX.B.1, the Chang-Fang-Yuen-Khalil device already includes a second diaphragm housing attached with the breast shield (e.g., above the nipple tunnel). *See* Analysis of Claim 15 in Ground 1B; EX1009, Fig. 7, [0019]-[0025]. When the Chang-Fang-Yuen-Khalil device is implemented based on the suggestions in Chen, the second diaphragm housing and breast shield would have their existing configuration/location according to Chang-Fang-Yuen-Khalil, and would be integrally formed.

232. A POSITA would have been prompted to combine Chen with Chang-Fang-Yuen-Khalil in order to obtain the express benefit of integral parts described by Chen. For example, Chen indicates that such integral parts can “make disassembly and assembly more convenient.” EX1015, [0015]. A POSITA would have been motivated to integrally form the breast shield and second diaphragm housing as a single part to provide this benefit in the Chang-Fang-Yuen-Khalil system. Relatedly, a POSITA would have recognized such combination to facilitate cleaning. Here again, a POSITA would have recognized from Chen’s express teachings the benefit of enhanced cleanability due to fewer interfaces between parts, and more a more streamlined cleaning process (e.g., due to fewer parts to assemble/disassemble during cleaning).

233. A POSITA would have additionally been prompted to implement Chen’s suggestion in the Chang-Fang-Yuen-Khalil combination because the

combination would have amounted to implementing the known technique of Chen's suggestion for an integral diaphragm housing and breast shield component to a known system that includes a diaphragm housing attached to a breast shield. The combination would have been predictable, and provided the benefits I noted above as suggested by Chen. I noted further that a POSITA would have had a reasonable expectation of success, especially in view of the similarity of the systems, and that Chen expressly teaches that such components be integrally formed.

2. Claim Analysis

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

234. In the Chang-Fang-Yuen-Khalil-Chen device, the second diaphragm housing is an integral part of the breast shield, in accordance with Chen's suggestion. EX1015, [0015]; See Section IX.D.1 (Chang-Fang-Yuen-Khalil-Chen combination).