

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Jonathan O'Toole et al.
U.S. Patent No.: 11,813,381 Attorney Docket No.: 58498-0004IP1
Issue Date: November 14, 2023
Appl. Serial No.: 17/203,292
Filing Date: March 16, 2021
Title: BREAST PUMP SYSTEM

Mail Stop Patent Board

Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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: February 3, 2025

By: /Ryan Bauer/
Ryan Bauer

I.	BACKGROUND AND QUALIFICATIONS.....	6
A.	Educational Background.....	6
B.	Professional Experience.....	6
II.	MATERIALS CONSIDERED	7
III.	LEVEL OF ORDINARY SKILL IN THE ART	9
IV.	TECHNOLOGY BACKGROUND.....	10
V.	THE '381 PATENT	21
A.	Specification.....	21
B.	Claims	26
C.	Prosecution History.....	31
VI.	RELEVANT LEGAL STANDARDS	41
VII.	CLAIM INTERPRETATION.....	45
VIII.	PRIOR ART	45
A.	Chang (EX1007)	45
B.	Fang (EX1009).....	50
C.	Khalil (EX1010).....	52
D.	Yuen629 (EX1011).....	56
E.	Makower794 (EX1014)	58
F.	Guthrie002 (EX1015)	61
G.	Kurihara (EX1016).....	63
IX.	THE CLAIMS OF THE '381 PATENT ARE OBVIOUS.....	65
A.	Ground 1A: Obviousness of Claims 1-13, 16, 17, 22, 23, 27, and 29 Over Chang-Fang	67
1.	Combination of Chang and Fang.....	67
2.	Claim Analysis.....	73
B.	Ground 1B: Obviousness of Claim 19 Over Chang-Fang- Yuen629	117
1.	Combination of Chang, Fang, and Yuen629	117

2. Analysis.....	119
C. Ground 1C: Obviousness of Claim 24 Over Chang-Fang-Makower794	122
1. Combination of Chang, Fang, and Makower794.....	122
2. Claim Analysis.....	124
D. Ground 1D: Obviousness of Claim 25 Over Chang-Fang-Makower794-Guthrie002.....	126
1. Combination of Chang, Fang, Makower794, and Guthrie002	126
2. Claim Analysis.....	128
E. Ground 2A: Obviousness of Claims 1-13, 16, 17, 22, 23, And 26-29 Over Chang-Fang-Kurihara.....	131
1. Combination of Chang, Fang, and Kurihara.....	131
2. Claim Analysis.....	134
F. Ground 3A: Obviousness of Claims 1-18, 20-23, 27, And 29 Over Chang-Fang-Khalil.....	136
1. Combination of Chang, Fang, and Khalil.....	136
2. Claim Analysis.....	144
G. Ground 4A: Obviousness of Claims 1-18, 20-23, 26-29 Over Chang-Fang-Khalil-Kurihara	162
3. Claim Analysis.....	163
H. Grounds 2B, 3B, 4B: Obviousness of Claim 19 Over Yuen629 in view of Chang-Fang-Kurihara (Ground 2B), Chang-Fang-Khalil (Ground 3B), and Chang-Fang-Khalil-Kurihara (Ground 4B)	164
1. Combination of Chang-Fang-Kurihara-Yuen629 (Ground 2B), Chang-Fang-Khalil-Yuen629 (Ground 3B), and Chang-Fang-Khalil-Kurihara-Yuen629 (Ground 4B)	164
2. Claim Analysis.....	164
I. Grounds 2C, 3C, 4C: Obviousness of Claim 24 Over Chang-Fang-Kurihara-Makower794 (Ground 2C), Chang-Fang-Khalil-Makower794 (Ground 3C), and Chang-Fang-Khalil-Kurihara-Makower794 (Ground 4C)	166

1.	Combination of Chang-Fang-Kurihara-Makower794 (Ground 2C), Chang-Fang-Khalil-Makower794 (Ground 3C), and Chang-Fang-Khalil-Kurihara-Makower794 (Ground 4C).....	166
2.	Claim Analysis.....	166
J.	Ground 2D, 3D, 4D: Obviousness of Claim 25 Over Chang-Fang-Kurihara-Makower794-Guthrie002 (Ground 2D), Chang-Fang-Khalil-Makower794-Guthrie002 (Ground 3D), and Chang-Fang-Khalil-Kurihara-Makower794-Guthrie002 (Ground 4D).....	167
1.	Combination of Chang-Fang-Kurihara-Makower794-Guthrie002 (Ground 2D), Chang-Fang-Khalil-Makower794-Guthrie002 (Ground 3D), and Chang-Fang-Khalil-Kurihara-Makower794-Guthrie002 (Ground 4D).....	167
2.	Claim Analysis.....	167

LIST OF EXHIBITS

Exhibit	Reference
1001	U.S. Patent No. 11,813,381 to Jonathan O'Toole et al. ("the '381 Patent")
1002	File History of Application 17/203,292 ("the File History")
1004	File History of Application No. 16/009,547
1005	File History of Application No. 17/181,057 (as of October 2, 2024)
1007	U.S. Patent Application Publication No. 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 No. 2013/0023821 ("Khalil")
1011	U.S. Patent No. 7,641,629 ("Yuen629")
1012	PCT Publication No. WO 2016/186452 ("Park KR")
1013	Certified English Translation of PCT Publication No. WO 2016/186452 ("Park")
1014	U.S. Patent Application Publication No. 2016/0206794 ("Makower794")
1015	U.S. Patent No. 10,483,002 ("Guthrie002")
1016	U.S. Patent Application Publication No. 2016/0271305 ("Kurihara")
1031	AU Patent Application Publication No. 2010300058 ("Weber")
1032	U.S. Patent Application Publication No. 2017/0080135

Exhibit	Reference
	(“Chen”)
1033	U.S. Application Publication No. 2015/0217033 (“Pollen”)
1034	U.S. Application Publication No. 2012/0116299 (“Tack”)
1035	U.S. Patent Application Publication No. 2016/0082166 (“Guthrie166”)
1036	U.S. Application Publication No. 2015/0157775 (“Hu”)
1037	PCT Publication No. WO 2002/102437 (“Myers437”)
1038	PCT Publication No. WO 2008/137678 (“Myers678”)
1039	U.S. Patent Application Publication No. 2007/0219486 (“Myers486”)
1054A	Elvie’s Disclosure of Asserted Claims and Initial Infringement Contentions Under Local Patent Rule 120, <i>Shenzhen Root Technology Co., Ltd., v. Chiaro Technology, Ltd.</i> , Case No. 23-cv-00631 (W.D. Wash.), served 6/10/2024
1054B	Elvie’s Disclosure of Asserted Claims and Supplemental Infringement Contentions Under Local Patent Rule 120, <i>Shenzhen Root Technology Co., Ltd., v. Chiaro Technology, Ltd.</i> , Case No. 23-cv-00631 (W.D. Wash.), served 8/1/2024
1054C	Exhibit 15 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product, <i>Shenzhen Root Technology Co., Ltd., v. Chiaro Technology, Ltd.</i> , Case No. 23-cv-00631 (W.D. Wash.), served 6/10/2024

I, Ryan Bauer, hereby declare:

I. BACKGROUND AND QUALIFICATIONS

1. I have been retained by Shenzhen Root Technology Co., Ltd. (“Shenzhen” or “Petitioner”) to provide my opinions regarding claims 1-29 of U.S. Patent 11,813,381 (“the ’381 Patent,” EX1001).

2. A copy of my current curriculum vitae is submitted herewith, 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 Requester 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 ’381 patent. Based on my education and experience, I was at the time the

earliest priority application leading to the '381 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 '381 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 1-29 ("Challenged Claims") of the '381 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 ’381 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 ’381 patent is June 15, 2017 (“Critical Date”). 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 may 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 (EX1033) [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 (EX1031), 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 (EX1010) [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 (EX1034) [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 (EX1036) [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 '381 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.*, EX1032, 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 (EX1034) 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.*, Myers437 (EX1037) at Figs.

20A and 20B, [0044]; Myers678 (EX1038) at Fig. 1, pp. 12-13; and Guthrie166 (EX1035) 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 '381 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:

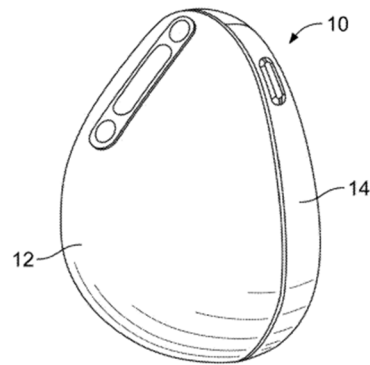


FIG. 1A

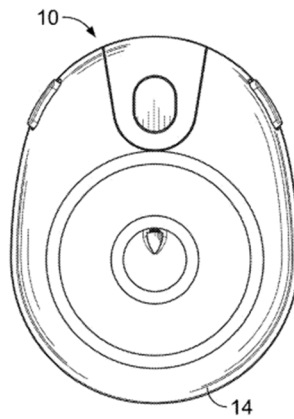


FIG. 1B

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.

37. Independent claim 1 of the '381 patent is directed to a “self-contained, in-bra wearable device.” *See* EX1001, 71:45-60. Such devices, which are worn and held entirely in a bra, were well-known in the prior art, as acknowledged by the '381 patent. *See, e.g., id.* at 2:7-17 (“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 2:45-59 (“A further integrated wearable breast pump system is shown in [Khalil]”).

V. THE '381 PATENT

A. Specification

38. The '381 patent is entitled "Breast Pump System." It generally discloses a breast pump that is wearable inside a bra. EX1001, 3:66-4:4. The specification of the '381 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 ("Makower794"):

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., 2:7-17.

39. The '381 patent states that Makower794'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 2:7-59 The '381 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 '381 patent purports to overcome such disadvantages. *Id.*

40. The '381 patent claims are generally directed to “a self-contained, in-bra wearable” breast pump device with a pump housing, a pump powered by a battery, a breast shield, a milk container, and a diaphragm (or membrane) that defines a recess or cavity with a diaphragm housing/external surface of the pump housing and deforms in response to changes in air pressure caused by the pump. EX1001, claim 1 (“a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge”).

41. The '381 patent specification describes that the breast shield engages with the user's breast. EX1001, 5:58-65. 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.*, 5:48-5:65. The breast shield and milk container are “directly removable or attachable from the housing.” *E.g., id.*, 5:66-6:15.

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:

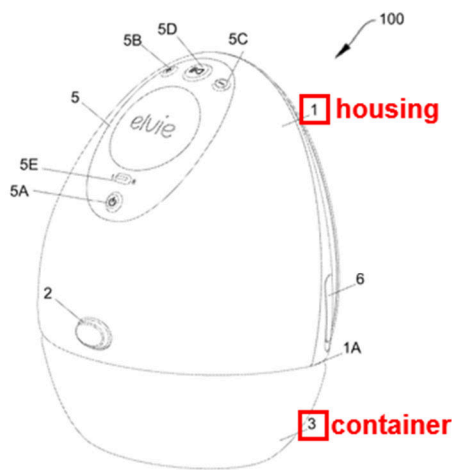


FIGURE 1

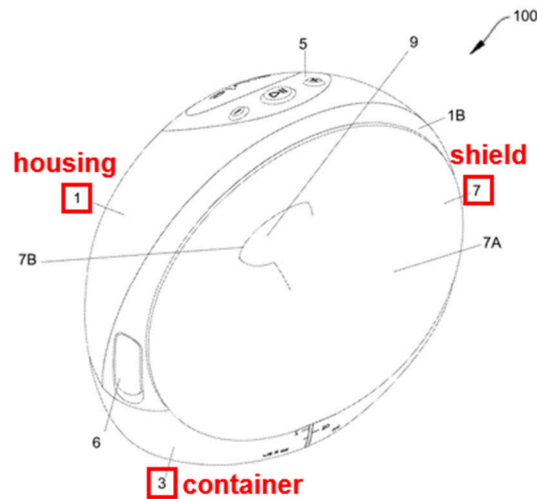


FIGURE 2

EX1001, Figs. 1, 2 (annotated), 5:66-6:15, 6:25-32

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.*, 8:65-9:9 (“The breast shield 7 is designed to engage with the user’s breast, and comprises a concave inner flange 7A which contacts the breast.”), 9:36-47 (“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.*, 9:48-62.

44. The '381 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. EX1001, 10:35-44, 11:10-17. Front and rear exploded views of the '381 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:

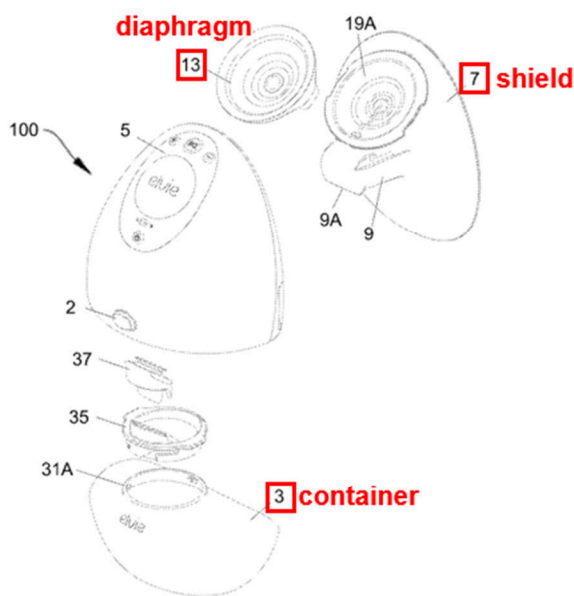


FIGURE 5

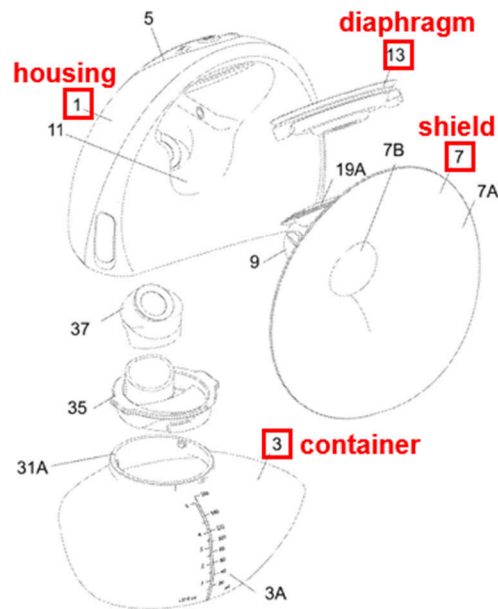


FIGURE 6

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.*, 10:35-44, 11:27-48. 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:

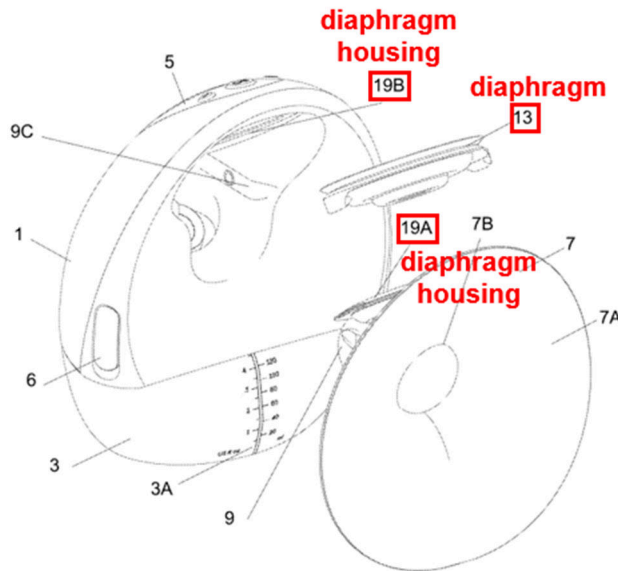


FIGURE 4

EX1001, Fig. 4 (annotated), 11:27-32

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 '381 patent were not new. Instead, prior art references, such as Chang, Fang, Kahlil, Yuen629, Makower794, Guthrie002, and Kurihara, demonstrate that the recited breast pump was known. Fang, for example, confirms that use of a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge. Chang also describes a breast shield with a breast flange and a nipple tunnel, where the nipple tunnel includes a closed end and a milk port intermediate to the breast flange. These features were known options for implementing a

diaphragm in a breast pump, as demonstrated by the combinations of Chang-Fang and Chang-Fang-Khalil.

B. Claims

47. The '381 patent has 29 claims, with claim 1 being independent claim.

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[a][1]	a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge;
1[a][2]	a housing that includes:
1[a][2][i]	a battery, and
1[a][2][ii]	the air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;
1[a][3]	a breast shield comprising a breast flange and a nipple tunnel extending from the breast flange,
1[a][3][i]	the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and
1[a][3][ii]	the breast shield being separate from the diaphragm; and
1[a][4]	a milk container that is configured to attach to the housing and receive expressed milk via the milk port.

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 integrates the breast flange and nipple tunnel as a one-piece item.
Claim 5	
[5]	The breast pump device of claim 1, wherein the breast flange and the nipple tunnel are a single, integral item with no joining stubs.
Claim 6	
[6]	The breast pump device of claim 1, wherein the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use.
Claim 7	
[7]	The breast pump device of claim 1, wherein the breast shield is configured to slide in and out from the housing, together with the diaphragm, on guide members in the breast shield.
Claim 8	
[8]	The breast pump device of claim 1, wherein the housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Claim 9	
[9]	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 housing in normal use or normal dis-assembly.
Claim 10	
[10]	The breast pump device of claim 1, wherein the diaphragm is substantially circular and is configured to self-seal under the negative air pressure to a substantially circular diaphragm holder that is part of the housing.
Claim 11	
[11]	The breast pump device of claim 1, wherein the diaphragm is a membrane, and the diaphragm deforms in response to changes in air pressure caused by the air pump to create negative air pressure in the nipple tunnel.
Claim 12	
[12]	The breast pump device of claim 1, wherein the diaphragm is removable from a diaphragm holder that sits above the breast flange and the nipple tunnel.
Claim 13	
[13]	The breast pump device of claim 1, wherein the milk container is substantially rigid.
Claim 14	
[14]	The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the housing and to form a flat bottomed base for the breast pump device.

Claim 15	
[15]	The breast pump device of claim 1, 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 the bra.
Claim 16	
[16]	The breast pump device of claim 1, wherein the milk container includes a flexible valve that self-seals under negative air pressure against the milk port in the nipple tunnel and that permits the expressed milk to flow into the milk container.
Claim 17	
[17]	The breast pump device of claim 1, 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 18	
[18]	The breast pump device of claim 1, wherein the milk container includes a cap that is removable from the milk container and a removable valve that enables milk to pass into the milk container in one direction.
Claim 19	
[19]	The breast pump device of claim 1, wherein a top of the milk container includes an optically clear region that is aligned below one or more light emitters positioned in a base of the housing.
Claim 20	
[20]	The breast pump device of claim 1, wherein the milk container is wider than the milk container is tall.

Claim 21	
[21]	The breast pump device of claim 1, wherein the nipple tunnel includes on a lower surface the milk port through which the expressed milk flows under gravity into the milk container.
Claim 22	
[22]	The breast pump device of claim 1, wherein the housing includes a wireless data communication system powered by the battery.
Claim 23	
[23]	The breast pump device of claim 1, wherein the housing has a front surface that is configured to fit inside a bra and to contact an inner surface of the bra, and a rear surface that is shaped to contact, at least in part, the breast shield.
Claim 24	
[24]	The breast pump device of claim 1, wherein the housing includes at least one of a visual or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.
Claim 25	
[25]	The breast pump device of claim 1, wherein the housing includes at least one of a visual or haptic indicator that indicates if the air pump is operating correctly to pump milk, based on whether a quantity or a height of liquid in the milk container above a base of the milk container is increasing above a threshold rate of increase.
Claim 26	
[26]	The breast pump device of claim 1, wherein the air pump comprises a piezo air pump system.
Claim 27	
[27]	The breast pump device of claim 1, wherein a total mass of the breast pump device, unfilled with milk, is less than 250 gm.

Claim 28	
[28]	The breast pump device of claim 1, wherein the breast pump device makes less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.
Claim 29	
[29]	The breast pump device of claim 1, wherein the air pump is configured to generate negative air pressure with a maximum suction of approximately 240 mmHg.

C. Prosecution History

48. The '381 patent issued from Application 17/203,292 ("292 application"; EX1002) filed on 3/16/2021, which is a continuation of Application 17/181,057 ("057 application"; EX1005), which is a continuation of Application 16/009,547 ("547 application"; EX1004). The '547 application claims priority GB Application No. 1709561.3 (filed 6/15/2017), GB Application No. 1709564.7 (filed 6/15/2017), GB Application No. 1709566.2 (filed 6/15/2017), and GB Application No. 1809036.5 (filed 6/1/2018). The earliest date to which the '381 patent claims priority is 6/15/2017. The '381 patent has one independent claim, claim 1. The claims were allowed after three Office Actions. *See* EX1002, 474-567 (Non-Final Office Action dated 6/24/2021), 811-34 (Final Office Action dated 11/23/2021), 1103-69 (Non-Final Office Action dated 7/12/2022).

49. In the Office Action dated 6/21/2021, the examiner did not include any prior art rejections over the original claims. EX1002, 474-567. The examiner noted the following in identifying allowable subject matter:

Allowable Subject Matter

Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), 2nd paragraph, set forth in this Office action and the double patenting rejections above.

The following is a statement of reasons for the indication of allowable subject matter: The closest piece of prior art is Khalil. Khalil does not teach or disclose a breast shield configured to slide out from the housing together with the diaphragm. The examiner notes that the term “together” is interpreted to mean that the breast shield and the diaphragm move at the same time and further notes that this interpretation appears consistent with Applicant’s specification (paragraph 82 discloses that the breast shield

holds the diaphragm and would, therefore, move with the diaphragm). Instead, Khalil discloses a substantially similar, self-contained, in-bra breast pump system (fig. 10) which comprises a breast shield (1 in fig. 11), a diaphragm (3 in fig. 11), and a housing (6' and 6" snap together to form a housing). Fig. 4 shows that the shield is engaged to the housing through a lip 11 and is capable of being removed from the housing. However, the diaphragm (3) is shown in fig. 10 to be positioned between the housing parts (6' and 6") so that the diaphragm holder pieces (2 and 4 in fig. 11) engage the vacuum pump (81 in fig. 11) through a hose (80 in fig. 10) and the milk container (7' in fig. 11). In order to remove the diaphragm from the housing, a user would need for first remove the breast shield from the housing in order to access the diaphragm through the opening in housing part 6' in order to disconnect the diaphragm from the vacuum pump for removal. For this reason, the diaphragm of Khalil is incapable of sliding together with the shield from the housing nor would a PHOSITA be motivated to modify the device of Khalil to perform this function.

EX1002, 564-65

50. In a response filed 9/24/2021, Applicant amended claim 1 to remove the feature the Examiner had identified as allowable. Applicant amended claim 1 as follows:

1. (Currently Amended) A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising and that includes:

(i) a housing that includes (a) a ~~rechargeable battery, and;~~ (b) ~~a power charging circuit for controlling the charging of the rechargeable battery;~~ (c) ~~control electronics powered by the rechargeable battery;~~ (d) (b) an air pump powered by the ~~rechargeable~~ battery and generating negative air pressure;

~~[[e)](ii)]~~ a diaphragm configured to prevent milk from reaching the pump ~~and seated in a diaphragm holder;~~

~~[[ii)](iii)]~~ a breast shield made up of a breast flange and a nipple tunnel and that is configured to slide out from the housing together with the diaphragm, ~~and the diaphragm is configured to be removable from a diaphragm holder for cleaning;~~ and

~~[[iii)](iv)]~~ a milk container that is configured to attach to the housing.

EX1002, 678

51. In the Office Action dated 11/23/2021, the examiner applied prior art rejections under anticipation and obviousness. EX1002, 811-34. Specifically, the examiner applied rejections of claims 1, 3-6, 8, 9, 13, 14, 23, 25, 31, and 32 under 35 U.S.C. § 102 by Myers (US 2008/027538). *Id.*, 814-18. The examiner also applied rejections of claim 10 under 35 U.S.C. § 103 over Myers in view of Miller (US 2016/0325031). *Id.*, 819-20. The examiner also applied rejections of claim 24 under 35 U.S.C. § 103 over Myers in view of Makower (US 2017/0072118). *Id.*, 820. Further, claims 26 and 27 were rejected under 35 U.S.C. § 103 over Myers in view of Makower⁷⁹⁴ (US 2016/0206794). *Id.*, 821-22. Claim 28 was also rejected under 35 U.S.C. § 103 over Myers in view of Takeuchi (US 2017/0043065). *Id.*, 822-23. Finally, claim 30 was rejected under 35 U.S.C. § 103 over Myers in view of Baker

(US 2009/0281485). *Id.*, 823. The examiner also identified allowable subject matter in claims 7, 12, and 15-22:

Allowable Subject Matter

Excepting for the double patenting rejections above, **claims 7, 12, and 15-22** would be allowable over the prior art of record.

Claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The closest piece of prior art is Myers. Myers does not teach or disclose the particulars of the aforementioned dependent claims. Specifically, as seen in figs. 9A/B, Myers does not teach a symmetrical breast shield. Myers teaches that the diaphragm is seated against a diaphragm holder (40 in fig. 5) but does not disclose that the diaphragm self-seals to the diaphragm holder. Additionally, Myers teaches that the container is a bag which hangs below the bra (fig. 1); as such, PHOSITA would not be motivated to modify the bag to be rigid, flat bottomed, or to fit inside a bra.

EX1002, 831-32

52. In a response filed 5/20/2022, Applicant amended claims 1, 3-10, and 12-32 without incorporating the features identified as allowable in claims 7, 12, 15-22, and 29. EX1002, 1081-93. Applicant further amended claim 1 as follows:

1. (Currently amended) A breast pump device ~~that is configured as a self-contained, in-bra wearable device, the breast pump device~~ comprising:
a self-contained, in-bra wearable device comprising:
a diaphragm configured to prevent milk from reaching the pump by forming a seal around its outer edge;
(i) —a housing that includes:
~~(a)~~ a battery, and
~~(b)~~ an air pump powered by the battery and configured to generate generating negative air pressure by driving the diaphragm;
(ii) —a diaphragm configured to prevent milk from reaching the pump;
(iii) —a breast shield comprising ~~made up of~~ a breast flange and a nipple tunnel and that is separate from the diaphragm ~~configured to slide out from the housing together with the diaphragm;~~ and
(iv) —a milk container that is configured to attach to the housing.

EX1002, 1082

53. In the Office Action dated 7/12/2022, the examiner applied prior art rejections under obviousness. EX1002, 1103-69. Specifically, the examiner applied rejections of claims 1, 3-7, 9, 12-14, 17-20, 22-25, and 31 under 35 U.S.C. § 103 by Khalil (US 2013/0023821) in view of Chang (US 2018/0333523). *Id.*, 1107-14. The examiner also applied rejections of claim 10 under 35 U.S.C. § 103 over Khalil, in view of Chang, and in further view of Miller (US 2016/0325031). *Id.*, 1114-15. The examiner also applied a rejection of claim 15 under 35 U.S.C. § 103 over Khalil, in view of Chang, and in further view of Phillips (US 2016/0296682). *Id.*, 1115. Further, claim 16 was rejected under 35 U.S.C. § 103 over Khalil, in view of Chang, and in further view of Thompson (US 7,662,018). *Id.*, 1115-16. Claim 21 was also

rejected under 35 U.S.C. § 103 over Khalil, in view of Chang, and in further view of Guthrie⁷⁴³ (US 2016/0220743). *Id.*, 1116-17. Claims 26 and 27 were rejected under 35 U.S.C. § 103 over Khalil, in view of Chang, and in further view of Makower⁷⁹⁴. *Id.*, 1117-18. Claim 28 was rejected under 35 U.S.C. § 103 over Khalil, in view of Chang, and in further view of Tanaka (US 2017/0035951). *Id.*, 1118-19. Claim 29 was rejected under 35 U.S.C. § 103 over Khalil, in view of Chang, and in further view of Baker (US 2009/0281485). *Id.*, 1119-20. Finally, claim 32 was rejected under 35 U.S.C. § 103 over Khalil, in view of Chang, and in further view of Myers (US 2008/0275386). *Id.*, 1120.

54. In a response filed 10/11/2022, Applicant further amended claim 1 to recite a “nipple tunnel” extending from the breast flange, the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and the breast shield being separate from the diaphragm.” EX1002, 1469. This is shown below:

1. (Currently amended) A breast pump device comprising:
 - a self-contained, in-bra wearable device comprising:
 - a diaphragm configured to prevent milk from reaching the pump by forming a seal around its outer edge;
 - a housing that includes:
 - a battery, and
 - an air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;
 - a breast shield comprising a breast flange and a nipple tunnel extending from the breast flange, the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and the breast shield being~~that is~~ separate from the diaphragm; and
 - a milk container that is configured to attach to the housing and receive expressed milk via the milk port.

EX1002, 1469

55. The examiner initiated an interview with the Applicant on 10/17/2022. EX1002, 1486-88. The Examiner then allowed the claims, with a Notice of Allowance being mailed on 2/2/2023. *Id.*, 2246-54. In the Notice of Allowance, the Examiner noted the following in regards to allowable subject matter:

Allowable Subject Matter

Claims 1, 3-10, 12-30, and 32 are allowed over the prior art of record.

The following is an examiner's statement of reasons for allowance: The claims in this application are allowed because the prior art of record fails to disclose either singly or in combination the claimed breast pump device.

The closest prior art of record is Khalil (US 20130023821) and Myers (US 20020193731).

Regarding independent claim 1, Khalil fails to teach among all the limitations or render obvious a nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, in combination with the total structure and function as claimed. Instead, Khalil teaches a substantially similar breast pump comprising a breast shield (interface 1 in fig. 11) having a breast flange (base part 12 in fig. 4) and a nipple tunnel (stub 10 in fig. 4). As seen in fig. 4, the "milk port" would be the distal end of nipple tunnel so that milk flows through the distal end of the nipple tunnel.

Additionally, the examiner notes that in the embodiment of figs. 9-11, which was primarily relied upon for the teaching of the claimed breast pump, the diaphragm (3 in fig. 11) and associated diaphragm housings (2, 4 in fig. 11) are shown to be

concentrically mounted to the nipple tunnel so that a coupling part of the milk container (72 in fig. 10) can be plugged into a milk port of the diaphragm housing (paragraph 69). For this reason, PHOSITA would not be motivated to modify the nipple tunnel to have a closed end with the milk port intermediate to the flange and closed end, as such modification would disrupt this connection with the milk container.

Regarding independent claim 1, Myers fails to teach among all the limitations or render obvious a breast pump comprising both a closed end of a nipple tunnel and a diaphragm, in combination with the total structure and function as claimed. Instead, Myers teaches a breast shield (fig. 10A) having a breast flange (flange 30 in fig. 1B) and a nipple tunnel (protruding part which forms vacuum chamber 60 in fig. 10A) with a milk port positioned intermediate to the distal end of the nipple tunnel and the breast flange (port 62 in fig. 10A). Myers teaches that the nipple tunnel comprises a closed end (fig. 10A); however, Myers also teaches that the closed end forms a diaphragm (flange top 35, paragraph 62). As such, Myers does not teach a shield having both a closed end and a diaphragm.

EX1002, 2252-53

Following an examiner-initiated interview on 1/23/2023, the claims were issued after a post-allowance amendment. EX1002, 2255, 2364-68, 2370-76, 2402-2408, 2508-09.

56. Based on my review of the prosecution history (summarized above), the examiner ignored the actual state of the art reflected by the references discussed in this Declaration. Specifically, Chang describes a breast shield with a milk port

intermediate to the breast flange and the closed end. *See* Analysis of 1[a][3][i]; EX1007, [0071], [0090]. Further, Fang describes a breast shield where a diaphragm holder is part of a nipple tunnel such that the breast shield is configured to “slide in and out from the housing, together with the diaphragm.” *See* Analysis of Claim 7; EX1009, [0019], [0024], FIG. 7. Chang and Fang taught the features that the Examiner believed to be missing from the prior art.

VI. RELEVANT LEGAL STANDARDS

57. 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.

58. In expressing my opinions and considering the subject matter of the claims of the '381 patent, I am relying upon certain basic legal principles that have been explained to me.

59. I understand that “the time the claimed invention was made” is often referred to as the priority or Critical Date.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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.

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

66. 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.

67. 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.

68. 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.

69. 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.

70. 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.

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

VII. CLAIM INTERPRETATION

72. 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 ’381 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. Applicant did not dispute the examiner’s construction. I apply this understanding in this declaration.

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

VIII. PRIOR ART

A. Chang (EX1007)

74. 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.

75. 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].

76. 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):

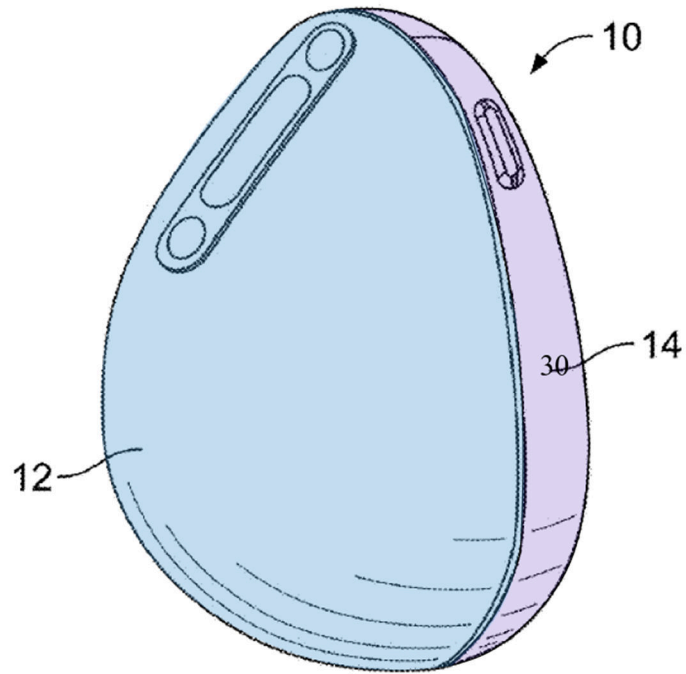


FIG. 1A

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

77. 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:

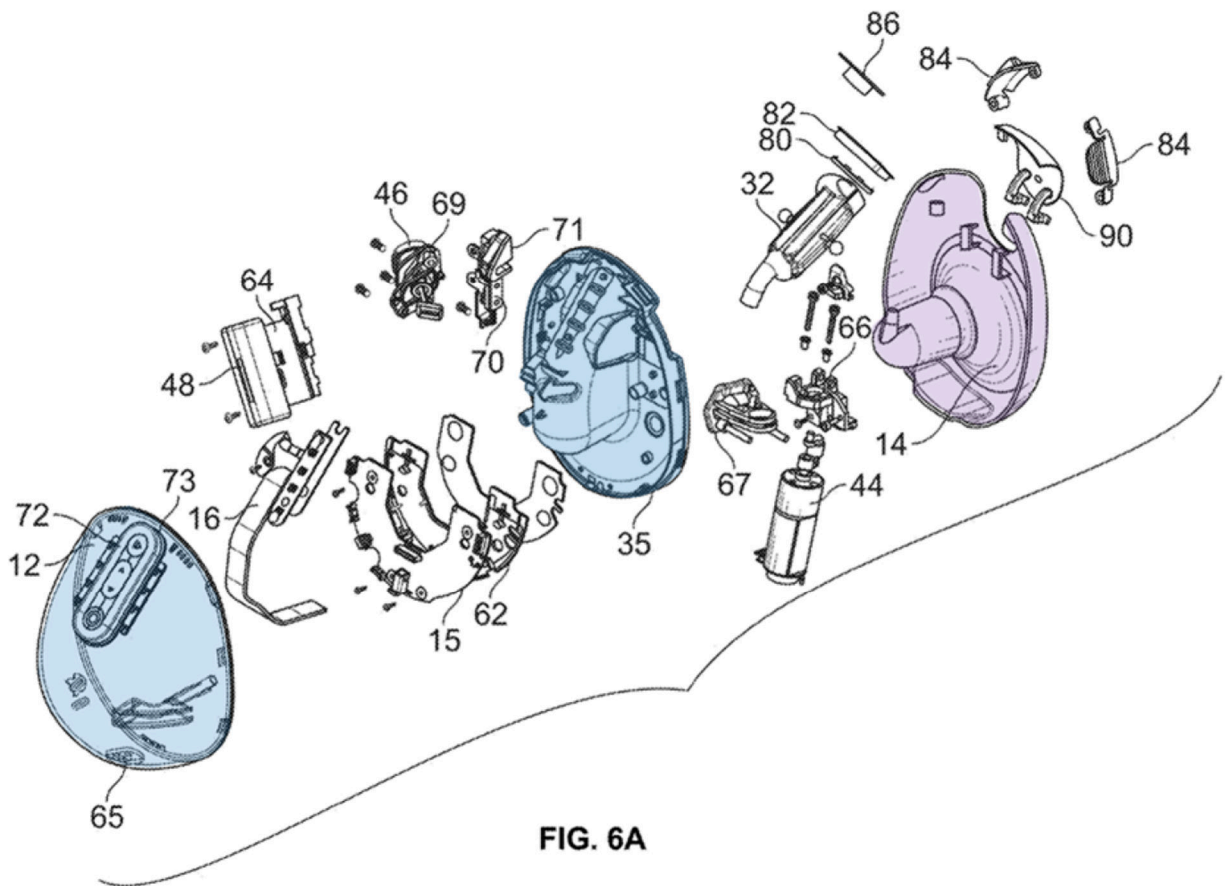


FIG. 6A

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

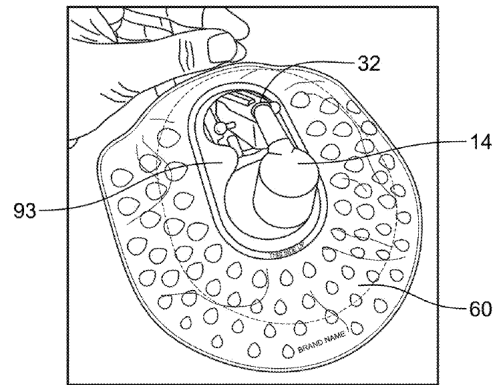
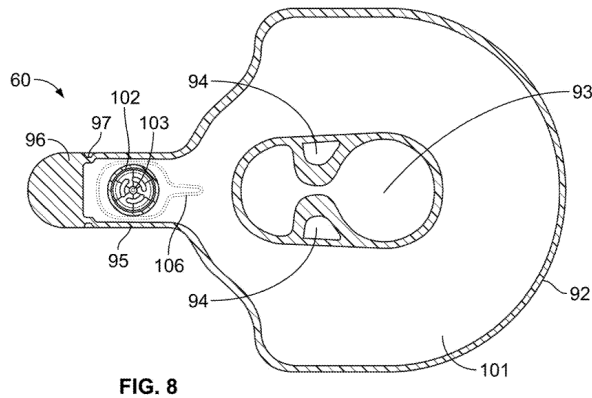
[0080]

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. All system components are contained within the device, between outer shell 12 and the flange 14. *Id.*, [0072], [0080]. The components include a “rechargeable battery” for powering the system, a “system controller” circuit board, and a pump (e.g., “motors 44, 46 are further provided and controlled electronically by the system to effect

manipulation of actuators (described below) operating on a conduit or flex-tube 32”).

Id. The “pump” is “known to those skilled in the art.” *Id.*, [0068].

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



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

79. 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.

EX1007, [0021]

80. 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. *Id.*, Fig. 6A, [0072], [0080].

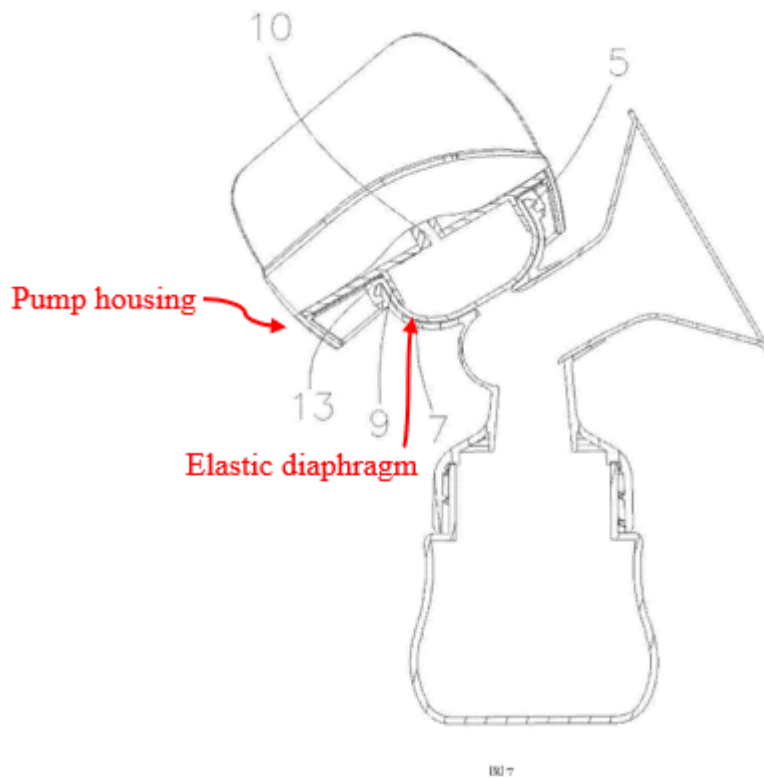
B. Fang (EX1009)

81. Fang is a certified English translation of 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 2/1/2017 from application (App. No. 201620663091.1) filed on 6/29/2016.

82. 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.”

83. 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. Khalil (EX1010)

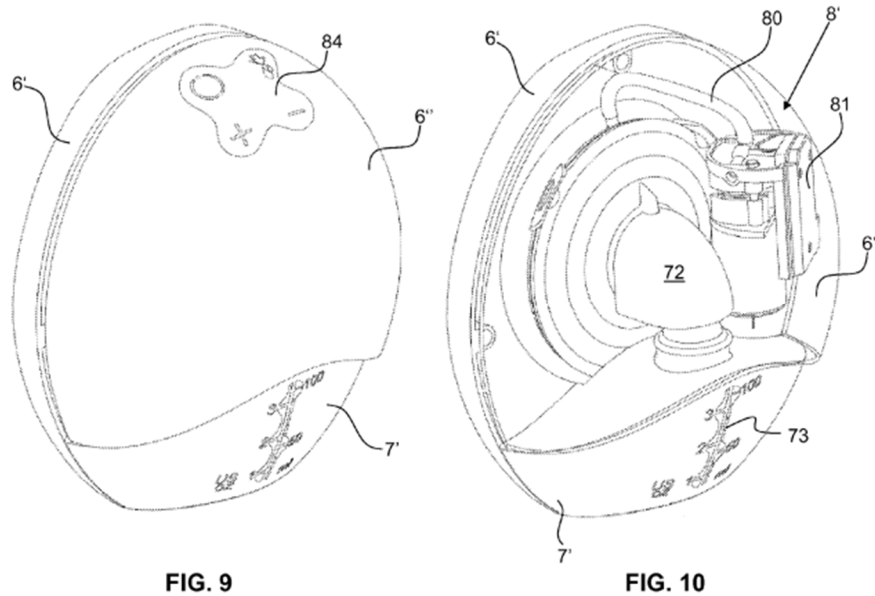
84. Khalil is a U.S. Patent Application Publication, entitled “Breastshield Unit.” *See* EX1010. Khalil was published on January 24, 2013.

85. Khalil is generally related to an integrated breast pump, referred to as a “breastshield unit.” EX1010, 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.”).

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



EX1010, Figs. 9-10; *see also id.* Fig. 11, Abstract, [0066]

87. 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].

88. Khalil discloses that its pump can include any “known” type of electric “diaphragm pump.” EX1010, [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.”).

89. 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.

EX1010, [0069]; *see also id.* Figs. 4, 9, 10.

90. 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”:

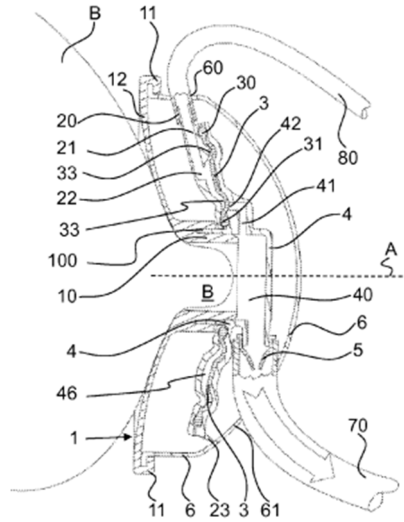


FIG. 4

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

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

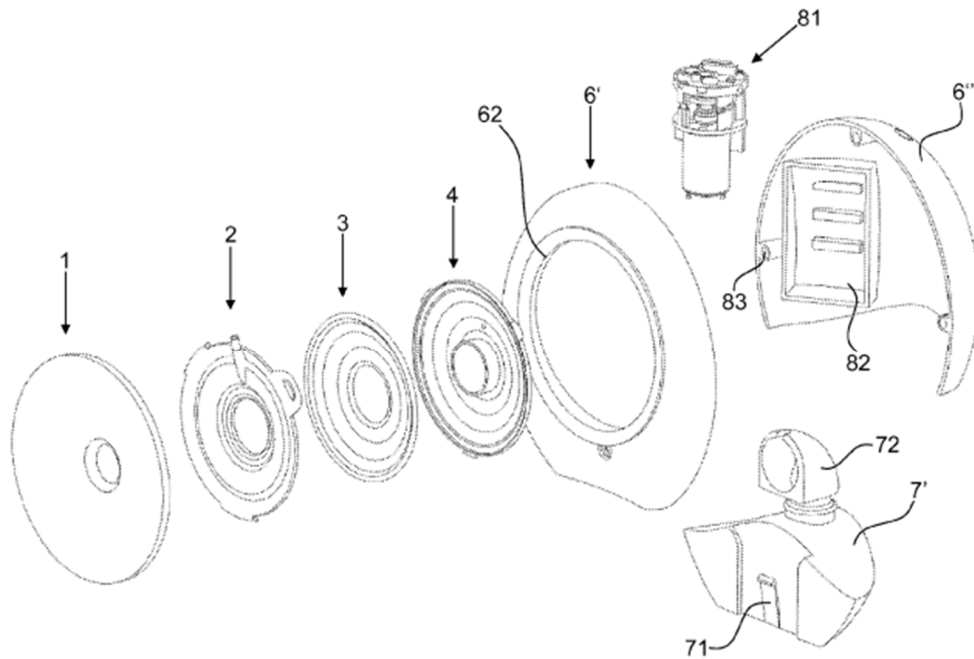


FIG. 11

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

92. 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].

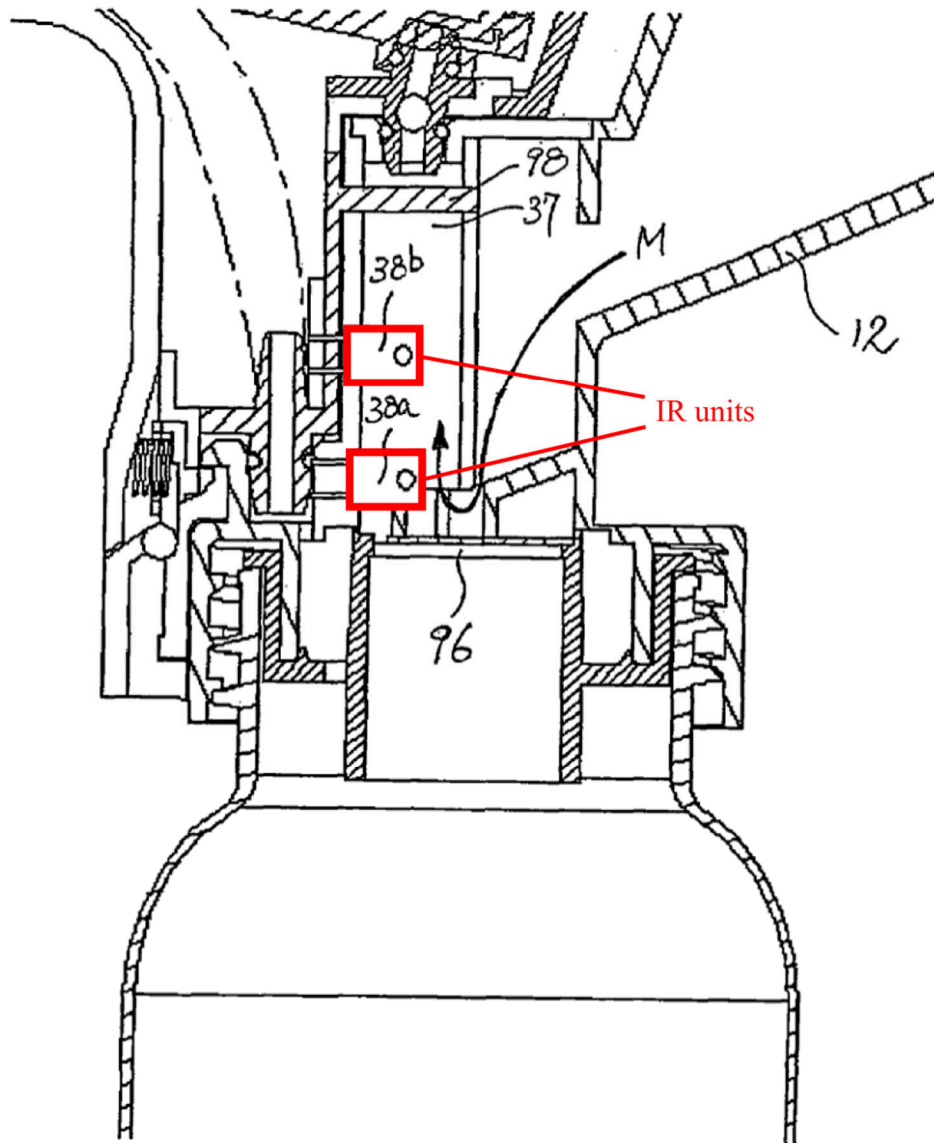
D. Yuen629 (EX1011)

93. Yuen629 is a U.S. Patent (No. 7,641,629) that was issued on January 5, 2010 and based on a U.S. patent application(10/821,924) filed on April 12, 2004.

94. Yuen629 describes an electric breast pump that “includes sensors for detecting the passing of milk, and a microcontroller for calculating the rate of flow of milk on the basis of data received from the sensors.” EX1011, Abstract. Specifically, a “beast pump 10” includes a “chamber 37” with “two infrared (IR)

units 38a, 38b, each including an IR transmitter and an IR receiver.” *Id.*, 3:12-21.

In operation, “[m]ilk from the breast of the user will flow into [a] hood 12 and subsequently into the chamber 37 in the direction of the arrow M,” which is shown in the annotated version of Figure 14 below. EX1011, 4:63-5:6.



EX1011, FIG. 14 (annotated))

95. As shown above, “the milk will accumulate in the chamber 37, first blocking the transmission of infrared signals between the transmitter and receiver of the lower IR unit 38b, and subsequently that between the transmitter and receiver of the upper IR unit 38b.” EX1011, 4:63-5:6. Further, “[w]hen the milk level rises to the upper IR unit 38b, [a] motor 43 will stop, thus releasing the ‘vacuum’ in the hood 12...” *Id.*, 5:7-28. In response, “milk in the chamber 37 will thus fall, on its own weight, through the one-way valve 96 into the bottle 18, during the course of which the level of milk in the chamber 37 will fall.” *Id.* This sensing technique ensures the breast pump 10 may “calculate the rate of flow of milk (in grams per second, g/s)” and also “count the number of times” milk is released from chamber 37 into bottle 18. *Id.*, 6:9-23.

E. Makower794 (EX1014)

96. Makower794 is a U.S. Patent Publication (No. 2016/0206794) that was published on July 21, 2016 and based on a U.S. application (15/084,714) filed on March 30, 2016.

97. Makower794 describes systems and methods for “pumping milk from a beast” under suction such that “milk is expelled from the pumping mechanism to a collection container under positive pressure.” EX1014, Abstract. Makower794 teaches that a wearable device (e.g., portable breast pump device) may be “designed with the capability of communicating to an external computer,” including “a

smartphone.” *Id.*, [0228]. As shown in FIG. 47 (below), a breast pump device may be configured to enable “transfer of data wirelessly from controller 52 [of the breast pump device] to smartphone 470.” *Id.*

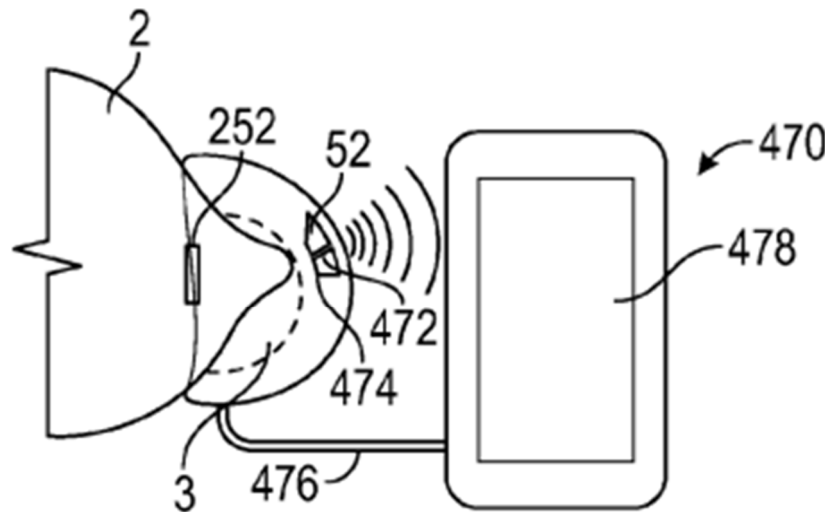


FIG. 47

EX1014, FIG. 47

Controller 52 includes “a wireless transmitter 472 that can be actuated by the user via controls 252 to send data to the external device 470 at will, so along as the external device 470 is in range of the transmitter 72.” EX1014, [0228]. As other examples, “controller 52 can be provided with a BLUETOOTH transmitter, so that data is automatically transmitted to the external device 470 whenever the external device 470 is in range of the BLUETOOTH transmitter.” *Id.*

98. Makower⁷⁹⁴ also describes embodiments where a breast pump system includes display elements for showing information relating to device operation. For

example, as shown in FIG. 57 (below), system 100 may be “provided with an indicator light 570.” EX1014, [0250].

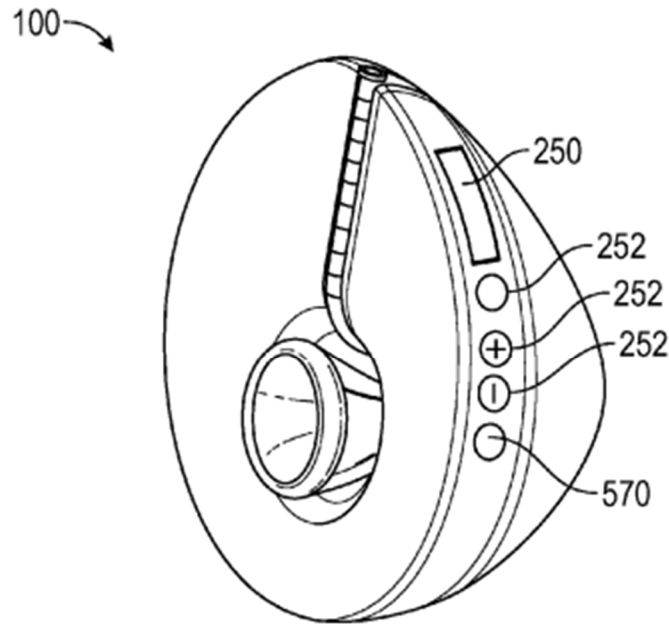


FIG. 57

EX1014, FIG. 57

99. Also shown above, system 100 includes a “display 250, which can be outputted to by controller 52” to indicate various types of information, such as “if an air leak develops, what the current suction/pressure reading in the adapter 10 tube 32 is, approximate value of milk Volume having been expressed, approximate flow rate of milk, pressure waveforms, phases of feeding timing, rest programming, heating applied to breast, vibration applied to breast, etc.” *Id.*, [0163].

F. Guthrie002 (EX1015)

100. Guthrie002 is a U.S. Patent (No. 10,483,002) that was issued on November 19, 2019 and based on a U.S. application (15/337,217) filed on October 28, 2016.

101. Guthrie002 describes a “breast pump sensor network” for breast pump devices. EX1015, Abstract. As described in Guthrie002, “breast pump accessory parts (including flanges, bottles and tubing) may be augmented with “sensors and accompanying software application that runs on the user’s smartphone or mobile device.” *Id.*, 1:28-51. The sensors “relay data such as volume pumped, flow rate and temperature data in real-time.” *Id.* The software application provides a “network for mothers to communicate with each other and with experts in the lactation, prenatal, pediatric and post-partum care fields.” *Id.*

102. Figure 5 shows an “example location” for one or more sensors being disposed in a breast pump device:

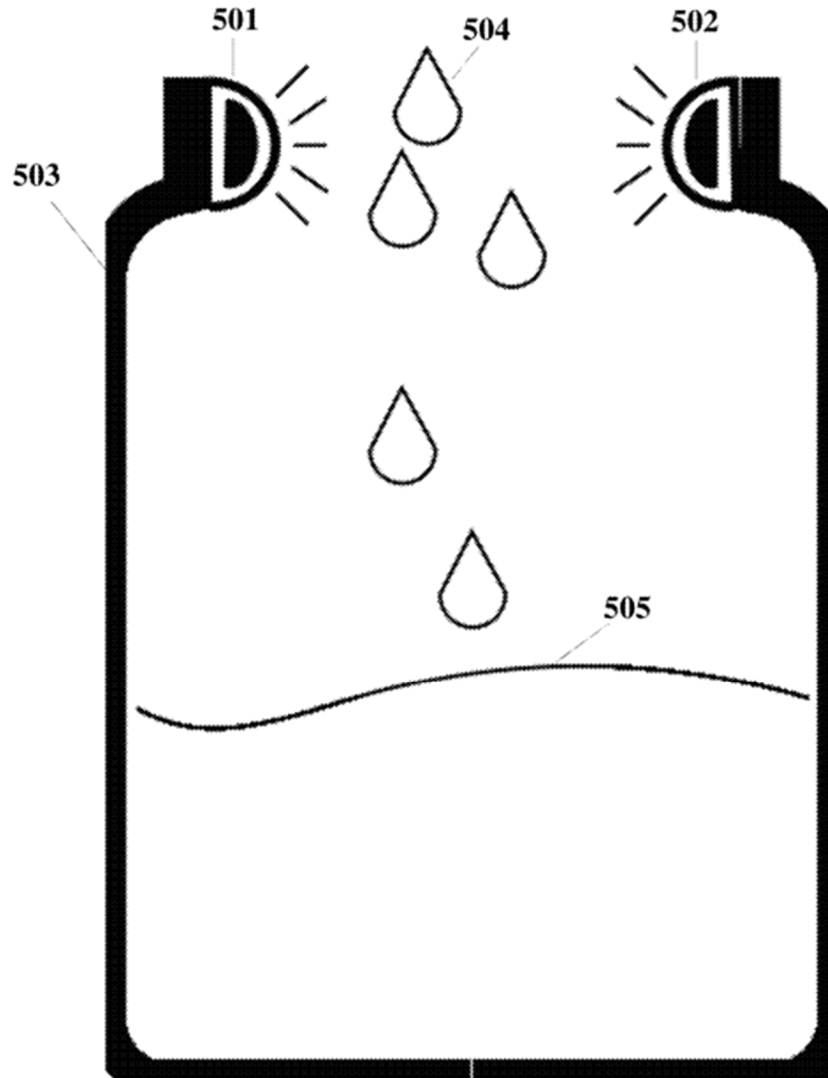


FIG. 5

EX1015, FIG. 5

103. In the configuration shown in Figure 5, sensors 501 and 502 “may be measuring flow rate or temperature or counting drops.” EX1015, 10:39-60.

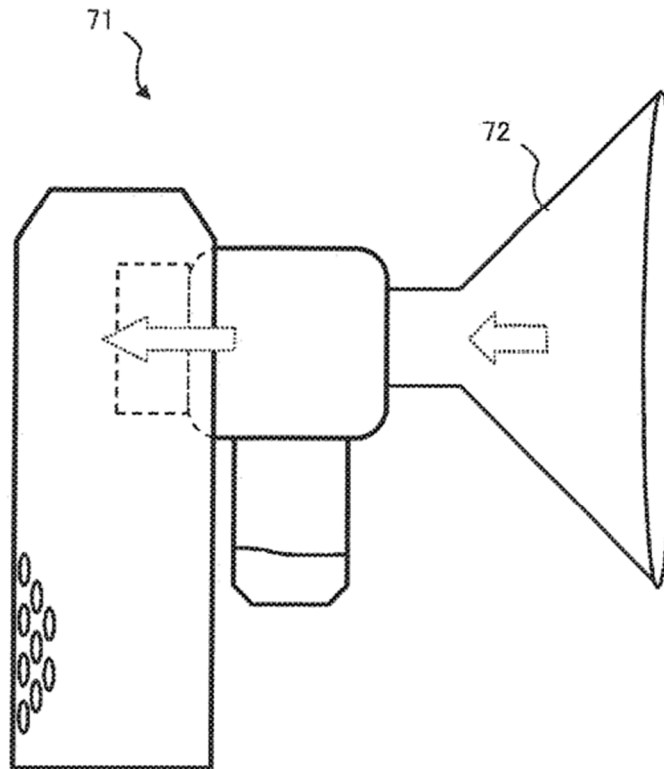
Additionally, “[f]low rate and volume sensors may be based on liquid level measurements by means of capacitive sensors, ultrasonic sensors, microphones or optical sensors based on light and sound reflectivity.” *Id.*

G. Kurihara (EX1016)

104. Kurihara is a U.S. Patent Publication (No. 2016/0271305) that was published on September 22, 2016 and based on a U.S. application (15/167,092) filed on May 27, 2016.

105. Kurihara describes a suction device that can “suppress sound and vibration device use.” EX1016, Abstract. Kurihara teaches examples of suction devices that may be used as breast milk suction devices. *Id.*, [0084], [0092], [0093], FIGS. 1, 6. For example, Figure 6 of Kurihara (below) shows an example of suction device 71:

FIG. 6



EX1016, FIG. 6

106. Suction device 71 is “configured as a breast-milk suction device, and the nozzle 72 is shaped like a funnel to be fit the shape of breasts.” EX1016, [0092]. This device “can configure a compact and silent breast-milk suction device.” *Id.*, [0093].

107. Kurihara describes a piezoelectric-driven pump system, which includes several components, such as a cylindrical body 31 that acts as the main structure housing the pump components, with internal suction and discharge ports. EX1016, [0061]-[0064]. Kurihara’s pump system also includes piezoelectric driving part 33,

which contains a piezoelectric element that deforms when a driving voltage is applied, creating movement that drives the pump. *Id.*, [0015]; *see id.*, [0063], [0065]. This part is integral to generating fluid flow within the cylindrical body. Further, a diaphragm forming plate 37A works in conjunction with the piezoelectric element to create a diaphragm that vibrates, generating the pumping action. *Id.*, [0065]-[0069]. An opposed plate 37B is positioned opposite the diaphragm to form a pump chamber where the pumping action takes place. *Id.*

IX. THE CLAIMS OF THE '381 PATENT ARE OBVIOUS

108. It is my opinion that all the claims of the '381 patent are obvious in view of prior art combinations discussed below. A POSITA would have understood that features recited in individual claims of the '381 patent refer to obvious concepts, as demonstrated by the prior art teachings referenced in this declaration. While the '381 patent's claims combine several of these obvious concepts, a POSITA would not have perceived the combination of concepts to be novel or non-obvious since the POSITA would have had a reasonable expectation of success in implementing the prior art combinations discussed in this declaration. In particular, the claims are obvious based on the following:

- Claims 1-13, 16, 17, 22, 23, 27, and 29 are obvious over the combination of Chang and Fang
- Claim 19 is obvious over the combination of Chang, Fang, and Yuen⁶²⁹

- Claim 24 is obvious over the combination of Chang, Fang, and Makower794
- Claim 25 is obvious over the combination of Chang, Fang, Makower794, and Guthrie002
- Claims 1-13, 16, 17, 22, 23, 26-29 are obvious over the combination of Chang, Fang, and Kurihara
- Claim 19 is obvious over the combination of Chang, Fang, Kurihara, and Yuen629
- Claim 24 is obvious over the combination of Chang, Fang, Kurihara, and Makower794
- Claim 25 is obvious over the combination of Chang, Fang, Kurihara, Makower794, and Guthrie002
- Claims 1-18, 20-23, 27, and 29 are obvious over the combination of Chang, Fang, and Khalil
- Claim 19 is obvious over the combination of Chang, Fang, Khalil, and Yuen629
- Claim 24 is obvious over the combination of Chang, Fang, Khalil, and Makower794
- Claim 25 is obvious over the combination of Chang, Fang, Khalil, Makower794, and Guthrie002

- Claims 1-18, 20-23, 26-29 are obvious over the combination of Chang, Fang, Khalil, and Kurihara
- Claim 19 is obvious over the combination of Chang, Fang, Khalil, Kurihara, and Yuen629
- Claim 24 is obvious over the combination of Chang, Fang, Khalil, Kurihara, and Makower794
- Claim 25 is obvious over the combination of Chang, Fang, Khalil, Kurihara Makower794, and Guthrie002

A. Ground 1A: Obviousness of Claims 1-13, 16, 17, 22, 23, 27, and 29 Over Chang-Fang

109. As discussed below, Chang and Fang provide each element of claims 1-13, 16, 17, 22, 23, 27, and 29.

1. Combination of Chang and Fang

110. Based on my knowledge and experience in the field, and my review of Chang and Fang, a POSITA would have been motivated to implement Chang's breast pump device using a pump system that utilizes a diaphragm to transmit negative pressure, based on Fang's suggestions. 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..."); [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.”); 84-86. Fang provides a straightforward suggestion of a diaphragm pump that includes a diaphragm and a diaphragm housing component that is formed in a pump housing wall. EX1009, [0024], [0025], FIG. 7.

111. In the Chang-Fang combination, a POSITA would have implemented the breast pump device to include a diaphragm pump having first and second diaphragm housing components and an elastic diaphragm, based on Fang’s express suggestions. EX1009, [0019]-[0025] (“flaring 4,” “ring rim 5,” “elastic diaphragm 7,” “flange 9”), FIGS. 4-5, FIG. 7. A first diaphragm housing would have been positioned in a recessed wall of the pump housing, and the elastic diaphragm and second diaphragm housing would have been predictably positioned at the opposing/mating location—attached with the breast shield. EX1009, FIG. 7. Indeed, Fang expressly describes a “flange 9” and adjacent surfaces that provide a first diaphragm housing and a recessed surface of “chassis 35 that provides a recessed wall of the pump housing, and a “flaring 4” and “ring rim 5,” for example, the provide a second diaphragm housing. The overall form factor of the Chang-Fang system generally would remain as taught by Chang, and would include an improved pump chamber defined between a recessed wall of the pump housing and the elastic diaphragm, based on Fang’s suggestions. As a result, a perimeter of the first

diaphragm housing surface would have been part of the pump housing wall (e.g., “chassis 35”) such that the diaphragm housing surface defines part of the surface of the pump housing, and the elastic diaphragm sealingly engages when the device is assembled—again, in accordance with Fang’s suggestions. This improved diaphragm pump arrangement would provide a milk flow path to the container, as described by Chang, along a milk-side of the diaphragm.

112. I note that a POSITA would have included vacuum pump components to generate a vacuum and drive the diaphragm, in accordance with Fang’s suggestions. Based on my knowledge and experience in the field, the use of a diaphragm pump in breast pump devices was widely known. This includes use of diaphragm pumps in “in-bra” devices. Accordingly, a POSITA would have readily implemented such pump components within the pump housing. For example, such components would have been located similar to the locations of Chang’s “motor” and “actuators,” and/or associated components. This is corroborated by known use of such components of a vacuum pump integrated into a housing. *See, e.g.*, EX1013. Moreover, the selection and sizing of such pump components for “in-bra” devices was a common and predictable task for a POSITA before the Critical Date.

113. A POSITA would have been motivated to combine Chang and Fang from multiple reasons. For example, a POSITA would have been motivated to implement Chang’s breast pump with diaphragm components based on Fang’s

suggestions in order to improve ease of cleaning and maintenance. Based on my knowledge and experience in the field and my review of Chang and Fang, a POSITA would have recognized from Fang's description that the elastic diaphragm components prevent flow of milk to the pump components and are also readily accessed for cleaning. Indeed, Fang explains that "elastic diaphragm 7 is used to prevent the milk from flowing into the air pump main unit 8." EX1009, [0019] The cleaning and maintenance benefits of diaphragm pump components were known to a POSITA and recognized as an advantageous feature in breast pump devices. *Id.*; *see also id.*, [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").

114. In the combined system, the first diaphragm housing is on a surface of the pump housing, according to Fang's express suggestion. A POSITA would have been prompted to implement the system in this configuration, based on Fang's suggestions, in order to facilitate a small number of parts to be assembled/disassembled, and reduce associated interfacing surfaces or small crevices. Moreover, a POSITA would have been motivated to utilize diaphragm components in accordance with Fang's suggestions in order to reduce the length of tubing to be cleaned (e.g., Chang's "flex tube" and associated tubing). A POSITA

would have recognized from Chang and Fang that reducing the length of tubing that was difficult to access and dry would have reduced cleaning difficulty and reduced the likelihood of mold and mildew growth over time.

115. Additionally, a POSITA would have been motivated to implement Chang using diaphragm pump components as described above, based on Fang's suggestions, in order to facilitate rapid assembly and disassembly, such as when a user is assembling and disassembling during use. For example, based on my knowledge and experience and my review of Chang and Fang, a POSITA would have recognized from Fang that the diaphragm components are readily slid into engagement during assembly, and would have been motivated to enhance Chang's device with easy engagement. Relatedly, a POSITA would have recognized from Chang and Fang that positioning the first diaphragm housing surface (e.g., as suggested by Fang's "flange 9" and adjacent surfaces) as part of the pump housing wall (e.g., "pump chassis 35"), in accordance with Fang's express teaching, would have facilitated reduced need for additional attachment features (e.g., to be manipulated and connected), and reduced interfaces between separate parts.

116. Implementation of Chang's breast pump using diaphragm pump components (as suggested by Fang) would have also been recognized as a particularly effective and suitable option to generate negative pressure within a breast pump. Chang itself proposes the use of other pump components (e.g., instead

of the “flex tube 32”), and Fang suggests suitable diaphragm pump features for a breast pump. Moreover, I note that a POSITA would have readily implemented the combination to achieve benefits I discuss herein without hindering Chang’s teachings and functionality. For example, a POSITA would have readily implemented the Chang-Fang pump components in accordance with Chang’s teachings of vacuum levels, including cycling between a “latch” vacuum and a “target” vacuum during extraction. EX1007, [0087]. Likewise, a POSITA would have readily implemented the combination to allow for monitoring of a volume change to facilitate tracking the volume of milk that is delivered into the collection container, consistent with Chang. EX1007, [0113].

117. I note that the combination of Chang and Fang discussed above involves the application of a known technique to a known device. Fang describes 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, and the primary Chang breast pump device generates negative pressure and has a recessed external pump housing and was ready for improvement to yield predictable results (including several benefits of the combination that I discussed above). The modifications would have amounted to a simple substitution of one known pump configuration for another.

118. 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. This is corroborated by Weber (EX1031), which describes a “diaphragm 14” that is “arranged in a recess 112 of the housing 10, which forms part of a pump chamber” (EX1031, 12:3-5) and a “breast shield[] connected directly to the first port of the chamber” (*id.*, 5:5-7). Other examples further corroborate the use of diaphragm pump components in the Chang-Fang device. *See* EX1016; EX1038; EX1031. Such well-known diaphragm pumps were used in “wearable” in-bra devices, as corroborated by Park. *See* EX1013, Fig. 5 (flexible membrane 500).

2. Claim Analysis

a. Claim 1

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

119. The Chang-Fang 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.

120. As discussed in Section IX.A.1 (Chang-Fang), use of diaphragm components within the Chang-Fang device would have been a predictable

implementation of a compact breast pump device. Such an implementation would have achieved a compact and efficient design, as diaphragms provide reliable suction control in a confined space. Diaphragms are commonly used in devices that require both precise fluid handling and portability, making them a logical choice for minimizing bulk while maintaining effective functionality in a small form factor. Additionally, their durability and ability to operate silently are advantageous in creating a discreet, user-friendly device.

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

121. The Chang-Fang device is an example of a *self-contained, in-bra wearable device* based on the suggestions of Chang and Fang. 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 the components of the device “all contained within a cup of a brassiere.” *Id.*, [0011], [0019]. Indeed, I note that a POSITA would have implemented the Chang-Fang device based on these suggestions so that the device 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); Analysis of Limitations 1[a][1]-[4]. This implementation would be predictable and also maintain the compact, in-bra configuration of the breast pump device.

(iii) 1[a][1]: a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge;

122. The Chang-Fang device includes a *diaphragm*, provided by, for example, an elastic diaphragm in accordance with for example, Fang's elastic diaphragm 7. EX1009, [0019]-[0021]; *see* Section IX.A.1 (Chang-Fang).

123. As previously discussed, the flexible diaphragm (i.e., a membrane) is configured to prevent milk from reaching the pump. EX1007, [0019]. The flexible diaphragm forms a watertight and airtight seal around its outer edge. In doing so, the diaphragm prevents the passage of milk from reaching the air pump and facilitates generation of negative pressure during operation. Fang also explains that the elastic diaphragm 7 deforms away from the nipple tunnel when a vacuum is created on a pumping chamber, which then creates negative air pressure in the nipple tunnel when a vacuum is created on a pumping chamber. *Id.*, [0019]-[0025].

124. The Chang-Fang device also provides an *air pump*, for example, Fang's air pump. Fang describes that its pump is pneumatically connected to the elastic diaphragm and configured to generate negative air pressure. EX1009, [0019], [0024], FIG. 7. A POSITA would have configured a pump in the Chang-Fang device based on the suggestions of Fang. This configuration is also consistent with Chang's teachings. For example, Chang describes that pump components (e.g., "motor") are positioned within the device housing. EX1007, [0072] (motor 46), [0080], FIG. 6A.

In the Chang-Fang device, pump components would have similarly been positioned within the device housing. Chang also describes that pump components are powered by a “rechargeable battery 48 assembly” and that “the system motor [] is powered by the battery.” *Id.*, [0080]; *see id.*, [0072]. The air pump in the Chang-Fang device is configured based on these suggestions and also powered by the rechargeable battery.

(iv) 1[a][2]: a housing that includes:

125. The Chang-Fang device includes a ***housing***, for example, a pump housing formed by Chang’s housing or outer shell 12 and pump chassis 35. EX1007, [0071], [0073], FIGS. 1A, 6A. The pump housing formed by the “outer shell” and the “pump chassis” accommodates pump components, as shown in Figures 1A and 6A below. *Id.*

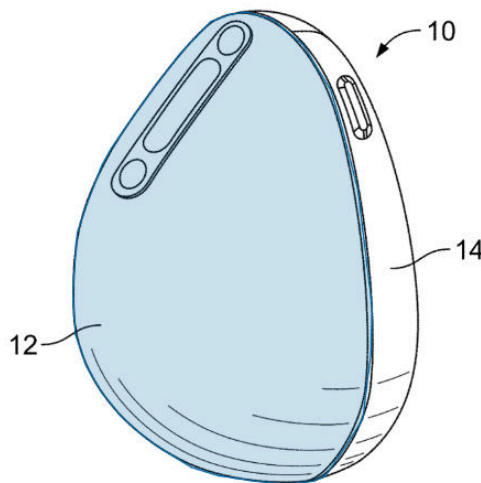
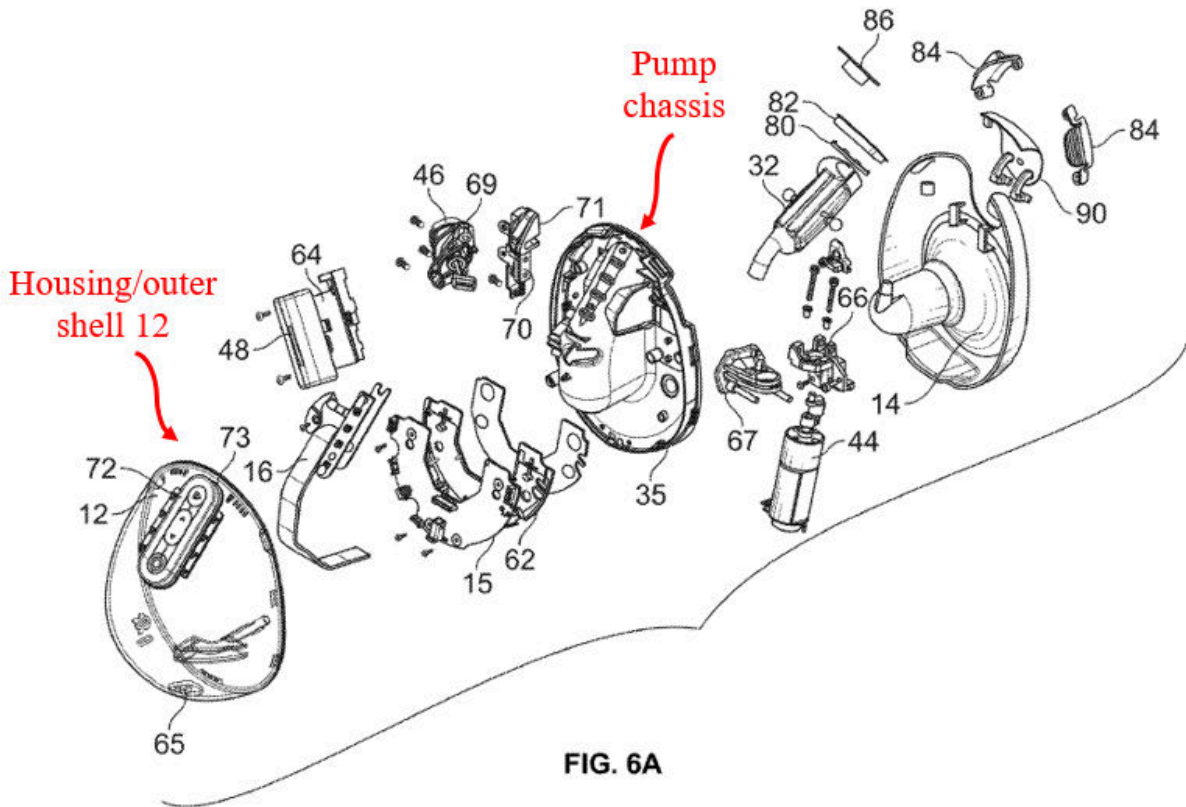


FIG. 1A



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

As shown above, when Chang’s device is assembled (shown in Figure 6A), outer shell 12 is attached to pump chassis 35 to house pump components, such as motors 44, 46. EX1007, [0072].

(v) 1[a][2][i]: a battery, and

126. The Chang-Fang device includes a **battery**, for example, Chang’s battery 48. Chang describes that “[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]; *see also, id.*, [0020] (“battery powered” and battery is “received in the compartment of the external shell”); [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. Based on these teachings, a POSITA would have implemented the Chang-Fang device to similarly include a rechargeable battery within the *housing* of the device, for example, a pump housing formed by Chang’s housing or outer shell 12 and pump chassis 35. EX1007, [0071], [0073], FIGS. 1A, 6A. Consistent with Chang, this configuration would have allowed the Chang-Fang device be used portably without being tethered to a power outlet. The rechargeable battery would have also enabled sustained operation over multiple sessions on a single charge, reducing interruptions and improving the pump’s practicality for busy lifestyles.

(vi) **1[a][2][ii]: the air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;**

127. As I discussed for limitation 1[a][1], the Chang-Fang device includes an *air pump*, for example, Fang’s air pump. Fang teaches that its air pump is pneumatically connected with the elastic diaphragm such that it is configured to *generate negative air pressure by driving the diaphragm*. EX1009, [0019], [0024], FIG. 7. A POSITA would have implemented the Chang-Fang device so that its air pump components are positioned within the *housing*, based on the suggestions of Chang and Fang. As previously noted, Chang teaches that pump components (e.g., “motor”) are positioned within a pump housing formed by a pump housing formed

by Chang's housing or outer shell 12 and pump chassis 35. EX1007, [0072] (motor 46), [0080], FIG. 6A. As I also explained for limitation 1[a][2][i], the air pump in the Chang-Fang device is also ***powered by the battery***, in accordance with Chang. EX1007, [0072], [0080]. Specifically, Chang teaches that a "rechargeable battery 48 assembly" is configured to "power[] the system 10" and that "the system motor [] is powered by the battery." *Id.*, [0072].

(vii) 1[a][3]: a breast shield comprising a breast flange and a nipple tunnel extending from the breast flange,

128. The Chang-Fang device includes a ***breast shield***, for example, Chang's breast shield. Chang's breast shield is "sized and shaped to engage a breast of a user," and "contoured to comfortably fit against a wide range of user's bodies and to provide structure for sealingly engaging with breast tissue." EX1007, [0071]. In Chang, the breast shield has "nipple receiving portion...contoured to more closely match the natural shape of the nipple" (*id.*, [0090]). Chang's breast shield also includes "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], [0090]). From these descriptions, a POSITA would have recognized that Chang's breast shield includes two portions, including a nipple receiving portion and a breast contact portion. *Id.*, [0071], [0090]. A POSITA would have similarly configured the ***breast shield*** of the Chang-Fang device such that it

includes a nipple receiving portion (*nipple tunnel*) and breast contact portion (*breast flange*). Figure 4 of Chang illustrates an example of a breast shield comprising the nipple receiving portion (green) and breast-contact portion (blue).

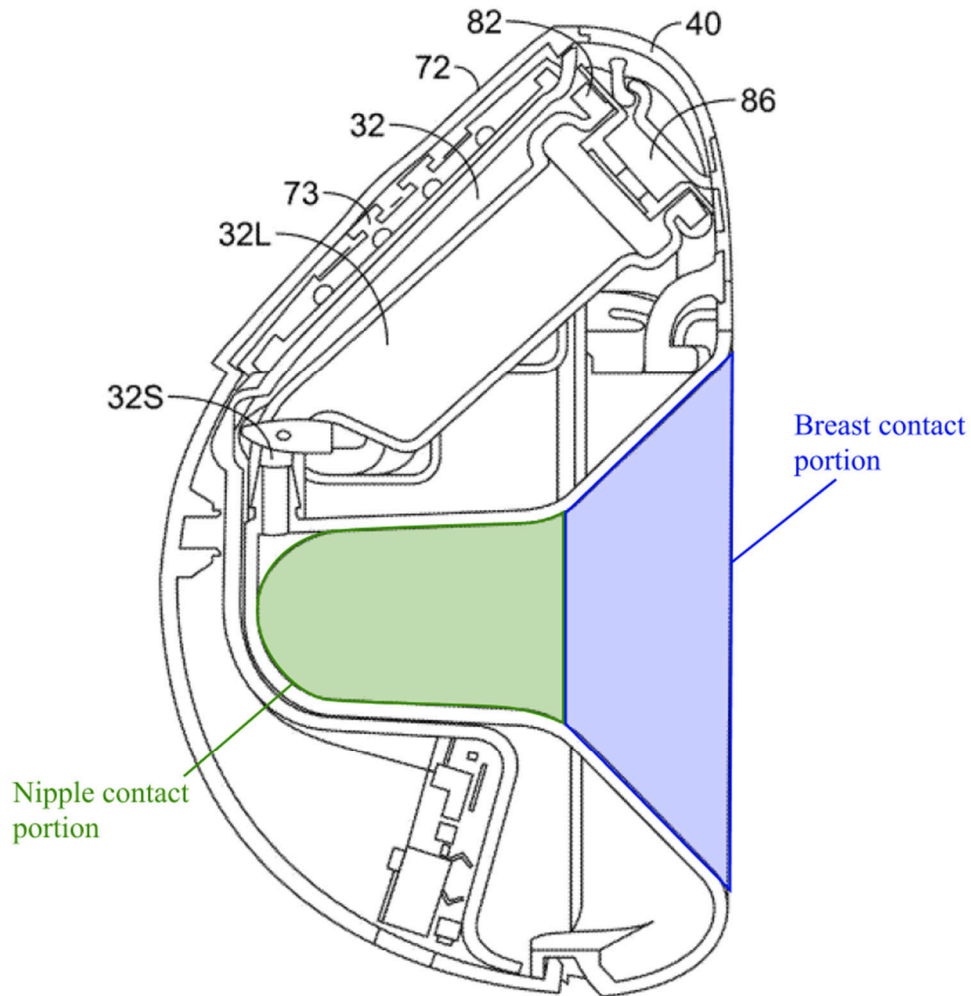
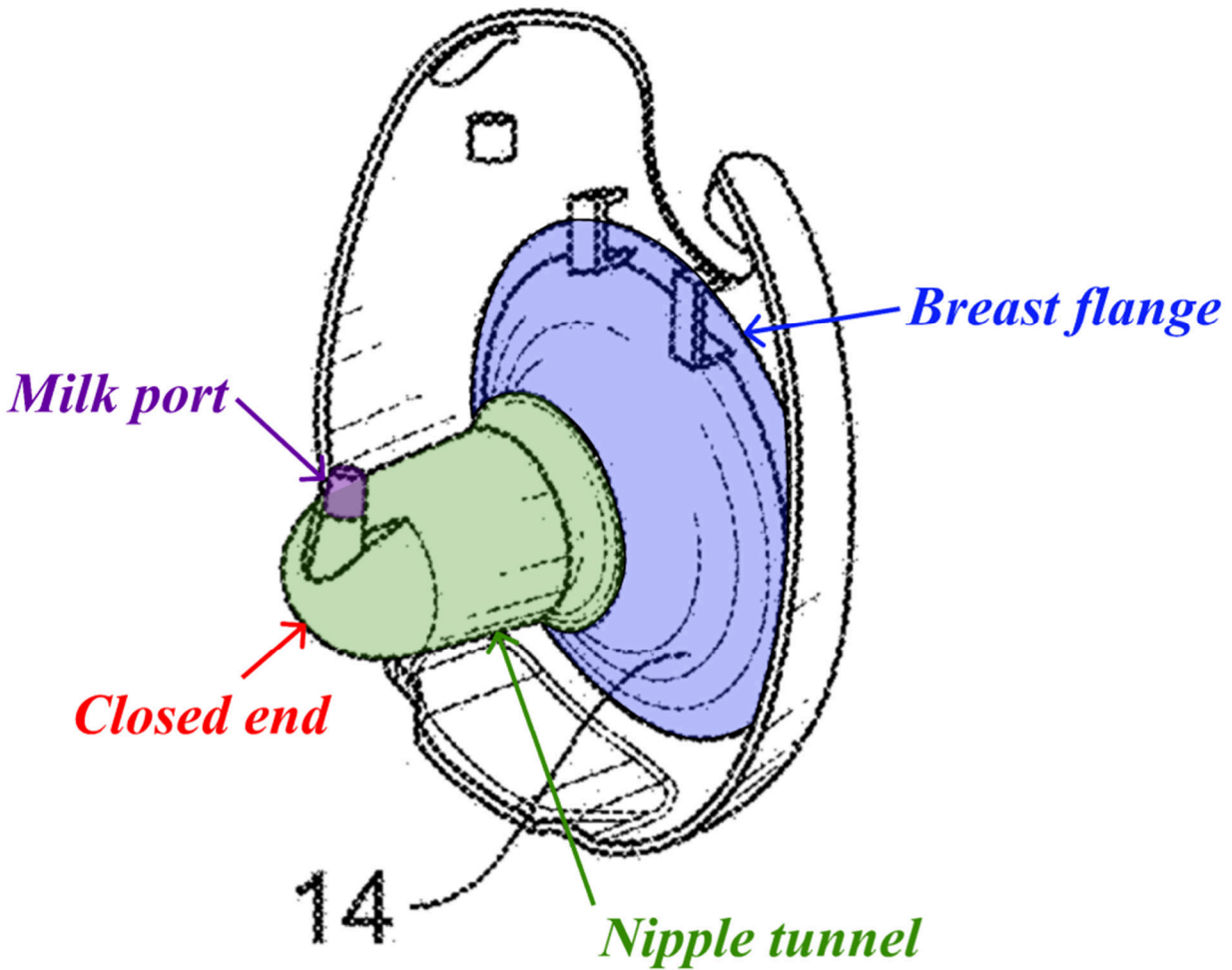


FIG. 4

EX1007, FIG. 4 (annotated)

(viii) 1[a][3][i]: the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and

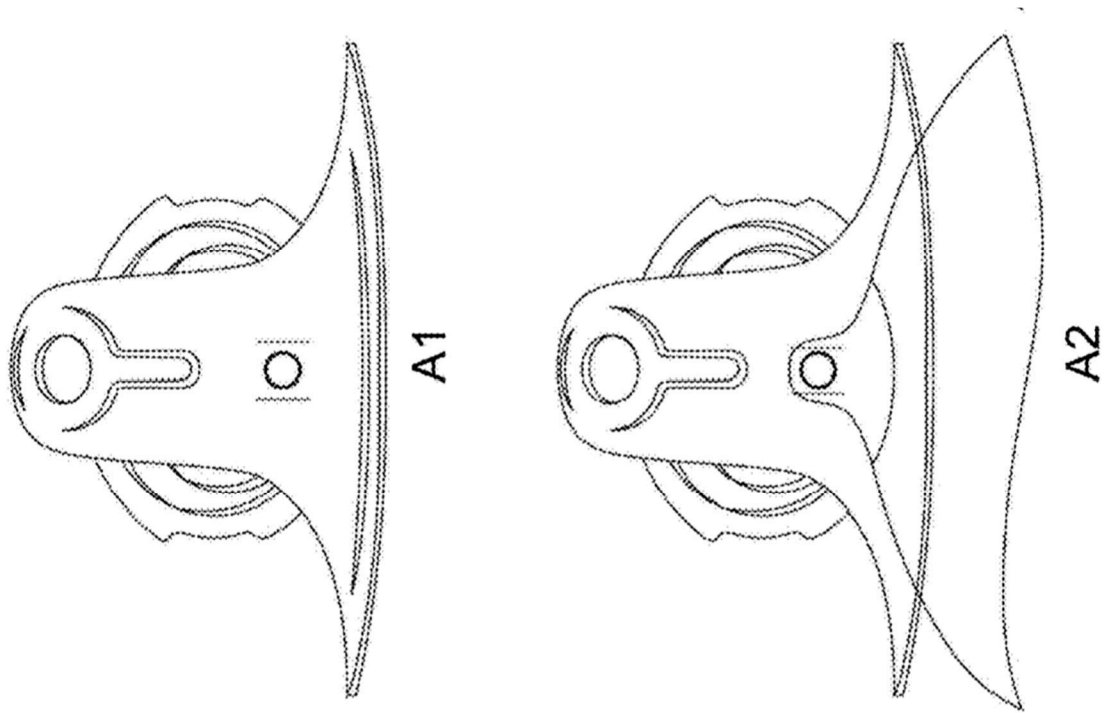
129. As I discussed for 1[a][3], the Chang-Fang device includes a *breast shield*, for example, Chang's breast shield. Based on Chang's teachings, the *breast shield* also includes a nipple receiving portion (*nipple tunnel*) and breast contact portion (*breast flange*). EX1007, [0071], [0090]. Chang's figures also show examples of the breast shield with a closed end and a milk port. *Id.*, FIGS. 4, 6A. For example, as shown in the annotated and excerpted version of Figure 6A (below), the nipple receiving portion includes a closed circular end (*closed end*) and a port (*milk port*).



EX1007, FIG. 6A (annotated and excerpted)

As shown above, in Chang's breast shield, the port is intermediate to the breast contact portion and the closed circular end. Based on my knowledge and experience in the field, a POSITA would have recognized that the structures providing the milk port in Chang's breast shield are intermediate to the breast contact portion and the closed circular end because the milk port structures are not positioned at a distal end of the nipple receiving portion (i.e., at the curved closed end). This positioning of the milk port occupies a location between the closed circular end and the curved

closed end. The positioning of the port in Chang's breast shield largely coincides with the positioning depicted in Figure 14 of the '381 patent:



EX1001, FIG. 14 (excerpt)

As shown in the figure above, the *milk port* is positioned to be *intermediate to the breast flange and the closed end* because the boundaries defining the *milk port* are between the outer end of the *closed end* (the left-most end of breast shield A1) and the outer end of the breast flange (the right-most end of breast shield A1). See EX1001, 18:56-19:16. This position is similar to the positioning of the port in Chang's breast shield. Further, this analysis is consistent with the examiner's statements during the prosecution history. See EX1002, 2252. Specifically, in allowing claim 1 over Khalil, the Examiner distinguished Khalil's "milk port" as

being “the distal end of nipple tunnel so that milk flows through the distal end of the nipple tunnel.” *Id.* (identifying “stub 10 in [Khalil’s] fig. 4” as the “nipple tunnel”).

Figure 4 of Khalil is reproduced below:

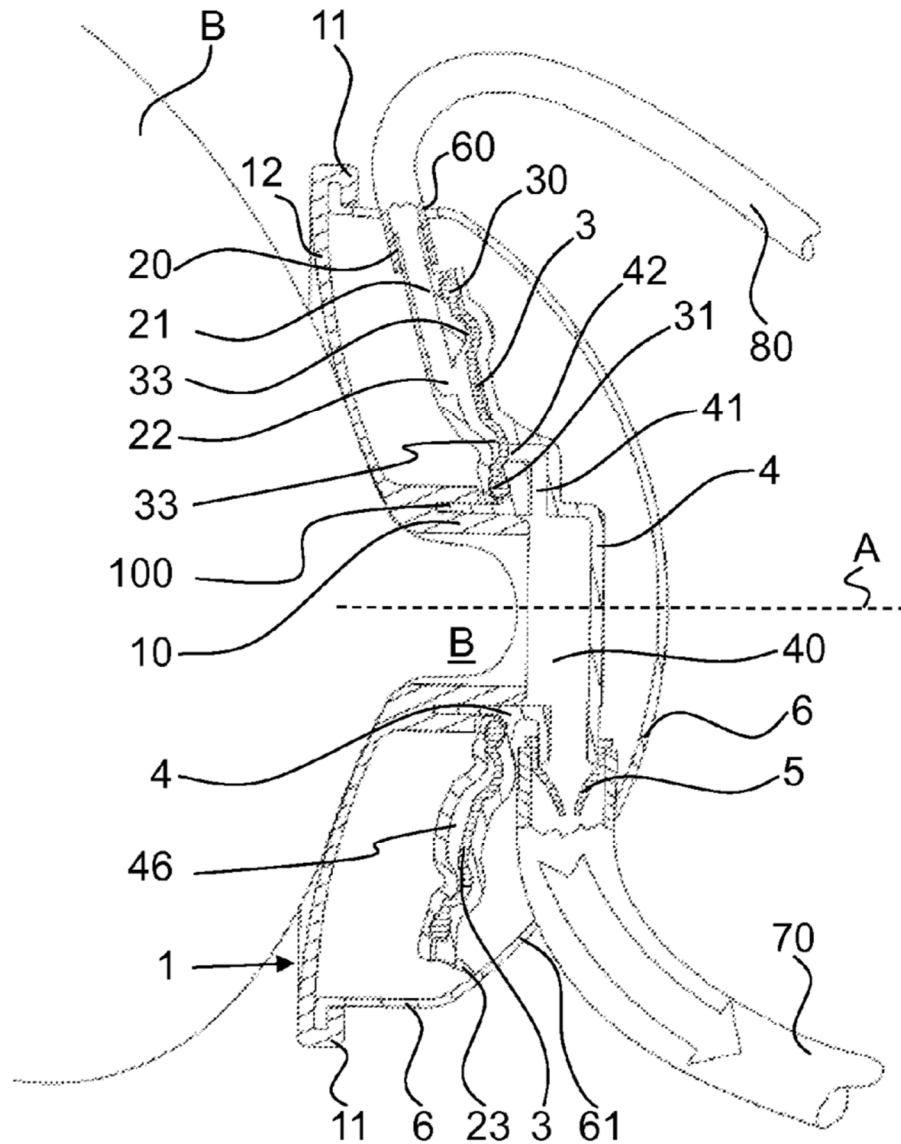
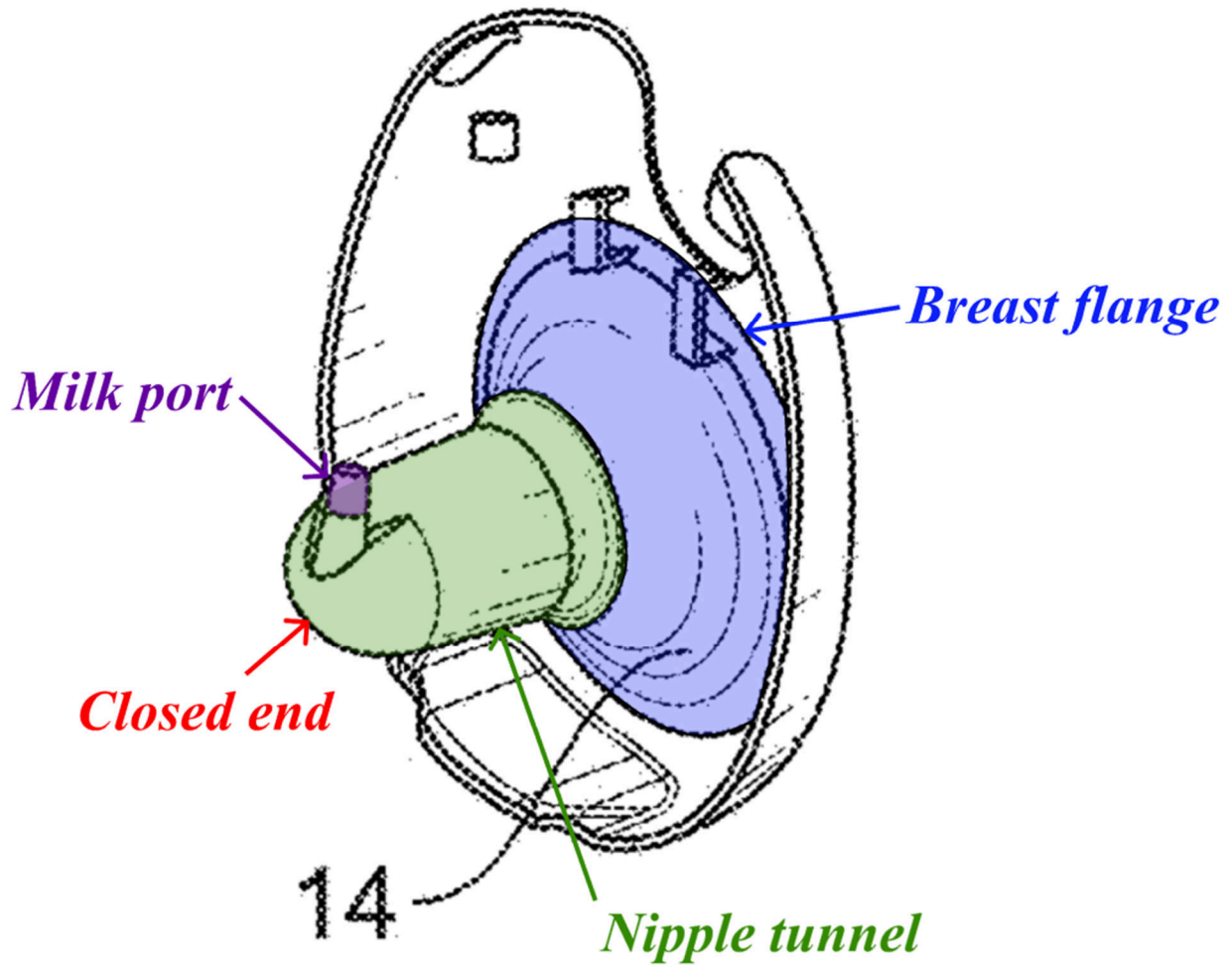


FIG. 4

EX1010, FIG. 4

The Examiner stated that “[a]s seen in Fig. 4, the ‘milk port’ would be at the distal end of nipple tunnel so that milk flows through the distal end of the nipple tunnel.” EX1002, 2252. Based on this statement, stub 10 has a distal end, and provides a milk flow path with a milk port. In this configuration, milk flows through a volume defined by stub 10 and through milk line 70 via a milk port that is at the “distal end.”

130. In contrast, in Chang’s Figure 6A breast shield, the port is not at the distal end of the nipple tunnel. There is some separation between the distal end (i.e., the furthest point on a structure associated with the nipple tunnel) and the volume defined by the milk port:



EX1007, FIG. 6A (annotated and excerpted)

A cross-sectional view of an example of Chang's breast shield is shown in Figure 4. When considering the Examiner's statements regarding the "intermediate" feature, Chang's Figure 4 breast shield is also different from the configuration shown in Khalil's Figure 4.

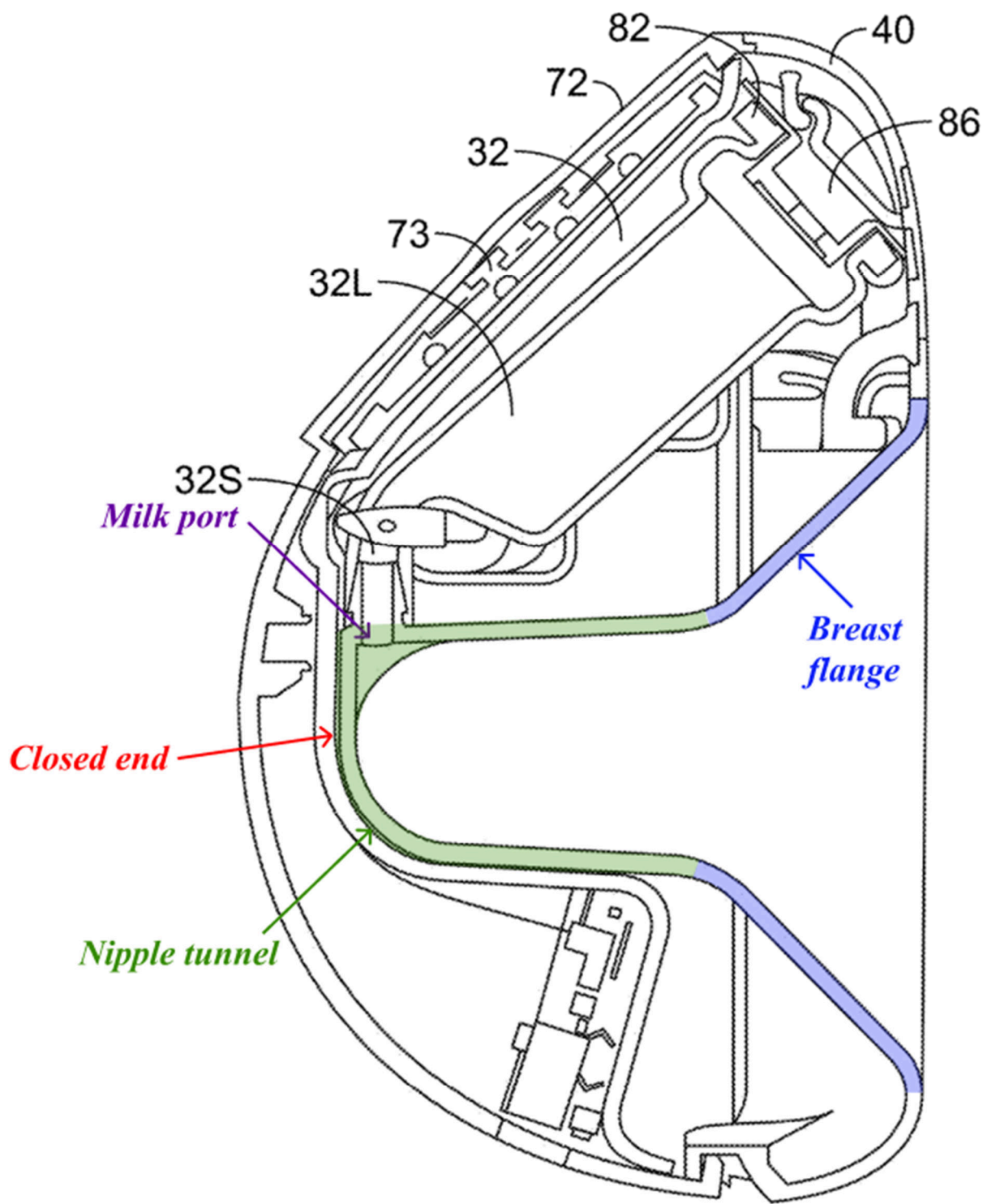
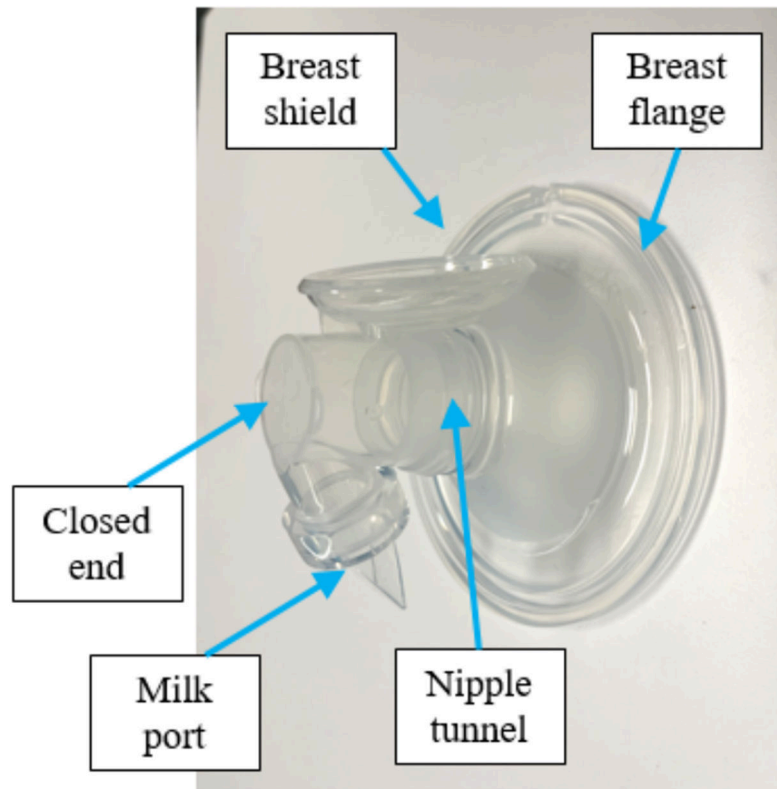


FIG. 4

EX1007, FIG. 4 (annotated)

As shown above, based on the Examiner’s statement regarding the “the distal end of nipple tunnel,” in Chang’s Figure 4 breast shield, the “distal end” (shown with a dashed orange line) also coincides with the *closed end* (shown in red). Further, the *milk port* (circled in purple) is not at the distal end because it is instead positioned between the *closed end* and the *breast flange* (shown in blue).

131. Additionally, the breast shield configurations in Chang’s Figures 4 and 6A are similar to Patent Owner’s allegations of infringement of limitation 1[a][3][i] before the district court. *See* EX1054C, 15. As shown below, in its preliminary infringement contentions for the Momcozy S9 Product, Patent Owner interpreted limitation 1[a][3][i] to be satisfied by a configuration where a “milk port” is positioned between a “closed end” and a “breast flange” along a lateral axis of a “nipple tunnel” that extends from the “breast flange” to the “closed end.”



EX1054-C, 15

132. Based on Patent Owner’s interpretation, the ports of the breast shields in Chang’s Figures 4 and 6A are similarly configured in that they are positioned such that their axial positions along a lateral axis of the “nipple tunnel” are intermediate to the respective axial positions of the “closed end” and the “breast flange.”

(ix) **1[a][3][ii]: the breast shield being separate from the diaphragm; and**

133. As I discussed for limitation 1[a][3], the Chang-Fang device includes a *breast shield*, for example, Chang’s nipple receiving portion and breast contact portion (collectively *breast shield*). EX1007, [0071], [0090]. Additionally, as I

explained for limitation 1[a][1], the Chang-Fang device also includes a *diaphragm*, for example, Fang's elastic diaphragm 7. EX1009, [0019]-[0021]; *see* Section IX.A.1 (Chang-Fang). Based on the suggestions of Chang and Fang, the breast shield would be *separate from* the flexible diaphragm. Chang describes the breast shield can be "removed from engagement with the remainder of" the device. EX1007, [0105]. Based on this description, a POSITA would have understood and found obvious that removability of the breast shield in the Chang-Fang device indicates that the breast shield is *separate from* the elastic diaphragm. *Id.*; *see* EX1007, [0021], [0023], [0081], [0086], [0092], [0099]-[0100].

134. Based on my knowledge and experience in the field, a removable breast shield would have been predictably designed for the recognized and understood benefits of easy attachment, removal, and cleaning. The type of breast shield provides a user-friendly interface directly in contact with the breast. An elastic diaphragm serves as part of the pump's suction mechanism, operating internally to create and regulate vacuum pressure. Separating these components allows each to fulfill its specific role without interfering with the other, thus improving both functionality and ease of use. This type of configuration also enables access to the breast shield during normal disassembly for cleaning.

- (x) **1[a][4]: a milk container that is configured to attach to the housing and receive expressed milk via the milk port.**

135. The Chang-Fang device includes a *milk container*, for example, Chang's container assembly. In Chang, the container assembly is "all contained within a cup of a brassiere." EX1007, [0019]. Additionally, Chang describes that "positioning of collection or container assembly 60 within a pump system 10." *Id.*, [0100]. Additionally, "the system is configured to pump into a sealed collection or container assembly 60" and "inside or outside of the pump housing." *Id.*, [0101]. Based on these descriptions, the container assembly of the Chang-Fang device would be positioned in a similar way such that it is configured to be directly connected to and removed from the pump housing such that the container assembly receives expressed milk via the milk port. EX1007, [0008], [0010], [0021], [0023], [0081], [0086], [0092], [0099], [0101]. Based on these descriptions of Chang, the *milk container* of the Chang-Fang device is configured to be attached to and removed from the *housing* such that it is within the device in a fixed position relative other components. *Id.*, [0019], [0106]-[0107], FIGS. 11A-11E.

b. Claim 2

- (i) **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.**

136. As I discussed for limitation 1[a][3], the Chang-Fang device includes a *breast shield*, for example, Chang's breast shield. A POSITA would have recognized that Chang's breast shield includes a nipple receiving portion (*nipple tunnel*) and a breast contact portion (*breast flange*). EX1007, [0071], [0090]. As described in Chang, the *breast shield* of the Chang-Fang device is "symmetrical about the nipple receiving portion," which is "cylindrical." EX1007, [0090]. The breast shield is also configured to be "disabled when the flange ["breast shield"] is not placed in an operating position." EX1007, [0017]. From these descriptions, a POSITA would have understood, and found obvious from Chang's description, the *breast shield* in the Chang-Fang device is symmetrical about the cylindrical nipple receiving portion, which enables correct alignment with the user's nipple to enable rotation in order for the diaphragm to be positioned on top of the nipple. *See* EX1001, 18:8-16, 37:7-10. The *breast shield* therefore is configured to *rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct operating position onto a breast*.

c. Claim 3

- (i) 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.**

137. In the Chang-Fang device, the *breast shield*, for example, Chang's breast shield, is configured as described in Chang. Chang describes that its breast

shield is a “skin contact member” or “configured to form a seal with the breast.” EX1007, [0008], [0071]. Thus, consistent with Chang, the *breast shield* in the Chang-Fang device also *presents a single continuous surface to a nipple and a breast. Id.*

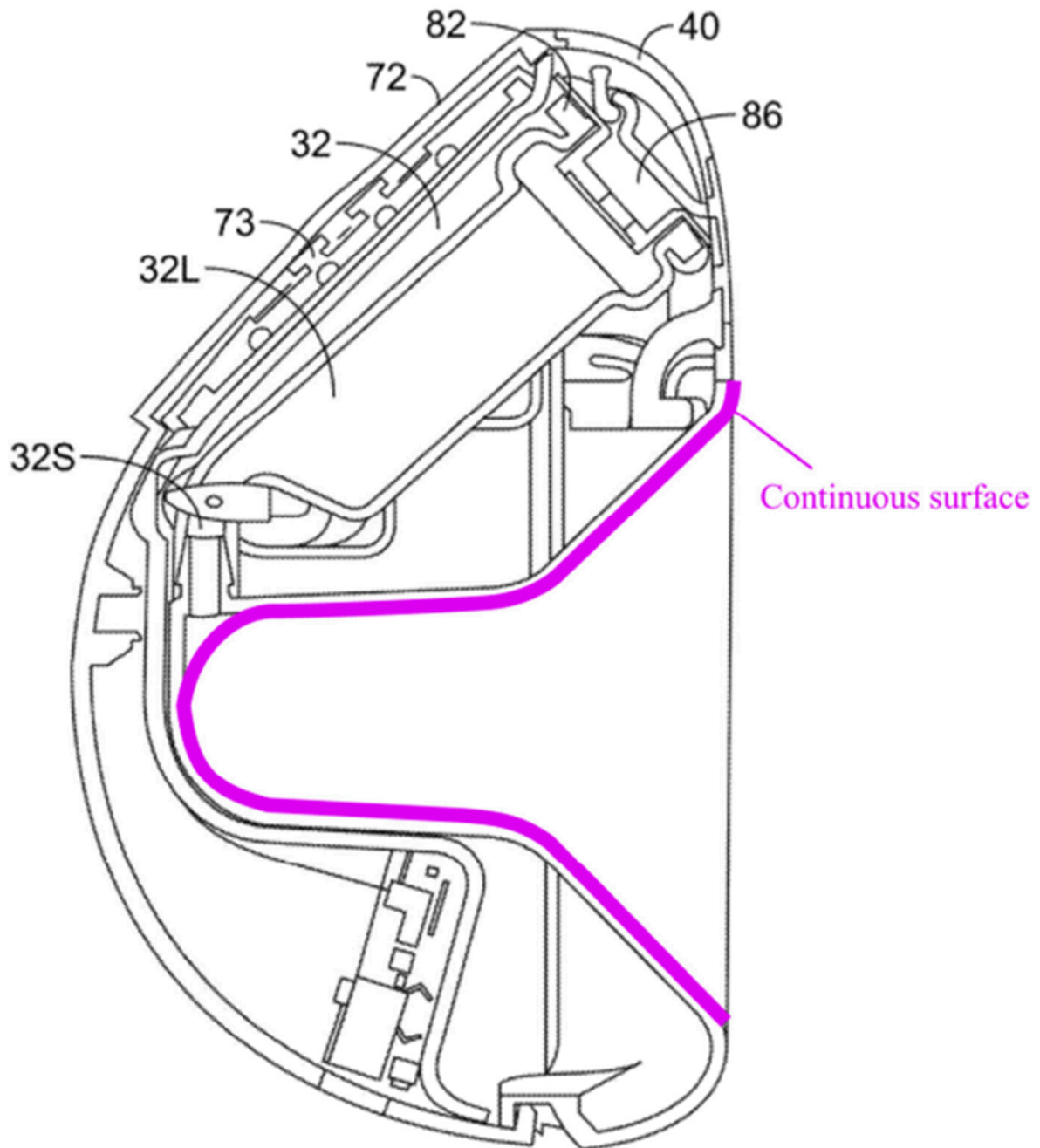


FIG. 4

EX1007, FIG. 4 (annotated)

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]; FIGS. 4-6A. Based on my knowledge and experience in the field, a POSITA would have also recognized and found obvious that the *breast shield* “form[s] a seal with the breast” (*id.*, [0022]), as described in Chang. This avoids edges or interfaces that may create discomfort when sealingly engaged with the breast during use.

d. Claim 4

- (i) The breast pump device of claim 1, wherein the breast shield integrates the breast flange and nipple tunnel as a one-piece item.**

138. As I discussed for limitation 1[a][3], the Chang-Fang device includes a *breast shield*, e.g., Chang’s breast shield, which includes a nipple receiving portion (*nipple tunnel*) and a breast contact portion (*breast flange*). EX1007, [0071], [0090]. Chang’s breast shield is “sized and shaped to engage a breast of a user,” and “contoured to comfortably fit against a wide range of user’s bodies and to provide structure for sealingly engaging with breast tissue.” EX1007, [0071]. Further, in Chang, outer shell 12 and pump chassis 35 are formed as a pump housing. The *breast shield* of the Chang-Fang device is similarly configured as a *one-piece item*. See EX1007, [0073], FIGS. 1A, 6A; see Analysis of Limitation 1[a][2].

e. Claim 5

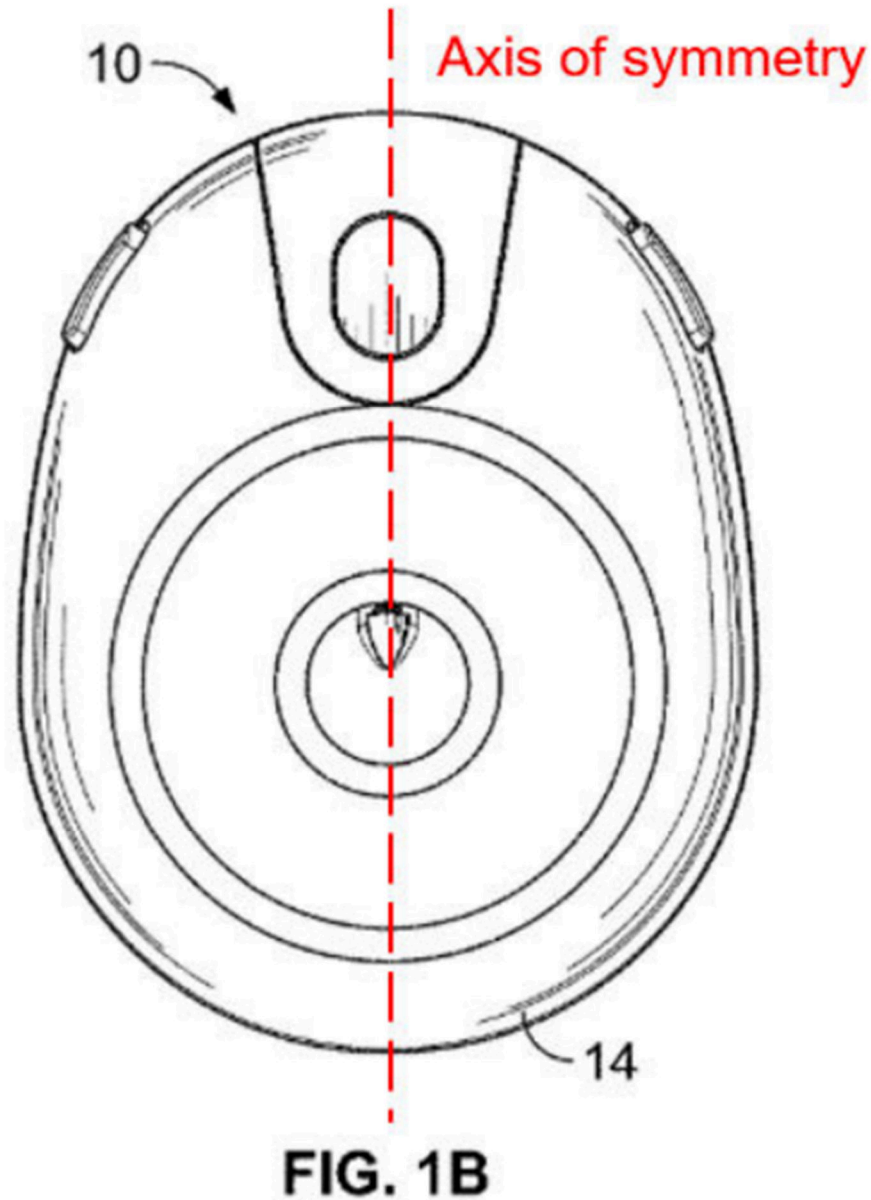
- (i) The breast pump device of claim 1, wherein the breast flange and the nipple tunnel are a single, integral item with no joining stubs.**

139. Based on Chang's suggestion, the *breast shield* of the Chang-Fang device is configured as a *single, integral item with no joining stubs*. See EX1007, [0071], [0073], FIGS. 1A, 6A; see Analysis of Limitation 1[a][2] and Claim 4.

f. Claim 6

- (i) The breast pump device of claim 1, wherein the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use.**

140. As I discussed for limitation 1[a][3], in the Chang-Fang device, the *breast shield* includes structures described in Chang, such as a nipple receiving portion and a breast contact portion. 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. EX1007, [0071]. Annotated Figure 1B below shows the breast shield has a top and bottom and is symmetrical about a center-line running from the top to the bottom of the breast shield when positioned upright for normal use.

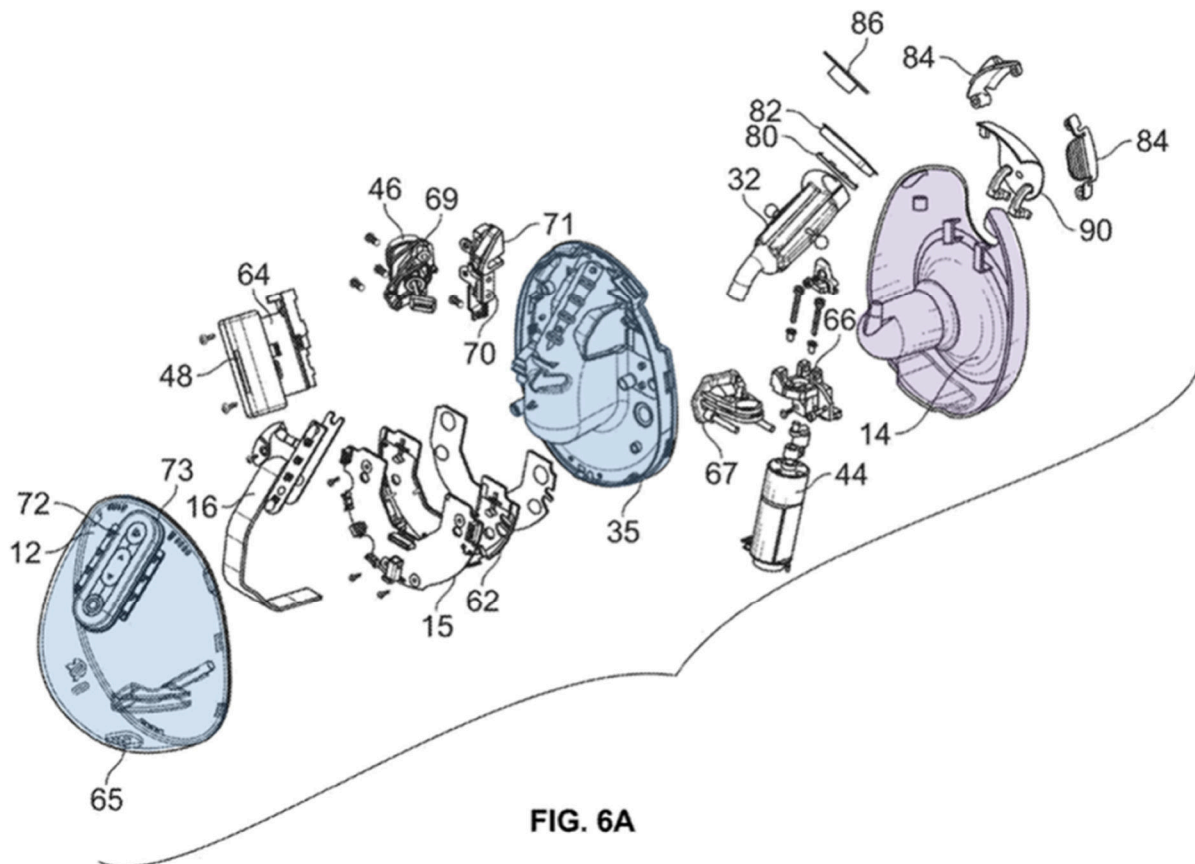


EX1007, FIG. 1B (annotated)

g. Claim 7

- (i) The breast pump device of claim 1, wherein the breast shield is configured to slide in and out from the housing, together with the diaphragm, on guide members in the breast shield.**

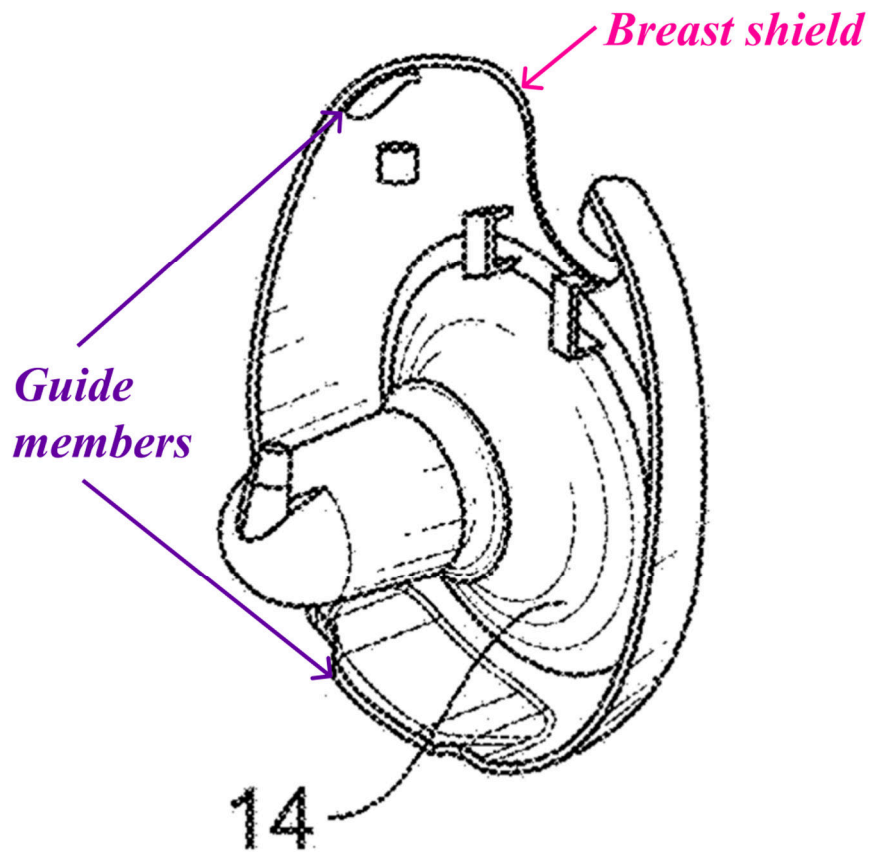
141. As I discussed for limitation 1[a][3], in the Chang-Fang device, the ***breast shield***, for example, Chang's breast shield, includes a nipple receiving portion and a breast contact portion. The Chang-Fang device includes a ***housing***, for example, a pump housing formed by Chang's "outer shell 12" and/or "chassis 35." EX1007, [0071], [0073], FIGS. 1A, 6A. As shown in the annotated figure below, in the Chang-Fang device, the ***breast shield*** and the ***housing*** are arranged like Chang's outer shell 12 and chassis 35 (blue) and the breast shield (magenta), with the breast shield configured to slide in and out when assembled and disassembled:



EX1007, FIG. 6A (annotated)

In the Chang-Fang device, the *diaphragm* (e.g. Fang’s elastic diaphragm 7) are also attached with the *breast shield*. See Section IX.A.1 (Chang-Fang); EX1009, [0019], FIG. 7. The *diaphragm* therefore *moves together with* the *breast shield* such that both are configured to slide in and out from the *housing*.

142. The *breast shield* in the Chang-Fang device is configured to include *guide members* to enable attachment to the device housing, consistent with Chang. Chang describes that “chassis 35” is “[c]onfigured between the housing 12 and flange 14,” and can “snap into engagement with the housing 12.” EX1007, [0080]. Chang also describes various ways of attaching flange 14, including use of “[a]alignment and attachment structure or holes” and “interface structure.” *Id.*, [0082]. Examples of *guide members* in Chang are shown below:



EX1007, FIG. 6A (annotated)

I note that Chang-Fang teachings actually provide more detail on this claim than the '381 patent, which largely repeats the same description of a housing “using guide members” without actually defining “guide members” or providing further detail regarding its scope. EX1001, 37:13-15, 38:26-28, 40:14-16, 41:1-3, 57:3-5, 64:57-60, 66:1-3, 67:1-3.

h. Claim 8

- (i) The breast pump device of claim 1, wherein the housing is configured to slide onto the breast**

shield, when the breast shield has been placed onto a breast, using guide members.

143. As I discussed for limitation 1[a][2], the Chang-Fang device includes a *housing*, for example, a pump housing formed by Chang's outer shell 12 and a recessed pump chassis 35. EX1007, [0071], [0073], FIGS. 1A, 6A. As previously noted, device components in the Chang-Fang device would have been attached or assembled based on the suggestions of Chang. When the breast shield has been placed onto a breast, the *housing is configured to slide onto the breast shield... using guide members*. See Analysis of Claim 7; EX1007, [0080], [0082]. Fang further suggests a pump housing that is configured to slide onto the breast shield using top annular edge 19 (*guide members*), as shown in Fang's Figure 7. EX1009, [0019], [0023], [0024], FIG. 7. This can be accomplished when the breast shield has been placed onto a breast. *Id.*

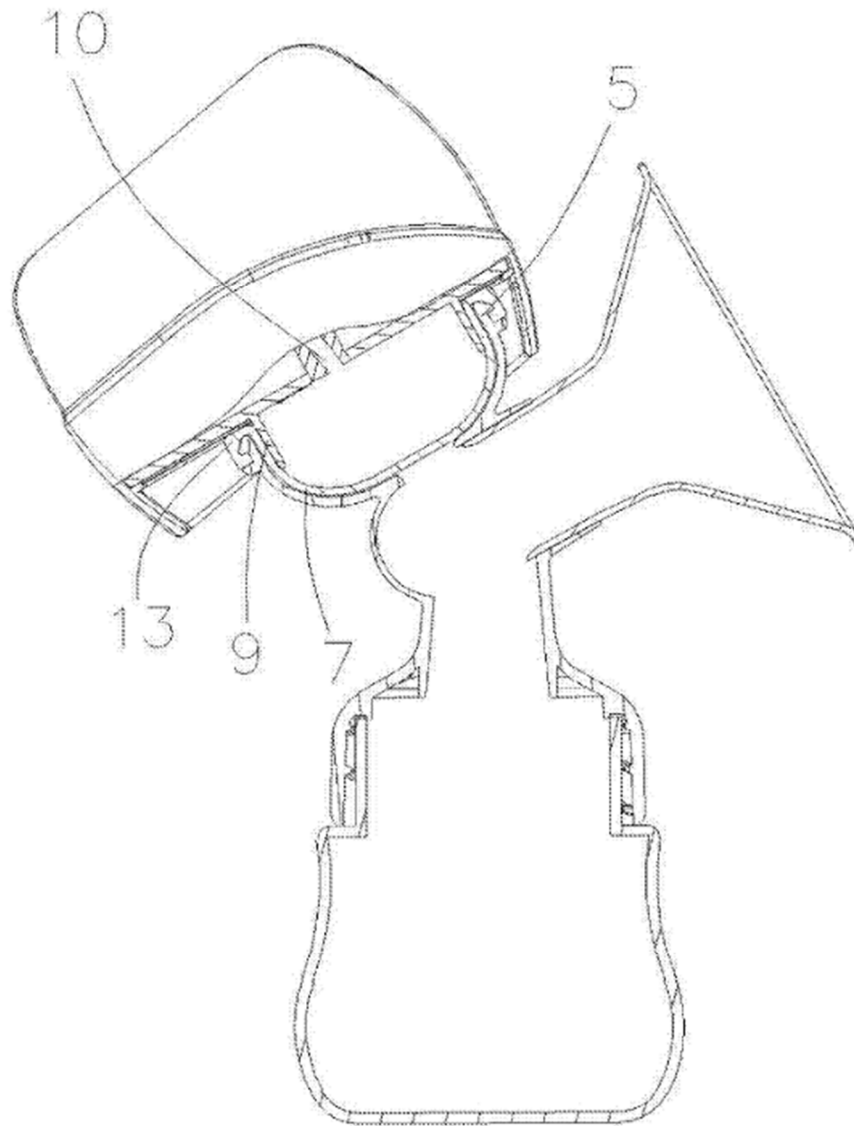


FIG. 7

EX1009, FIG. 7

i. Claim 9

- (i) The breast pump device of claim 1, wherein the breast pump device includes only the breast shield and the milk container that are directly**

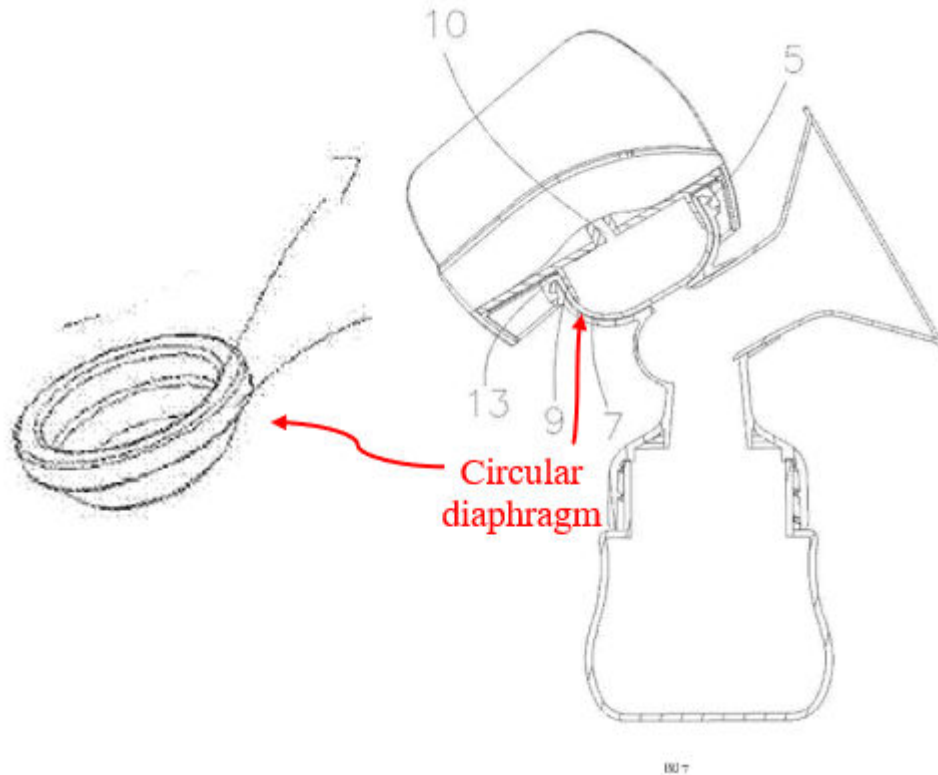
removable from the housing in normal use or normal dis-assembly.

144. In the Chang-Fang device, the *breast shield*, for example, Chang's breast shield, and the *milk container*, for example, Chang's container assembly, are each *directly removable* from the *housing* based on the suggestions of Chang. *See* Analysis of Limitation 1[a][2]-[4]. As described in Chang, the breast shield can be "removed from engagement with the remainder of" the device. EX1007, [0105]. The *milk container* in the Chang-Fang device is similarly removable from the *housing*, based on Chang's teachings. EX1007, [0021], [0023], [0081], [0086], [0092], [0099]-[0100]. In normal use or disassembly (e.g., to empty the milk container or clean the milk flowpath), only the breast shield and container assembly are directly removable from the pump housing. *See also*, EX1001, 5:66-6:15. Doing so provides access to empty the container assembly and clean the diaphragm components, for example, without requiring further disassembly. *Id.*

j. Claim 10

- (i) The breast pump device of claim 1, wherein the diaphragm is substantially circular and is configured to self-seal under the negative air pressure to a substantially circular diaphragm holder that is part of the housing.**

145. In the Chang-Fang device, the *diaphragm* is substantially circular based on the suggestions in Fang. Fang shows elastic diaphragm 7 to have a substantially circular shape:

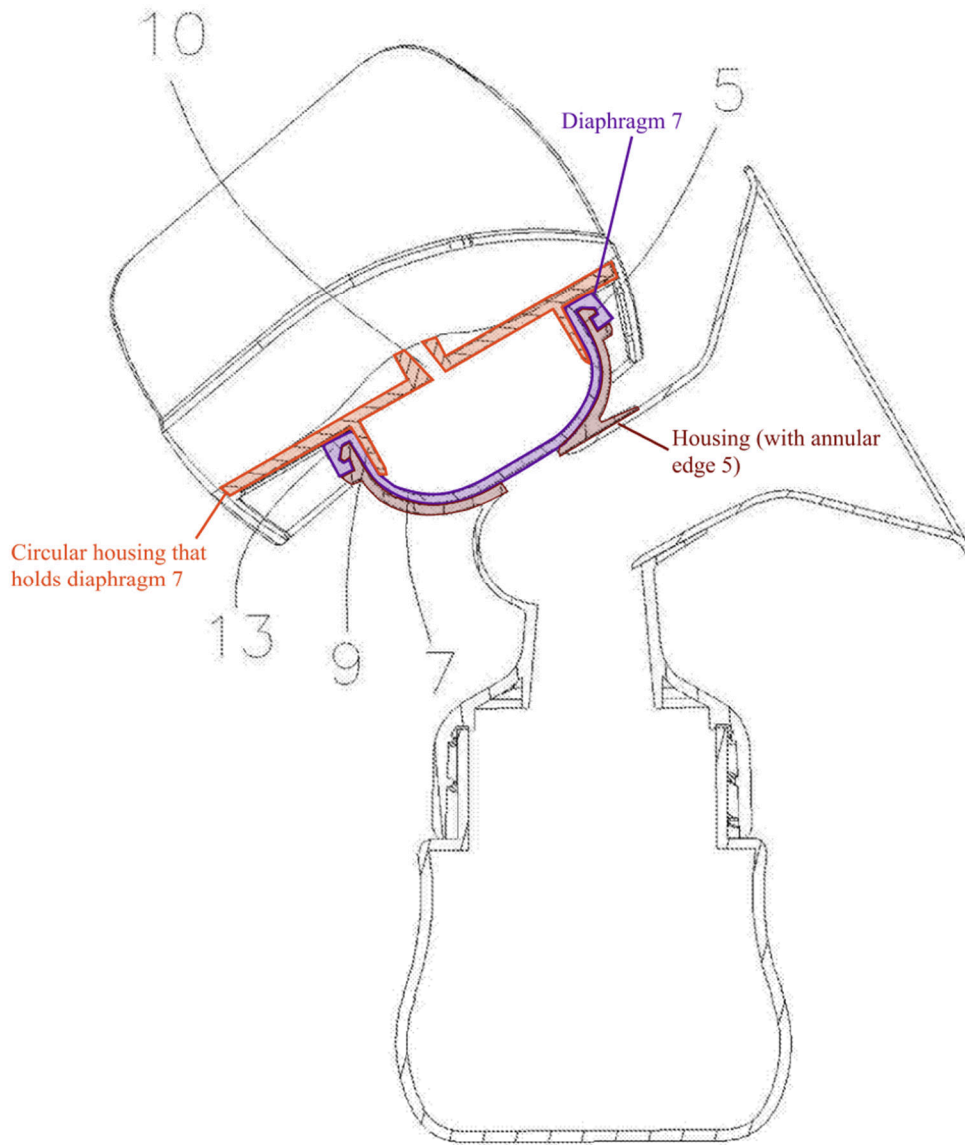


EX1009, Fig. 5 (partial), FIG. 7 (both annotated); *see also* EX1009, [0020]

Based on Fang, the **diaphragm housing** in the Chang-Fang device is similarly **substantially circular**, and engages with, and secures, the **diaphragm**. EX1009, [0020]-[0025]; FIG. 7.

146. Further, in the Chang-Fang device, the **diaphragm**, for example, 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 Limitation 1[a][1]; EX1001, 6:33-60. A POSITA would have understood, and found obvious, that this configuration provides a watertight and airtight seal around the recess or cavity in the housing (e.g., Fang's flange 9), thereby

preventing passage of milk and providing for generating of negative pressure. *Id.*, [0020]; *see id.*, [0025] (“secure installation”); *see also id.*, [0010]; FIG. 7.



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

k. Claim 11

- (i) The breast pump device of claim 1, wherein the diaphragm is a membrane, and the diaphragm deforms in response to changes in air pressure**

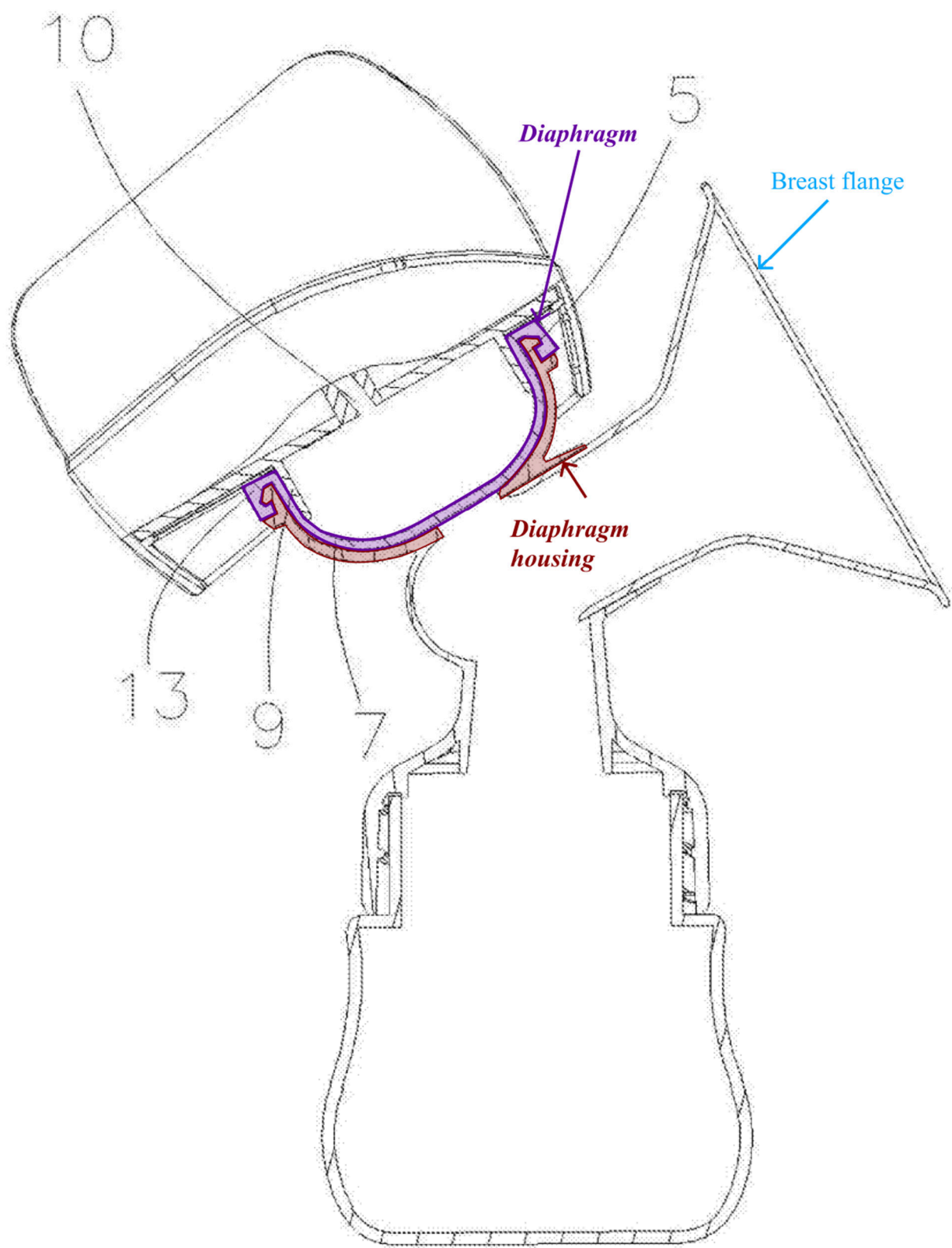
caused by the air pump to create negative air pressure in the nipple tunnel.

147. As I discussed for limitation 1[a][1], the *diaphragm* of the Chang-Fang device, for example, Fang's elastic diaphragm 7, is a *membrane* configured to prevent milk from reaching the pump. EX1009, [0019]-[0021]. The *diaphragm* also *deforms in response to changes in air pressure caused by the pump* to create negative air pressure in the nipple tunnel, consistent with Fang. As explained in Fang, when a vacuum is created on the pumping chamber, elastic diaphragm 7 deforms away from the nipple tunnel, creating negative air pressure in the nipple tunnel. EX1009, [0019]-[0025].

I. Claim 12

- (i) The breast pump device of claim 1, wherein the diaphragm is removable from a diaphragm holder that sits above the breast flange and the nipple tunnel.**

148. As I discussed for limitation 1[a][1], the Chang-Fang device includes a diaphragm, for example, Fang's elastic diaphragm 7, which is configured to prevent milk from reaching the pump. EX1009, [0019]; see Section IX.A.1 (Chang-Fang). In the Chang-Fang device, the diaphragm is seated against a diaphragm holder (e.g., flaring 4, alone or together with annular edge 5) that sits above a breast flange, in accordance with Fang's suggestions. As shown in the annotated Figure 7 of Fang below, the diaphragm housing is attached to the nipple tunnel such that it sits above it. EX1009, FIG. 7.



EX1009, FIG. 7 (annotated)

The *diaphragm housing* is configured to define a milk-flow side chamber with the *diaphragm*, as shown above.

149. Further, in the Chang-Fang device, the *diaphragm*, for example, Fang's elastic diaphragm 7) is similarly arranged such that it is *removable* from a *diaphragm holder*, for example, Fang's diaphragm housing, that *sits above* the *breast shield*. As previously noted, based on Chang, the *breast shield* includes a nipple receiving portion (*nipple tunnel*) and a breast contact portion (*breast flange*). EX1007, [0071], [0090]; *see* Analysis of limitation 1[a][3].

m. Claim 13

(i) The breast pump device of claim 1, wherein the milk container is substantially rigid.

150. As I discussed for limitation 1[a][4], the Chang-Fang device includes a *milk container* (e.g., Chang's container assembly). *See* EX1007, [0008], [0010], [0019], [0021], [0023], [0081], [0086], [0092], [0099], [0100], [0101]. Chang describes that its milk container may be "flexible or rigid, or disposable or reusable." *Id.*, [0021]; *see* EX1001, 11:49-12:15 ("Preferably, the milk collection container 3 is a substantially rigid component").

n. Claim 16

(i) The breast pump device of claim 1, wherein the milk container includes a flexible valve that self-seals under negative air pressure against the milk port in the nipple tunnel and that permits the expressed milk to flow into the milk container.

151. As I discussed for limitation 1[a][4], the Chang-Fang device includes a *milk container*, for example, Chang's container assembly. EX1007, [0008], [0010], [0019], [0021], [0023], [0081], [0086], [0092], [0099], [0100], [0101]. Chang describes a "one-way valve that permits milk inflow into [a] milk collection container but prevents milk backflow from the milk collection container to the conduit." *Id.*, [0021]. The valve "facilitates creating a seal with the container to establish a closed system[,]" e.g., "a one-way valve" that "can assume a myriad of shapes and kinds including an umbrella valve, a duckbill valve, a ball valve or other valve." *Id.* Chang teaches other types of valves that similarly enable a closed system commonly used to self-seal under negative pressure. *See id.*, [0099], [0101], [0102]. Based on these descriptions, a POSITA would have understood and/or found obvious that the integral valve of the container assembly in the Chang-Fang device is configured to *self-seal[] under negative air pressure against a milk opening in the nipple tunnel and that permits milk to flow into the milk container.*

o. Claim 17

- (i) The breast pump device of claim 1, 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.**

152. As I discussed for limitation 1[a][4], the Chang-Fang device includes a *milk container*, e.g., Chang's container assembly. EX1007, [0008], [0010], [0019],

[0021], [0023], [0081], [0086], [0092], [0099], [0100], [0101]. Chang describes that its container assembly 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]. The “sealing component” thus 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.* The attachment secures the milk container with the pump housing, and allows the milk container to be released (e.g., after a pump session).

p. Claim 22

- (i) The breast pump device of claim 1, wherein the housing includes a wireless data communication system powered by the battery.**

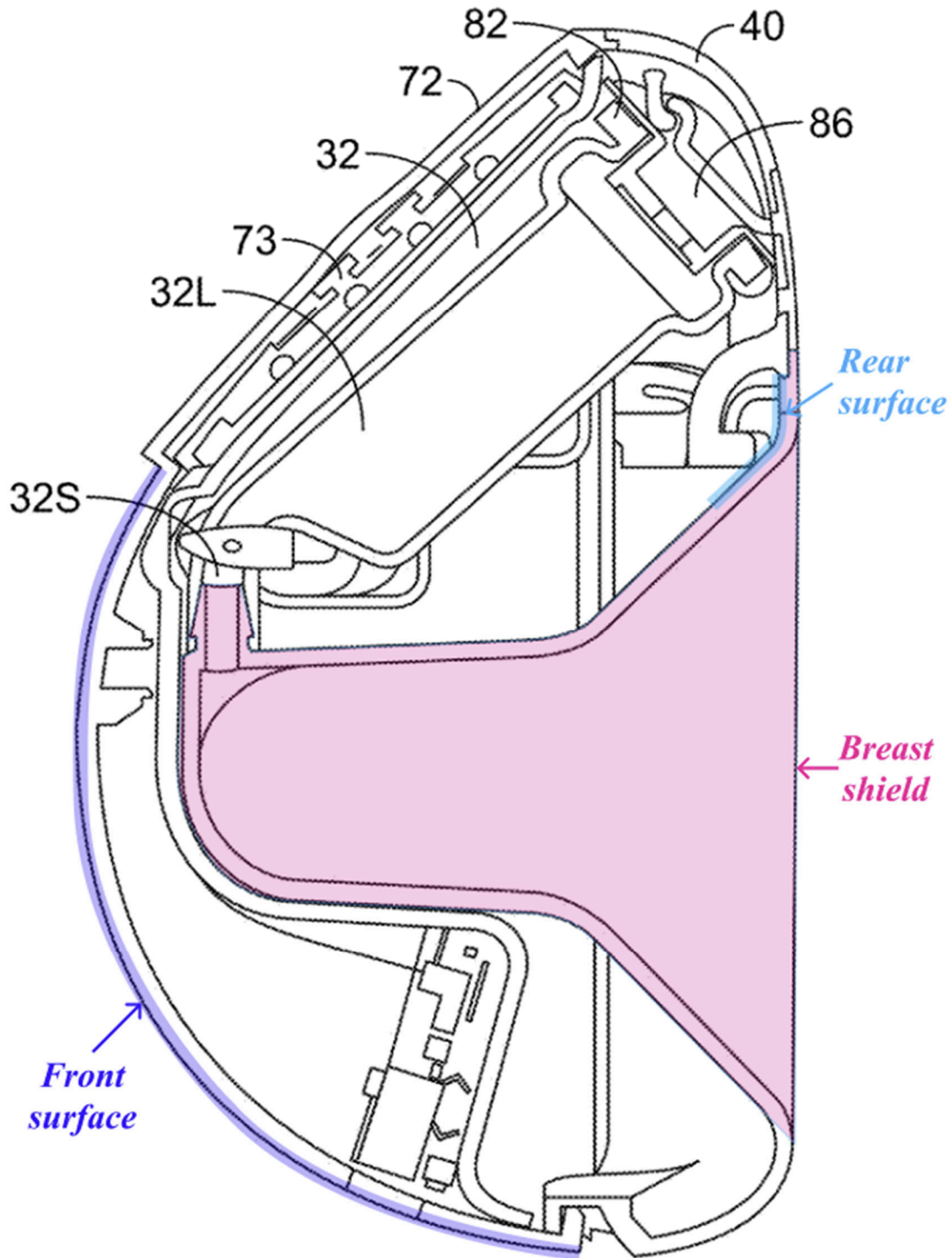
153. The *housing* of the Chang-Fang device would have included components that enable wireless communications (*wireless data communications system*) that are powered by a rechargeable battery (*battery*). EX1007, [0124]. Chang describes “various aspects of remote control and data collection approaches,” including an embodiment in which its breast pump device is “configured to communicate with a server, a remote computer, smartphone or other device such as through signal, such as by Wi-Fi, BLUETOOTH, BLUETOOTH Low Energy (BTLE), RFID, NFC or the like.” EX1007, [0124]. Further, “one or more chips can be incorporated into the controller of the pumping system 10 (by hard wire and/or

wirelessly, preferably wirelessly) and configured to be in communication with an external computer.” *Id.* The associated device may communicate “sensor(s)/chip(s) which indicate(s) when the system is in use, and can track usage.” *Id.*

q. Claim 23

- (i) The breast pump device of claim 1, wherein the housing has a front surface that is configured to fit inside a bra and to contact an inner surface of the bra, and a rear surface that is shaped to contact, at least in part, the breast shield.**

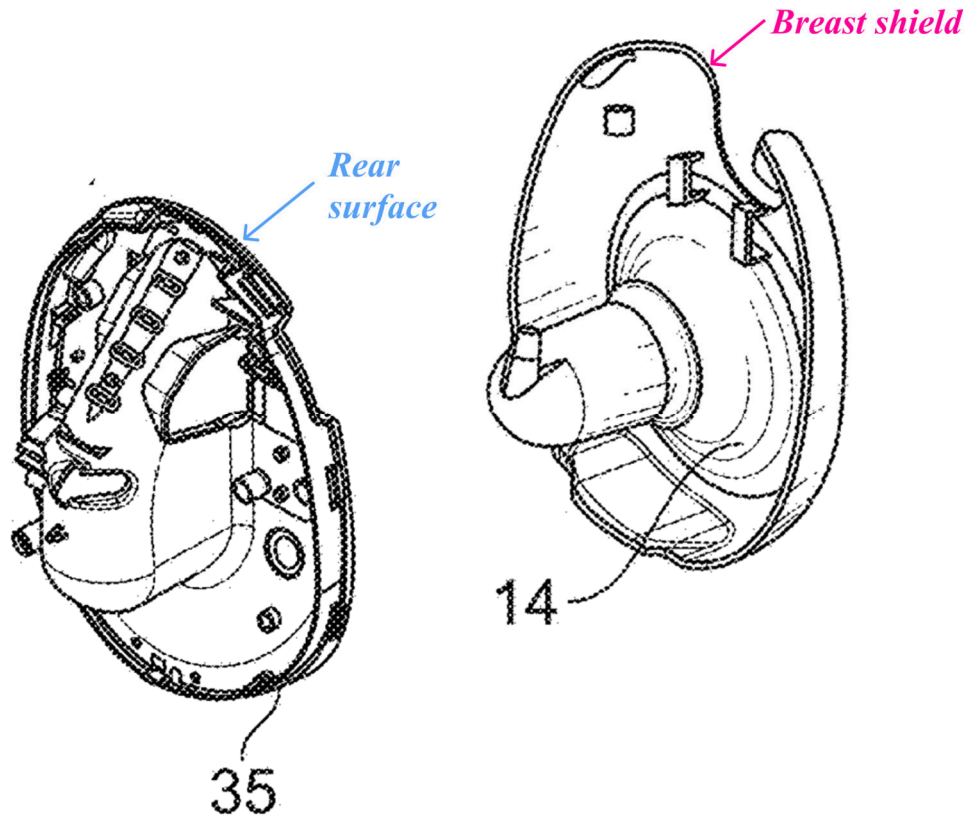
154. As I discussed for limitation 1[a][2], the Chang-Fang device includes a ***housing***, for example, a device housing formed by Chang’s housing or outer shell 12 and pump chassis 35. EX1007, [0071], [0073], FIGS. 1A, 6A. As shown in the annotated version of Chang’s Figure 4 (below), this configuration would have included a surface on the housing/outer shell 12 (***front surface***) that contacts an inner surface of the bra when worn (***configured to fit inside a bra and to contact an inner surface of the bra***), and a surface (***rear surface***) that contacts the ***breast shield***.



EX1007, FIG. 4 (annotated)

155. Additionally, as shown in the excerpted and annotated version of Chang's Figure 6A below, Chang's pump chassis 35 also includes one or more

surfaces near its periphery (including a *rear surface*) that contact the *breast shield* when assembled.



EX1007, FIG. 6A (excerpted and annotated)

r. Claim 27

- (i) The breast pump device of claim 1, wherein a total mass of the breast pump device, unfilled with milk, is less than 250 gm.**

156. The Chang-Fang device would have provided the features recited in this claim based on the teachings of Chang and Fang. Chang focuses on “**portable** breast pump systems and methods for collecting milk from a breast of a nursing mother.” EX1007, [0001]. Fang similarly recognizes that advantages of certain breast pump

systems is having “fewer handheld parts” and including “equipment [that] is relatively light...” EX1009, [0002]. From these descriptions, a POSITA would have found it obvious that the Chang-Fang device, when unfilled with milk, has a certain weight that provides comfort during use.

157. Additionally, around the Critical Date, portable breast pump systems were designed to be lightweight by incorporating compact, efficient motors and soft, wearable components to ensure comfortable, hands-free use for busy mothers while maintaining discretion and mobility. This is because a breast pump that is too heavy would be undesirable because it may cause discomfort, strain, and inconvenience during use. Heavier pumps may cause the device to pull down on the breast, leading to discomfort or even pain, especially if worn for extended periods. A POSITA would have found it obvious that the weight would be less than 250 grams. EX1007, [0001]; EX1009, [0002].

158. Based on my knowledge and experience in the field, and my review of Chang and Fang, lightweight breast pump systems were common and predictable for engineers in the field before the Critical Date. This is corroborated by, for example, Myers486, which disclosed a portable breast pump system with the total mass, unfilled with milk, to be about 2.4 ounces without batteries (68 grams) or 4.2 ounces (119 grams) with batteries ten years before the Critical Date. EX1039, [0053]. Like Chang and Fang, Myers486’s breast pump includes a compact unit that

gives the “natural appearance of the shape of a breast” and is meant to be “concealed underneath the user’s clothing.” *Id.*, [0045].

159. Further, like the Chang-Fang device, the Myers486 breast pump includes a breast shield, breast flange, and a vacuum driven with a battery, and the pump being located within a pump housing. *Id.*, [0047]. And, like Chang, extracted milk flows into a discrete collection bag. *Id.*, [0084]; FIG. 20B. Myers486’s disclosure corroborates that a POSITA would have found it obvious to implement the Chang-Fang device to have a total mass of less than 250 grams when unfilled with milk.

160. Moreover, as discussed in Ground 1A, implementing the Chang-Fang device to have a specific weight, e.g., less than 250 gm, was an obvious design choice because these types of devices were designed to be lightweight, compact, and portable to ensure convenient and user-friendly use. This is also confirmed by the ’381 patent specification, which describes that “lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focused on minimizing the number of components.” EX1001, 7:18-24.

s. Claim 29

- (i) The breast pump device of claim 1, wherein the air pump is configured to generate negative air pressure with a maximum suction of approximately 240 mmHg.**

161. Chang describes that its breast pump device may function “by operating a control system that tracks internal pressure of the system against a known waveform,” where the waveform is a “vacuum waveform indicative of pressures applied to a breast, and can define a sine wave fluctuating between about 60 mmHg of vacuum to a vacuum from about 120 mmHg to about 250 mmHg, or other desirable or useful waveform.” EX1007, [0012]; *id.*, [0087]-[0088].

162. A POSITA would have understood and found obvious that Chang’s reference to “about 250 mmHg” corresponds to *a maximum suction of approximately 240 mmHg*. EX1001, 33:47-34:38. In my opinion, for portable breast pump systems around the Critical Date, a POSITA would have recognized that the difference between a maximum suction of 240 mmHg (as claimed) and 250 mmHg (as described in Chang) was not clinically significant because this difference did not meaningfully change the functionality of the breast pump device in extracting milk. A clinically effective vacuum for breast pumping also typically encompasses a range for lactating women as disclosed by Chang. Additionally, a powered breast pump is a Class II device and requires pre-market clearance through a 510(k) submission to legally market the device in the United States. As part of that process, a device submitted for clearance is compared against a predicate device already cleared and reviewed by the FDA.

163. One example of a cleared device is the Elvie pump described in the 510(k) submission numbered K18186 which corroborates my analysis.¹ In this submission, Elvie cited the Medela Freestyle as their predicate device, which is summarized in the 510(k) submission numbered K150499² (decision date 4/21/2015). In the K150499 submission, the specific vacuum ranges for the Freestyle is between 45-245 mmHg in expression mode with a maximum vacuum of 270 mmHg. This is further evidence that corroborates my analysis that a POSITA would have found it obvious, based on Chang and Fang's description, to implement known breast pump devices around the Critical Date to *generate negative air pressure with a maximum suction of approximately 240 mmHg*.

B. Ground 1B: Obviousness of Claim 19 Over Chang-Fang-Yuen629

1. Combination of Chang, Fang, and Yuen629

164. As discussed in Section VIII.A, Chang describes a portable breast pump device designed to fit within a bra, and Fang introduces an elastic diaphragm pump that prevents milk from entering the pump's main body, thus ensuring ease of cleaning and maintenance. EX1007, [0019]; EX1009, [0020]. Based on my knowledge and experience in the field, and my review of Chang, Fang and Yuen629,

¹ See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K181863>

² See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K150499>

A POSITA would have recognized the benefits of combining these technologies to improve the overall functionality, hygiene, and user convenience of a breast pump system.

165. For example, Yuen629 describes incorporating sensors that detect the flow of milk and a microcontroller that calculates the rate of milk flow based on this data. EX1011, Abstract. The Yuen629 system uses IR units to monitor milk accumulation and control the pump's operation in real-time. *Id.*, 4:63-5:6. When the milk reaches a certain level, the system stops the pump, allowing the milk to flow into a collection bottle, and then resumes pumping as needed. *Id.*

166. Based on my knowledge and experience in the field, a POSITA would have wanted to integrate Yuen629's sensor and control technology into the Chang-Fang breast pump system to not only provide efficient and hygienic milk extraction, but also offer real-time monitoring and control of the extraction process, as suggested by Yuen629. By combining these teachings, the combined device would have enhanced functionality to monitor milk flow in real-time and adjust the vacuum pressure dynamically. For example, Yuen629's sensors are configured to detect when the milk flow slows down and trigger the diaphragm pump to adjust the suction accordingly. This configuration enhances milk extraction efficiency. This dynamic adjustment would have ensured that the milk is extracted gently and effectively, reducing the risk of discomfort or injury to the user.

167. Fang's diaphragm pump design isolates the milk from the pump components, which is further enhanced by Yuen629's ability to monitor milk flow and prevent overflow. The sensor-based system described in Yuen629 would allow for precise control over when the pump operates, preventing the milk from contacting any part of the pump mechanism other than the milk collection chamber and associated tubing, thus maintaining a high level of hygiene. EX1011, 5:7-28; EX1009, [0019].

168. Integration of Yuen629's technology into Chang's compact and wearable breast pump system would have also resulted in a highly convenient device that not only fits discreetly within a bra but also provides real-time feedback on the milk extraction process. The sensor data would be used to inform the user of the amount of milk collected, the rate of flow, and even potential issues such as blockages or reduced suction efficiency, for example, thereby allowing for immediate adjustments. This feature would have significantly enhanced the user experience by providing more control and information during the milk extraction process. *See* EX1007, [0011]; EX1011, 6:9-23.

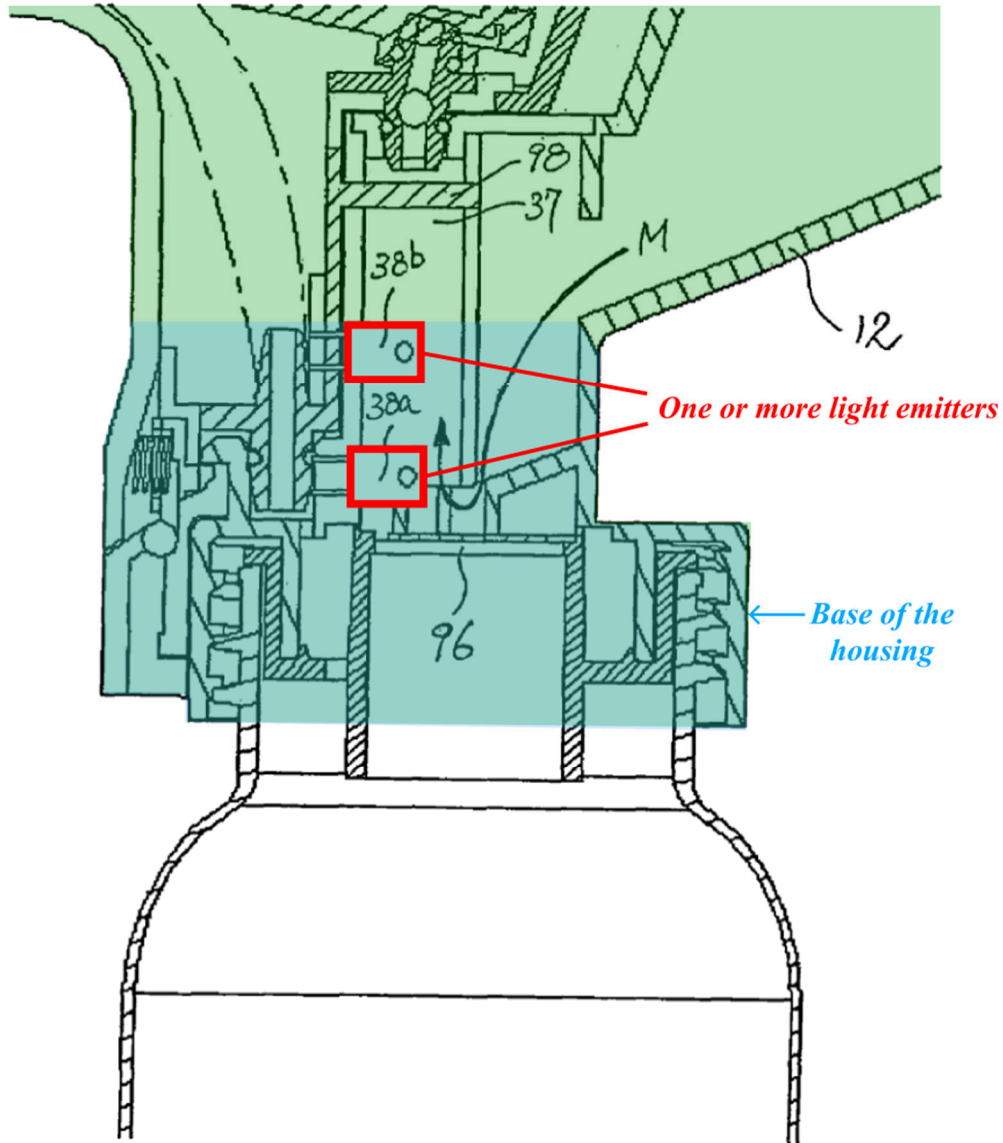
2. Analysis

a. Claim 19

- (i) The breast pump device of claim 1, wherein a top of the milk container includes an optically clear region that is aligned below one or more**

light emitters positioned in a base of the housing.

169. The Chang-Fang-Yuen629 device includes *one or more light emitters*, for example, Yuen629's IR units 38a and 38b positioned in a base of a pump housing (*base of the housing*), in accordance with Yuen629's suggestions. EX1011, 4:63-5:6, 5:7-28, 6:9-23, FIG. 14. Yuen629 describes that the flow of milk "block[s] the transmission of infrared signals between the transmitter and receiver of" IR units, which enables the calculation of "the rate of flow of milk (in grams per second, g/s)." EX1011, 4:63-5:6, 6:9-23. In the Chang-Fang-Yuen629 device, the *one or more light emitters* are also positioned near a bottom portion (*in a base*) of a pump housing (*housing*). This is consistent with Yuen629's suggestions of IR units 38a, 38b being positioned in a bottom portion of "head portion 22" of the "breast pump 10," as shown in the annotated version of Yuen629's Figure 14 below. EX1011, 3:22-32.



EX1011, FIG. 14 (annotated)

170. As suggested by Yuen629, it would have been obvious that a *milk container* of the Chang-Fang-Yuen629 device (e.g., Chang's container assembly) includes an *optically clear region* aligned below the IR units. EX1007, [0099]. In my opinion, it would have been obvious that Chang's container assembly is optically

clear given Chang's door assembly being "transparent so that a direct view to the container assembly is provided." *Id.*, [0081]; EX1011, 2:60-3:11; 6:9-23.

171. Milk containers with optically clear regions in portable breast pump systems were also obvious design choices by the Critical Date. An optically clear milk container allows a user to visually identify how much milk had been collected using a portable breast pump system, which makes it a useful feature. This is why optically clear milk containers were highly desirable for use in the types of portable breast pump devices described in Chang, Fang, and Yuen⁶²⁹.

C. Ground 1C: Obviousness of Claim 24 Over Chang-Fang-Makower⁷⁹⁴

1. Combination of Chang, Fang, and Makower⁷⁹⁴

172. As previously discussed, Chang-Fang (Ground 1A) offers a portable breast pump system that uses a diaphragm to create negative pressure, as suggested by Fang, to achieve known benefits. *See* Section IX.A.1. Based on my knowledge and experience in the field, the teachings of Makower⁷⁹⁴ complement the Chang-Fang device by incorporating a display that provides real-time feedback on critical operational parameters. Examples of critical operational parameters include suction levels, milk volume, and flow rate. In the resulting system, the breast pump device would include a display to show this information.

173. Improving user feedback and control was recognized as valuable while operating a breast pump. Around the Critical Date, user control and feedback were

well-known necessities in portable breast pump systems, especially for mothers wanting to track and optimize their milk expression. By integrating Makower⁷⁹⁴'s display with the Chang-Fang device, a POSITA would see that the addition of a display would allow users to monitor the diaphragm pump's effectiveness (based on Fang's teachings) and easily adjust suction levels or pumping rhythms (from Chang's teachings). Makower⁷⁹⁴'s display enhances the Chang-Fang system by providing real-time visual feedback, helping users track the pump's performance, troubleshoot issues like air leaks or improper suction, and monitor milk output during each session.

174. Adding a display to the Chang-Fang device would also have been recognized as advantageous since it allows the monitoring process to be simpler and more convenient for users. According to Makower⁷⁹⁴, placing a display on the device housing provides key information such as suction pressure, the phase of feeding, and whether an air leak has occurred. Breast pumps often included features that allowed mothers to monitor the device's performance without needing to stop and check multiple components. The real-time display also eliminates the need for users to rely solely on tactile or auditory cues, allowing them to continue other activities while easily glancing at the pump's status. This improves the portability and ease of use of the Chang-Fang system, which is critical for an in-bra, wearable breast pump where discretion and convenience are key.

175. The Chang-Fang-Makower794 combination would have also enhanced data logic capabilities based on Makower794's description of wireless communication with external devices. Around the Critical Date, many portable breast pumps were becoming smarter and more connected, often syncing with mobile apps for tracking data like volume expressed and session duration. The integration of a display would provide a useful onsite summary of key metrics, while still allowing users to access more detailed data on their smartphones later. Additionally, pairing a display with wireless data transfer would allow the Chang-Fang device to give users immediate feedback directly on the pump while syncing detailed information with an external device. This makes the breast pump more modern and data-driven, aligning with the trend toward smart health devices. The display would offer real-time feedback without requiring users to check their phones during every session, simplifying the experience for busy, multitasking mothers.

2. Claim Analysis

a. Claim 24

- (i) The breast pump device of claim 1, wherein the housing includes at least one of a visual or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.**

176. The Chang-Fang-Makower794 device includes a *display*, as suggested by Makower794's display 250, configured to display *at least one of a visual...indicator*. As shown in Makower794's Figure 57, a display 250 on a device

housing may be used to display information “outputted to by controller 52.”

EX1014, [0163].

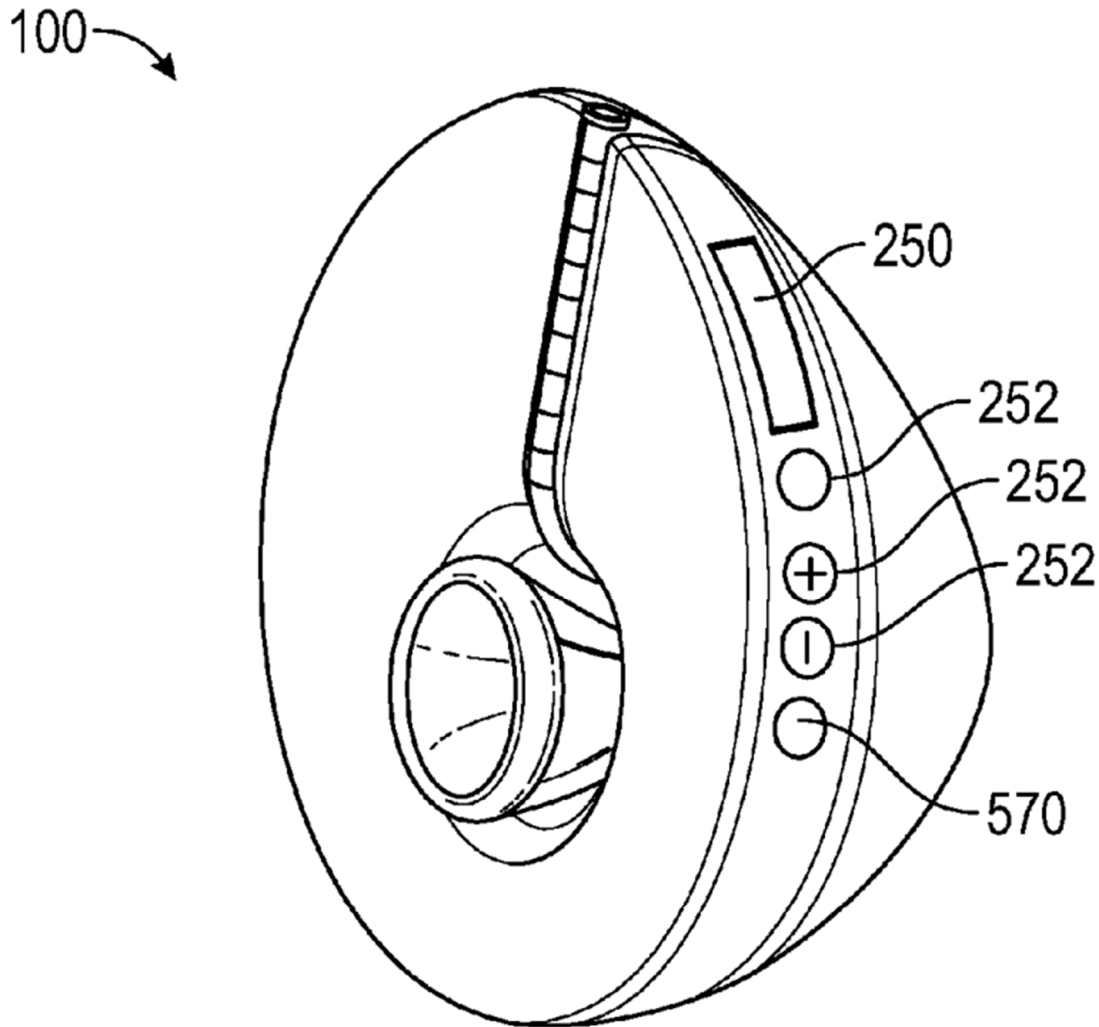


FIG. 57

EX1014, FIG. 57

177. Displayed information includes indications relating to “if an air leak develops, what the current suction/pressure reading in the adapter 10 tube 32 is,

approximate value of milk Volume having been expressed, approximate flow rate of milk, pressure waveforms, phases of feeding timing, rest programming, heating applied to breast, vibration applied to breast, etc.” EX1014, [0163]. The *display* of the Chang-Fang-Makower794 device indicates “approximate flow rate of milk” (*whether milk is flowing or not flowing into the milk container*).

D. Ground 1D: Obviousness of Claim 25 Over Chang-Fang-Makower794-Guthrie002

1. Combination of Chang, Fang, Makower794, and Guthrie002

178. As mentioned earlier, the combination of the Chang-Fang-Makower794 device (Ground 1C) provides a portable breast pump system that includes an integrated display for showing important parameters. *See* Section IX.C.1. Based on my knowledge and experience in the field, the display of these important parameters is also related to monitoring of the same. For example, Guthrie002 further describes examples of using embedded sensors within breast pump devices to monitor various operational metrics, such as the rate of milk collection and the progression of the pumping session. Given the complementary nature of these teachings, a POSITA would have been motivated to combine functionality of the Chang-Fang-Makower794 device (displaying parameters on an integrated display) and the suggestions of Guthrie002 (monitoring parameters using embedded sensors) into a combined device. In the combined device, a breast pump

includes embedded sensors designed to monitor parameters related to its operation, such as the rate of milk collection and the progression of the pumping session.

179. Based on my knowledge and experience in the field, Guthrie002's teachings would have improved the real-time monitoring capabilities of the Chang-Fang-Makower794 system by giving users more precise control over the breast pump device, particularly in portable systems where maximizing milk expression is critical. Around the Critical Date, it was common for portable breast pumps to include real-time data monitoring, as mothers sought more data-driven insights to improve efficiency. By integrating the sensors from Guthrie002 into the Chang-Fang-Makower794 system, the device provides real-time feedback on important parameters such as flow rate, volume pumped, and temperature, enabling users to make immediate adjustments. This integration would allow for continuous feedback on key pumping parameters, making the system more responsive and efficient. With these sensors embedded in the device, users may monitor detailed metrics in real time, adjusting settings like suction strength or pumping rhythm to optimize milk extraction and improve the overall performance of the system.

180. Around the Critical Date, it was also common for health devices to log and analyze performance metrics over time, providing valuable insights for users. By combining the sensor-driven data logging from Guthrie002 with the Chang-Fang-Makower794 system, users would be able to track long-term metrics, such as

total milk volume and pumping frequency. This data would help mothers optimize their routines and better understand pumping trends, ultimately improving the user experience by offering a more comprehensive overview of their pumping history.

181. Based on my knowledge and experience in the field, the combination also enhances user comfort and personalize pumping sessions, especially in the context of wearable pumps, where adaptability is key. In the combined device, sensors proposed by Guthrie002 monitor conditions, such as temperature. This allows the combined system to make automatic adjustments for improved comfort. Around the Critical Date, a significant focus in breast pump design was on user comfort, and by integrating Guthrie002's sensors into the Chang-Fang-Makower794 system, the combined device offers a more personalized experience, adapting in real time to the user's needs. For instance, sensors monitoring temperature and flow rate enable the pump to automatically adjust suction levels or rhythm based on the data being collected, thereby improving both comfort and performance. If the sensors detect a temperature drop, the device adjusts its settings to avoid discomfort, making it more user-friendly and suitable for extended or frequent pumping sessions.

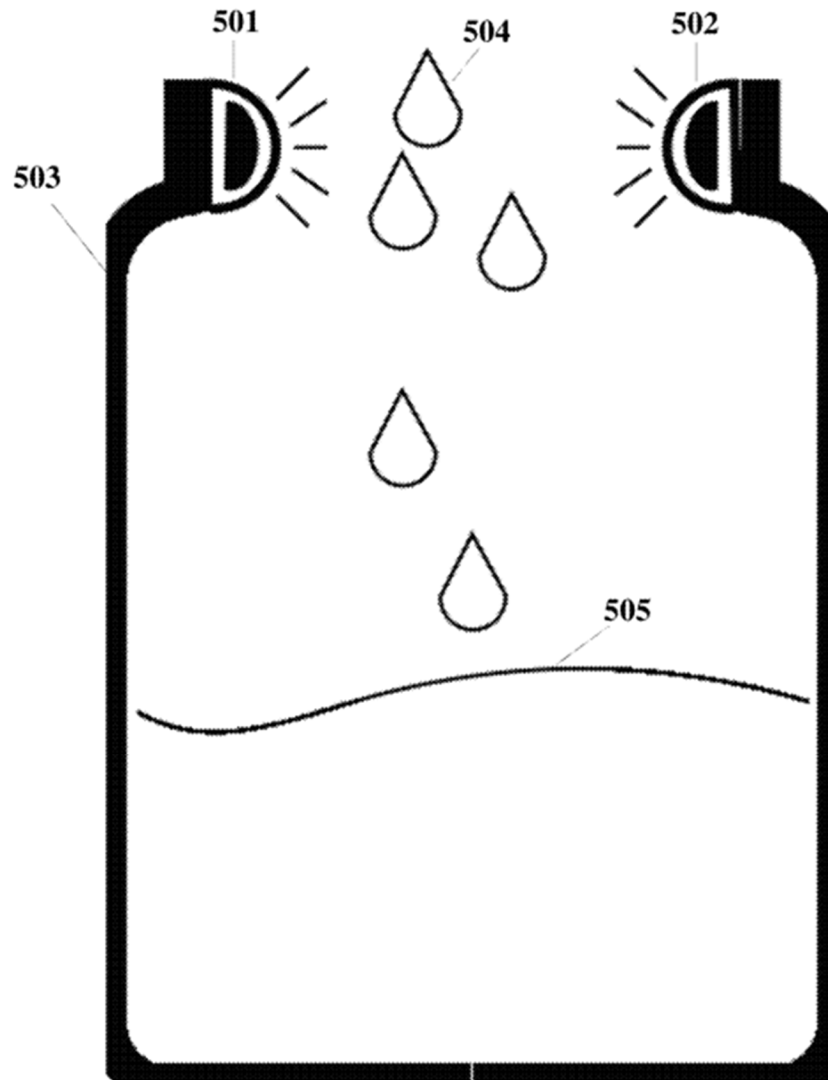
2. Claim Analysis

a. Claim 25

- (i) The breast pump device of claim 1, wherein the housing includes at least one of a visual or haptic indicator that indicates if the air pump is operating correctly to pump milk, based on**

whether a quantity or a height of liquid in the milk container above a base of the milk container is increasing above a threshold rate of increase.

182. In the Chang-Fang-Makower794-Guthrie002 device, a display (e.g., Makower794's display 250) is configured to display the types of information described in Makower794 and Guthrie002. For example, Makower794 describes that the display shows indication information relating to "if an air leak develops, what the current suction/pressure reading in the adapter 10 tube 32 is, approximate value of milk volume having been expressed, approximate flow rate of milk, pressure waveforms, phases of feeding timing, rest programming, heating applied to breast, vibration applied to breast, etc." EX1014, [0163]. Guthrie002 further describes examples of sensor networks that includes sensors embedded in a portable breast pump device. For instance, as shown in Guthrie002's Figure 5 (below), a collection container 503 of a breast pump device includes sensors 501 and 503 "located at the neck." EX1015, 10:39-60.



EX1015, FIG. 5

183. In the configuration shown in Figure 5, sensors 501 and 502 “may be measuring flow rate or temperature or counting drops.” EX1015, 10:39-60. Additionally, “[f]low rate and volume sensors may be based on liquid level measurements by means of capacitive sensors, ultrasonic sensors, microphones or optical sensors based on light and sound reflectivity.” *Id.* Based on the disclosures

of Makower794 and Guthrie002, the Chang-Fang-Makower794-Guthrie002 device includes the sensing elements (e.g., Guthrie002's sensors 501, 502) and display elements (e.g., Makower794's display 250) to display indication information relating to breast pump device operation, e.g., *if the pump is operating correctly to pump milk*. Further, based on the sensing functions described in Makower794, such as flow rate and liquid level measurements based on various methodologies (e.g., optical, capacitive, ultrasonic, light/sound reflectivity), it would have been obvious that the Chang-Fang-Makower794-Guthrie002 device is also configured to determine and assess whether *a quantity or a height of liquid in the milk container above a base of the milk container is increasing above a threshold rate of increase*.

E. Ground 2A: Obviousness of Claims 1-13, 16, 17, 22, 23, And 26-29 Over Chang-Fang-Kurihara

1. Combination of Chang, Fang, and Kurihara

184. Based on my knowledge and experience in the field, a piezoelectric system offers various advantages for the operation of a portable breast pump system. These types of systems enable precise control of the pumping action, which leads to more effective and comfortable milk expression. Around the Critical Date, piezoelectric pumps were also known for their low energy consumption, which would extend the battery life of the breast pump, making it more practical for prolonged use. The design of Kurihara's system, particularly with the integration of the cylindrical body and flow passage, would have reduced operational noise,

rendering the device more discreet and suitable for use in diverse environments. EX1016, [0093], [0123].

185. Based on my knowledge and experience in the field, and my review of Chang, Fang, and Kurihara, replacing or augmenting the existing pump mechanism in the Chang-Fang device with Kurihara's piezoelectric system would have involved a straightforward substitution that leverages the known benefits of piezoelectric actuation. These benefits include precision, efficiency, light-weight, silent operation, and compact design, all of which are within a well-understood framework of breast pump design. The piezoelectric system's ability to create a precise and consistent negative pressure would enhance the milk expression process in a more compact and integrated design.

186. Kurihara's cylindrical body and piezoelectric components are designed to be compact. This allows seamless integration into the existing structure of the Chang-Fang pump, particularly within the diaphragm housing. This configuration maintains the portability and in-bra usability of the device while enhancing its performance. *Id.* Further, Kurihara's teachings of including a filter to prevent liquid from reaching the piezoelectric driving part aligns with Fang's generalized concern about keeping milk separate from the pump's internal mechanisms. *See* EX1009, [0040]; EX1016, [0061]. Consistent with Fang and Kurihara, the Chang-Fang-

Kurihara device would have reduced the risk of contamination and make the device easier to clean and maintain.

187. Based on my knowledge and experience in the field, a piezoelectric system also provides various advantages to the operation of a portable breast pump system. A piezoelectric system allows for precise control of the pumping action, leading to more effective and comfortable milk expression. Piezoelectric pumps were often known for their low energy consumption, which would enhance the battery life of the breast pump, making it more practical for extended use. *Id.* Further, Kurihara's system would likely reduce operational noise, making the device more discreet and suitable for use in various environments. EX1016, [0093], [0123].

188. Replacing or augmenting the existing pump mechanism in the Chang-Fang device with Kurihara's piezoelectric system would have also represented a straightforward substitution that leverages the known benefits of piezoelectric actuation. The use of piezoelectric elements in pumps around the Critical Date was also well-documented, and their integration into a breast pump system was well within the skill set of a POSITA. Based on my knowledge and experience in the field, a POSITA would have had a reasonable expectation of success in combining Kurihara's technology with the Chang-Fang device. This is because the compatibility of the components and the established benefits of piezoelectric actuation. The implementation of piezoelectric-driven pumps in compact, portable

devices was also well-established at the time, further supporting its feasibility and predictability.

2. Claim Analysis

a. Element 1[a][1] / Claim 26

(i) The breast pump device of claim 1, wherein the air pump comprises a piezo air pump system.

189. The Chang-Fang-Kurihara device includes a pump, for example, Kurihara's piezoelectric driving part 33, such that the device is configured as a *piezo air pump system* based on the teachings of Kurihara. Kurihara describes that the "piezoelectric driving part 33" includes "a piezoelectric element 34A, a reinforcing plate 34B, a floating terminal 34C, a diaphragm forming plate 37A, an opposed plate 37B, a case portion 35A, and a cover portion 35B." EX1016, [0065]. The piezoelectric element "deforms by the application of a driving voltage and an elastic member to which the piezoelectric member is attached." *Id.*, [0015]. The piezoelectric driving part 33 is configured to "generate[], inside of [a] flow-passage forming section 1 (flow passage 2), a flow of fluid directed from the suction port 20 to the discharge port 29 via the flow passage 21, the upper chamber 23, and the flow passage 28." *Id.*, [0063].

190. In the context of the Chang-Fang-Kurihara system, a POSITA would have understood and/or found obvious that Kurihara's piezoelectric driving part 33 may be configured as a piezoelectric pump that "applies a driving voltage to an

elastic member” to generate a flow of air to deform, for example, Fang’s flexible diaphragm. EX1009, [0019], FIG. 7; EX1016, [0015]. Additionally, because Kurihara describes using piezoelectric elements (e.g., piezoelectric driving part 33) to move a flexible diaphragm to generate pressure differences, a POSITA would have understood and/or found obvious that the piezoelectric pump of the Chang-Fang-Kurihara device is configured as a *piezo air pump system*. *Id.* Accordingly, Chang-Fang-Kurihara renders obvious Claim 26. To be clear, even if “an air pump” structure of Element 1[a][1] in Claim 1 was viewed as referring to a Piezo air pump like embodiments described in the ’381 patent, claim 1 is likewise rendered obvious by the predictable Chang-Fang-Kurihara combination for the reasons I articulated above. To be clear, where I do not address Kurihara in the Ground 2A analysis, the Ground 1A analysis applies fully (e.g., as to the other elements of Claim 1 and claims 2-13, 16, 17, 22, 23, 27, 29 (e.g., refer to paragraphs 109-163)).

b. Claim 28

- (i) The breast pump device of claim 1, wherein the breast pump device makes less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.**

191. The Chang-Fang-Kurihara device would have been configured according to the suggestions of Kurihara to “configure a compact and silent breast-milk suction device,” thereby rendering this claim obvious. EX1016, [0093].

192. Additionally, based on my knowledge and experience in the field, and my review of Chang, Fang, and Kurihara, silent operation of portable breast pump systems was common and predictable for engineers in the field before the Critical Date. This is corroborated by, for example, Baker, which describes an “irrigation and aspiration device” having a noise level of 20 dB. EX1040, [0121]. While Baker’s device is used for irrigation and extraction of nasal mucus, a POSITA would have found its teachings to be applicable to portable breast pump systems. Kurihara also describes both nasal aspiration and breast pumping embodiments where the primary difference is the type of nozzle used. *See generally* EX1016.

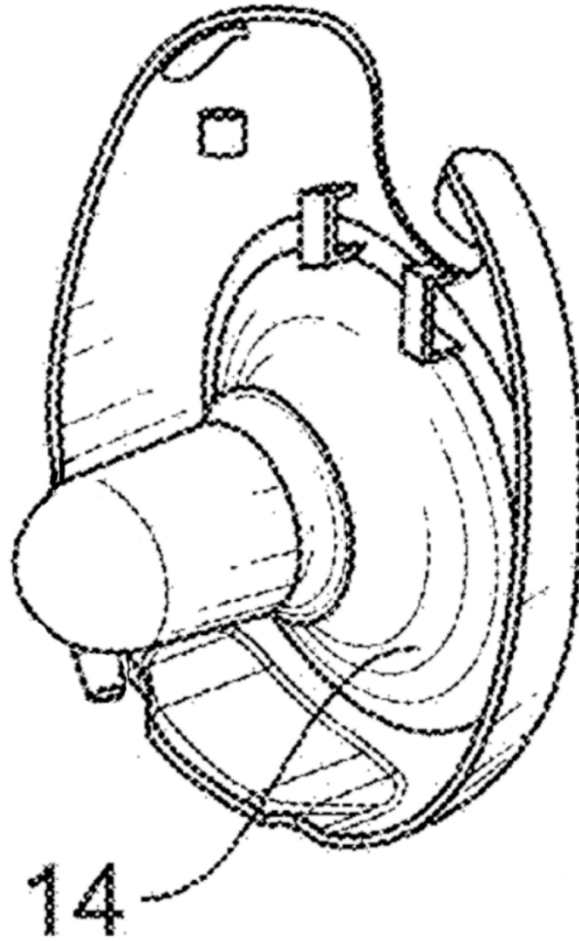
F. Ground 3A: Obviousness of Claims 1-18, 20-23, 27, And 29 Over Chang-Fang-Khalil

1. Combination of Chang, Fang, and Khalil

193. Based on my knowledge and experience in the field, and my review of Chang, Fang, and Khalil, a POSITA would have been motivated to implement the Chang-Fang combination (Ground 1A) based on Khalil’s suggestion to incorporate a rigid container at the lower portion of the device. This configuration would have provided a downward flow of milk to the container to achieve known benefits. Chang specifically mentions that its device can be designed with a “rigid” milk container and that this container can be placed in “alternative locations.” EX1007, [0021], [0105]. Khalil provides a straightforward suggestion for incorporating a rigid container into a wearable, in-bra device. EX1010, [0032] (“the invention can be

designed as a hands-free unit and worn under a bra”). Khalil also discloses the use of a rigid “milk collection container... integrated in the housing of the unit or coupled directly thereto.” EX1010, [0069]; *see also id.*, [0050], [0067].

194. In the Chang-Fang-Khalil combination, the breast pump device features an integrated milk container located at the lower portion of the device, as suggested by Khalil. This container would be contoured to match the shape of other parts of the device (such as the "outer shell 12") and support its wearable, in-bra design. Milk flows through the nipple tunnel and then downward through a one-way valve into the container. EX1010, [0053], [0069]. The container attaches to the pump housing (such as the “chassis 35” and/or “outer shell 12”) with a removable connection, ensuring fluidic communication with the nipple tunnel. *Id.*, [0069]. To enable the positioning of the milk container according to Khalil’s teachings, a POSITA would have modified the direction of the milk port of Chang’s breast shield such that it is configured to point downwards. *Id.* This modification is shown in a modified version of Chang’s Figure 6A below:



EX1007, FIG. 6A (excerpted and modified)

Based on the modification shown above, milk flows through the nipple tunnel and then downward through the modified milk port (with a one-way valve) into the container. EX1010, EX1010, [0053] (“non-return valve 5”/“duckbill valve”), [0069]. The container includes a removable attachment with the pump housing (e.g., “chassis 35” and/or “outer shell 12”), and fluidic connection with the nipple tunnel via the modified milk port. 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”).

195. As explained in Ground 1A, based on Chang’s suggestions, the positioning of the modified milk port is intermediate to a closed end of the nipple tunnel and a breast flange of the breast shield. *See* EX1007, FIG 6A. For example, the structures providing the milk port are not positioned at a distal end of the nipple receiving portion (i.e., at the curved closed end). This analysis is consistent with the examiner’s statements during the prosecution history (*see* EX1002, 2252) and Patent Owner’s allegations of infringement of limitation 1[a][3][i] before the district court (*see* EX1054C, 15).

196. Based on my knowledge and experience in the field, and my review of Chang, Fang, and Khalil, the positioning of a milk port to be intermediate to a closed end of a nipple tunnel and a breast flange of a breast shield was common and predictable for engineers in the field before the Critical Date. Various breast pumps were known to include milk ports that were positioned intermediate to a closed end of a nipple tunnel and a breast flange. This is corroborated by, for example, Myers⁴³⁷, which describes a portable breast pump system with a flange 30 that “includes an outlet 62 through which the milk drawn from the breast flows out of the flange 30.” EX1037, [32]. As shown in Figures 10A and 10B below, the outlet 62 (which provides a milk port) is intermediate to portion of flange 30 that contacts

a breast (i.e., breast flange) and an end formed by a flange top 35 enclosing a vacuum chamber 60 (i.e., closed end of a nipple tunnel). *Id.*, [33]. Additionally, in Figure 10B “the outlet 62 is funnel-shaped so as to direct the milk flow out of the flange 30 and prevent the milk from flowing back towards the breast.” *Id.*

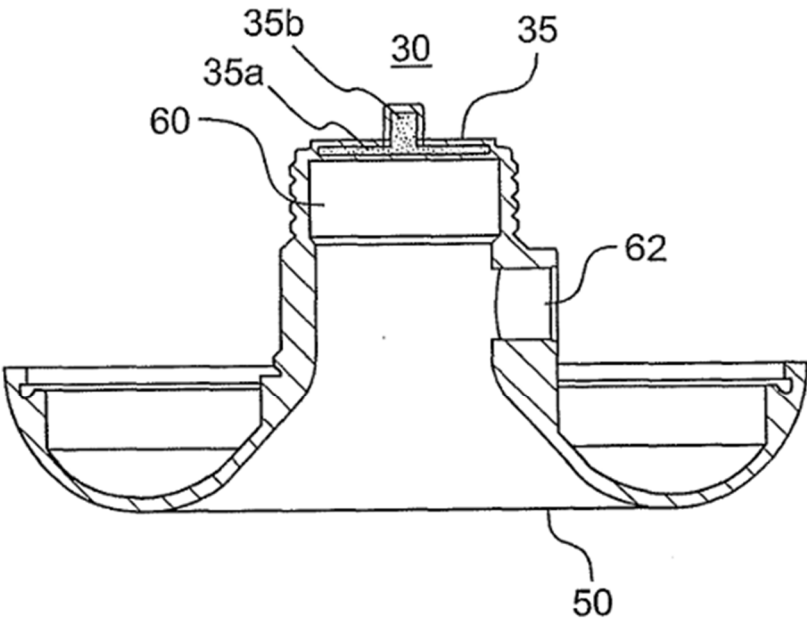


FIG. 10A

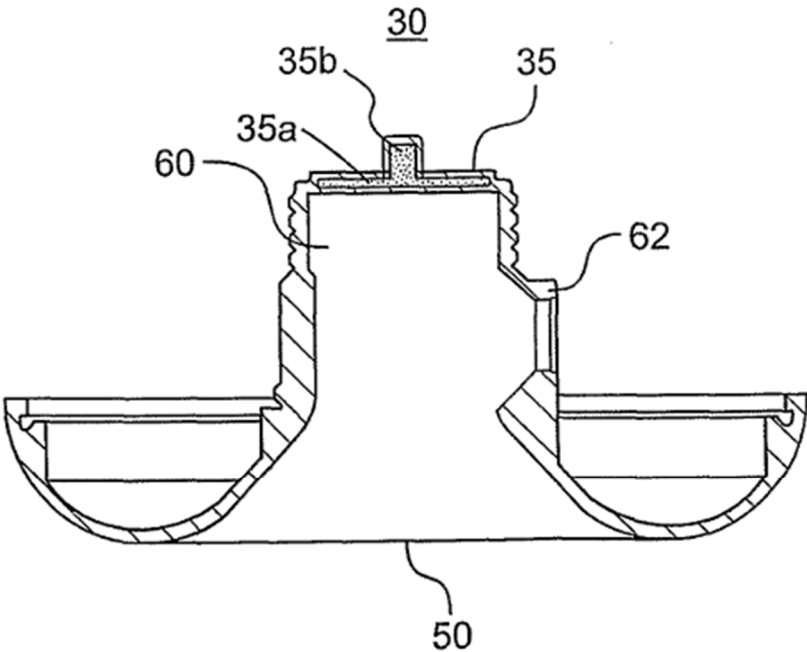


FIG. 10B

EX1037, FIG. 10A, 10B

197. A POSITA would have recognized that one well-known configuration of the modified milk port in the Chang-Fang-Khalil device is a positioning that is intermediate to the closed end of a nipple tunnel and a breast flange. This understanding is corroborated by the configuration shown in Myers437's Figure 10B, where the outlet 62 is positioned intermediate to the closed end and the nipple tunnel to "direct the milk flow out of the flange 30 and prevent the milk from flowing back towards the breast." EX1037, [32]. In my opinion, positioning the modified milk port in the Chang-Fang-Khalil device to be arranged in a similar fashion was an obvious design choice to, for instance, reduce backflow of milk towards the breast, which would have been recognized by a POSITA based on Chang, Fang, and Khalil's description, which is further corroborated by Myers437. *Id.*

198. The combination of Khalil with Chang and Fang improves the cleanability and ease of assembly/disassembly in a wearable device with a diaphragm. Khalil highlights the advantages of a design that is "small and easy to clean" and "worn in the bra." EX1010, [0070]. A POSITA would have been motivated to enhance these benefits in the Chang-Fang-Khalil device by positioning the milk container at the lower portion, making it easier to assemble and disassemble the device, as Khalil suggests. *Id.*, [0069]. Additionally, a POSITA would recognize the advantages of a downward flow of milk, keeping the milk path below the

diaphragm components, as proposed by Fang and Khalil. This setup would further improve the separation of the pump components from the milk flow, enhancing the device's overall performance. *Id.*

199. The combination also improves the user experience during the removal of the pump from the breast after a pumping session. The diaphragm configuration and the downward flow of milk into a lower container (where the milk is collected during each pump stroke) would make it easier to remove the pump without requiring the user to lean forward or adjust their body position to avoid spilling the milk contained within the device. EX1010, [0069].

200. Khalil's rigid milk container is also a suitable option for the Chang-Fang device, as it provides an effective way to collect expressed milk within the system. Chang explicitly mentions that the milk container can be rigid and positioned in various locations. EX1007, [0021], [0101]. Khalil offers a practical example of how to implement a rigid container at the lower portion of the device in an integrated way. EX1010, [0069].

201. The combination of Khalil and the Chang-Fang device also represents the application of a known technique (Khalil's milk container in a wearable diaphragm breast pump) to a known device (the Chang-Fang wearable breast pump). This combination would produce predictable results, including the benefits outlined

above. Given the similarities in the breast pump configurations, a POSITA would have had a reasonable expectation of success in making this modification.

2. Claim Analysis

a. Claim 1

202. The Chang-Fang-Khalil device includes limitations 1[pre], 1[a], 1[a][1], 1[a][2], 1[a][2][i], 1[a][2][ii], 1[a][3], 1[a][3][i], and 1[a][3][ii] for the same reasons as discussed above for Chang-Fang based on the teachings of Chang and Fang. *See* Section IX.A.2(a) (Ground 1A).

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

203. *See* Section XI.A.2(a)(i). The Chang-Fang-Khalil device is an example of a ***breast pump device***. EX1007, [0001], Abstract, [0004], [0011], [0019], FIGS. 1-21.

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

204. *See* Section XI.A.2(a)(ii). The Chang-Fang device is an example of a ***self-contained, in-bra wearable device***. EX1007, [0004], [0011], [0019].

(iii) 1[a][1]: a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge;

205. *See* Section XI.A.2(a)(iii). The Chang-Fang-Khalil device includes a ***diaphragm***, for example, Fang's elastic diaphragm 7. EX1009, [0010], [0019]-[0021], FIG. 7; EX1007, [0019]. The Chang-Fang-Khalil device also provides an ***air***

pump, e.g., Fang's air pump. EX1009, [0019], [0024], FIG. 7; *see* EX1007, [0072], [0080], FIG. 6A.

(iv) 1[a][2]: a housing that includes:

206. *See* Section XI.A.2(a)(iv). The Chang-Fang-Khalil device includes a *housing*, for example, a housing formed by Chang's housing or outer shell 12 and pump chassis 35. EX1007, [0071], [0073], FIGS. 1A, 6A.

(v) 1[a][2][i]: a battery, and

207. *See* Section XI.A.2(a)(v). The Chang-Fang-Khalil device includes a *battery* located in the *housing*. EX1007, [0072]; *see id.*, [0020], [0080], FIG. 6A.

(vi) 1[a][2][ii]: the air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;

208. *See* Section XI.A.2(a)(vi). The Chang-Fang-Khalil device includes an *air pump*, for example, Fang's air pump. The pump is pneumatically connected with the elastic diaphragm and configured to *generate negative air pressure by driving the diaphragm*, as taught by Fang. EX1009, [0019], [0024], FIG. 7; EX1007, [0072], [0080], FIG. 6A.

(vii) 1[a][3]: a breast shield comprising a breast flange and a nipple tunnel extending from the breast flange,

209. *See* Section XI.A.2(a)(vii). The Chang-Fang-Khalil device includes a *breast shield*, for example, Chang's breast shield, which includes a nipple receiving

portion (*nipple tunnel*) and breast contact portion (*breast flange*). EX1007, [0071], [0090], FIG. 4.

(viii) 1[a][3][i]: the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and

210. See Section XI.A.2(a)(viii). In the Chang-Fang-Khalil device, the nipple receiving portion includes a closed circular end (*closed end*) and a port (*milk port*). EX1007, [0071], [0090], FIG. 6. The port is *intermediate to* the breast contact portion and the closed circular end. For example, the structures providing the milk port are not positioned at a distal end of the nipple receiving portion (i.e., at the curved closed end). See EX1002, 2252; EX1054C, 15.

(ix) 1[a][3][ii]: the breast shield being separate from the diaphragm; and

211. See Section XI.A.2(a)(ix). A POSITA would have understood and found obvious that removability of the breast shield in the Chang-Fang-Khalil device indicates that the breast shield is *separate from* the elastic diaphragm. See EX1007, [0021], [0023], [0081], [0086], [0092], [0099]-[0100].

(x) 1[a][4]: a milk container that is configured to attach to the housing and receive expressed milk via the milk port.

212. The Chang-Fang-Khalil device includes a *milk container*, as suggested by Khalil. Khalil describes a rigid “milk collection container...integrated in the housing of the unit or coupled directly thereto.” EX1010, [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]. In the predictable combination, the breast pump device would have included an integrated milk container at a lower location of the device. *See* Section IX.F.1 (Chang-Fang-Khalil). Such a conventional container is configured to be attached to and removed from the pump housing, and it receives expressed milk via the milk port (e.g., milk port in accordance with Chang, located at the lower side of the nipple tunnel). EX1010, [0069]; *see* Section IX.F.1 (Chang-Fang-Khalil).

b. Claim 2

- (i) 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.**

213. *See* Analysis of Claim 2 in Ground 1A. A POSITA would have understood, and found obvious from Chang’s description, the *breast shield* in the Chang-Fang-Khalil device is symmetrical about the cylindrical nipple receiving portion and has an operating position. The *breast shield* is configured to *rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct operating position onto a breast*. EX1007, [0017], [0071], [0090].

c. Claim 3

- (i) 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.

214. *See* Analysis of Claim 3 in Ground 1A. In the Chang-Fang-Khalil device, the ***breast shield*** (e.g., Chang’s breast shield, which includes a nipple receiving portion and a breast contact portion) is a “skin contact member” or “configured to form a seal with the breast.” EX1007, [0008], [0071]. The ***breast shield*** also ***presents a single continuous surface to a nipple and a breast***, in accordance with Chang. *Id.*, [0090], FIGS. 4-6A.

d. Claim 4

(i) The breast pump device of claim 1, wherein the breast shield integrates the breast flange and nipple tunnel as a one-piece item.

215. *See* Analysis of Claim 4 in Ground 1A. In the Chang-Fang-Khalil device, a pump housing is formed by, e.g., Chang’s outer shell 12 and pump chassis 35. The ***breast shield*** is similarly configured as a ***one-piece item***. EX1007, [0073], FIGS. 1A, 6A; *see* Analysis of Limitation 1[a][2] (Ground 1A).

e. Claim 5

(i) The breast pump device of claim 1, wherein the breast flange and the nipple tunnel are a single, integral item with no joining stubs.

216. *See* Analysis of Claim 5 in Ground 1A. Based on Chang’s suggestion, the ***breast shield*** of the Chang-Fang-Khalil device is configured as a ***single, integral***

item with no joining stubs. EX1007, [0073], FIGS. 1A, 6A; *see* Analysis of Limitation 1[a][2] (Ground 1A).

f. Claim 6

- (i) The breast pump device of claim 1, wherein the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use.**

217. *See* Analysis of Claim 6 in Ground 1A. In the Chang-Fang-Khalil device, the ***breast shield*** includes structures based on Chang’s suggestions (e.g., nipple receiving portion, breast contact portion). 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. EX1007, [0071].

g. Claim 7

- (i) The breast pump device of claim 1, wherein the breast shield is configured to slide in and out from the housing, together with the diaphragm, on guide members in the breast shield.**

218. *See* Analysis of Claim 7 in Ground 1A. In the Chang-Fang-Khalil device, the ***breast shield*** (e.g., Chang’s breast shield, which includes a nipple receiving portion and a breast contact portion) and ***housing*** (e.g., Chang’s “outer shell 12” and/or “chassis 35”) are arranged based on Chang’s teachings. EX1007, [0071], [0073], FIGS. 1A, 6A. The ***breast shield*** and the ***housing*** would have been arranged like Chang’s outer shell 12 and chassis 35 and the breast shield, with the

breast shield configured to slide in and out - 42 - when assembled/disassembled. In the Chang-Fang-Khalil device, the *diaphragm* (e.g., Fang's elastic diaphragm 7) are also attached with the *breast shield*. See Section IX.A.1 (Chang-Fang); EX1009, [0019], FIG. 7. The *diaphragm* therefore *moves together with* the *breast shield* such that both are configured to slide in and out from the *housing*. Further, the *breast shield* in the Chang-Fang-Khalil device is configured to include *guide members* to enable attachment to the device housing, consistent with Chang. EX1007, [0080], [0082], FIG. 6A.

h. Claim 8

- (i) The breast pump device of claim 1, wherein the housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.**

219. See Analysis of Claim 8 in Ground 1A. In the Chang-Fang-Khalil device, device components would have been attached or assembled based on the suggestions of Chang. The *housing is configured to slide onto the breast shield... using guide members*. See Analysis of Claim 7; EX1007, [0071], [0080], [0082], FIGS. 1A, 6A. Fang further suggests a pump housing that is configured to slide onto the breast shield using top annular edge 19 (*guide members*), as shown in Fang's Figure 7. EX1009, [0019], [0023], [0024], FIG. 7.

i. Claim 9

- (i) 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 housing in normal use or normal dis-assembly.

220. See Analysis of Claim 9 in Ground 1A. In the Chang-Fang-Khalil device, the *breast shield* (e.g., Chang's breast shield) and *milk container* (e.g., Khalil's milk container) are each *directly removable* from the *housing* based on the suggestions of Chang and Khalil. See Analysis of Limitation 1[a][2]-[4]; EX1001, 5:66-6:15.

j. Claim 10

- (i) The breast pump device of claim 1, wherein the diaphragm is substantially circular and is configured to self-seal under the negative air pressure to a substantially circular diaphragm holder that is part of the housing.**

221. See Analysis of Claim 10 in Ground 1A. In the Chang-Fang-Khalil device, the *diaphragm* is substantially circular based on the suggestions in Fang. Fang shows elastic diaphragm 7 to have a substantially circular shape. EX1009, [0020]-[0025], FIGS 5, 7. The *diaphragm housing* in the Chang-Fang-Khalil device is also *substantially circular*, and thereby engages with, and secures, the *diaphragm*. EX1009, [0020]-[0025]; FIG. 7. Further, in the Chang-Fang-Khalil device, the *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 Limitation 1[a][1] in Ground 1A; EX1001, 6:33-60.

k. Claim 11

- (i) The breast pump device of claim 1, wherein the diaphragm is a membrane, and the diaphragm deforms in response to changes in air pressure caused by the air pump to create negative air pressure in the nipple tunnel.**

222. See Analysis of Claim 11 in Ground 1A. The *diaphragm* of the Chang-Fang-Khalil device 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. EX1009, [0019]-[0025], FIG. 7; see Section IX.A.1 (Chang-Fang).

l. Claim 12

- (i) The breast pump device of claim 1, wherein the diaphragm is removable from a diaphragm holder that sits above the breast flange and the nipple tunnel.**

223. See Analysis of Claim 12 in Ground 1A. In the Chang-Fang-Khalil device, the *diaphragm* is seated against a *diaphragm holder* (e.g., flaring 4, alone or together with annular edge 5) that sits above a breast flange such that the *diaphragm housing sits above* the nipple tunnel. EX1009, [0019]; see Section IX.A.1 (Chang-Fang); EX1009, FIG. 7. Further, in the Chang-Fang-Khalil device, the *diaphragm* (e.g., Fang's elastic diaphragm 7) is similarly arranged such that it is *removable* from a *diaphragm holder* (e.g., Fang's diaphragm housing) that *sits above* the *breast shield* (e.g., Chang's breast shield, which includes a nipple

receiving portion (*nipple tunnel*) and a breast contact portion (*breast flange*)).

EX1007, [0071], [0090]; *see* Analysis of limitation 1[a][3].

m. Claim 13

- (i) The breast pump device of claim 1, wherein the milk container is substantially rigid.**

224. *See* Analysis of Claim 13 in Ground 1A. The Chang-Fang-Khalil device includes a *milk container* (e.g., Khalil’s milk container), which may be “rigid” and “made of plastic.” EX1010, [0050]; *see id.*, [0067], [0069]; *see* Section IX.F.1 (Chang-Fang-Khalil).

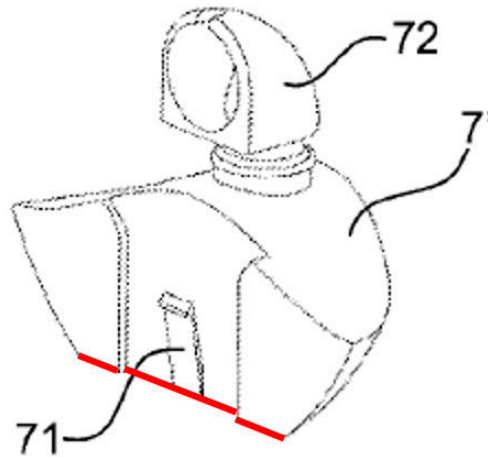
n. Claim 14

- (i) The breast pump device of claim 1, wherein the milk container is configured to attach to a lower part of the housing and to form a flat bottomed base for the breast pump device.**

225. In the Chang-Fang-Khalil device, the *milk container* is configured to attach to a lower part of the pump housing (e.g., “chassis 35”). *See* Section IX.F.1 (Chang-Fang-Khalil). Khalil describes complementary mating features between the milk container and the pump housing such that the milk container is releasably attachable with a lower part of the pump housing. EX1010, [0069].

226. The container forms a flat-bottomed base for the device, consistent with Khalil. EX1010, FIGS. 10-11. Indeed, 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).



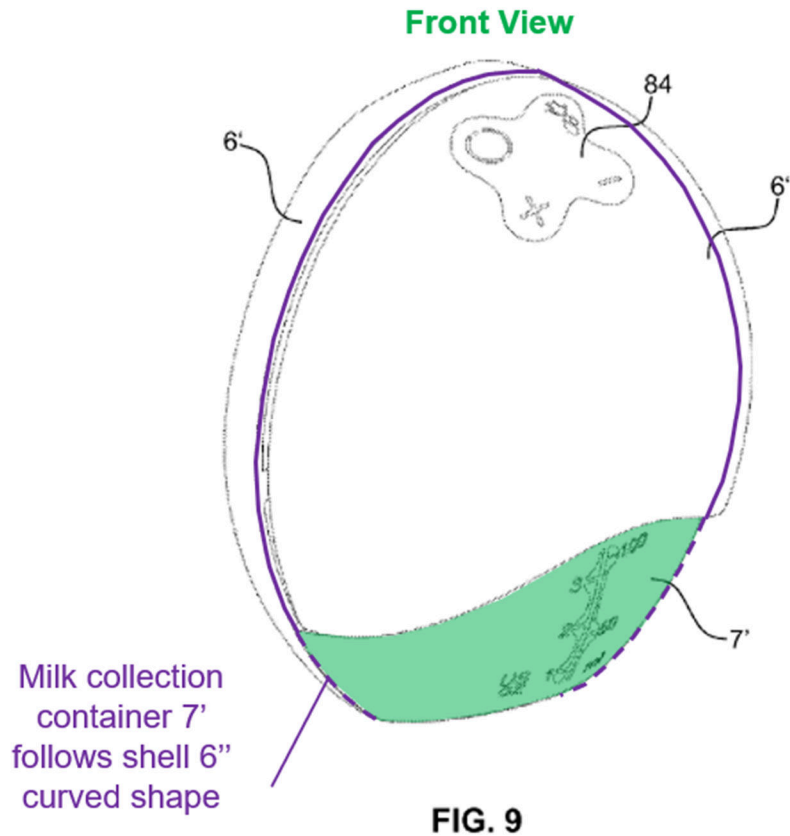
EX1010, FIG. 11 (partial, annotated)

o. Claim 15

- (i) The breast pump device of claim 1, 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 the bra.**

227. The Chang-Fang-Khalil device includes the elements of claim 15, as suggested by Chang and Khalil. 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. 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]. Furthering these express design objectives of Chang and Khalil, Khalil describes a milk container (green) in a curved shape that continues the curved shape of the pump housing.



EX1010, FIG. 9 (annotated)

p. Claim 16

- (i) The breast pump device of claim 1, wherein the milk container includes a flexible valve that self-seals under negative air pressure against the milk port in the nipple tunnel and that permits the expressed milk to flow into the milk container.**

228. As discussed in Section IX.F.1 (Chang-Fang-Khalil), the combined device would have provided a milk container according to Khalil's teachings, which a POSITA would have implemented by modifying the direction of the milk port of Chang's breast shield such that it is configured to point downwards. With this modification, the Chang-Fang-Khalil device *permits the expressed milk to flow* through the modified milk port (*milk port*) and a flexible valve *into the milk container* such that the valve *self-seals under negative air pressure*. *Id.*; EX1007, [0008], [0010], [0019], [0021], [0023], [0081], [0086], [0092], [0099], [0100], [0101].

q. Claim 17

- (i) The breast pump device of claim 1, 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.**

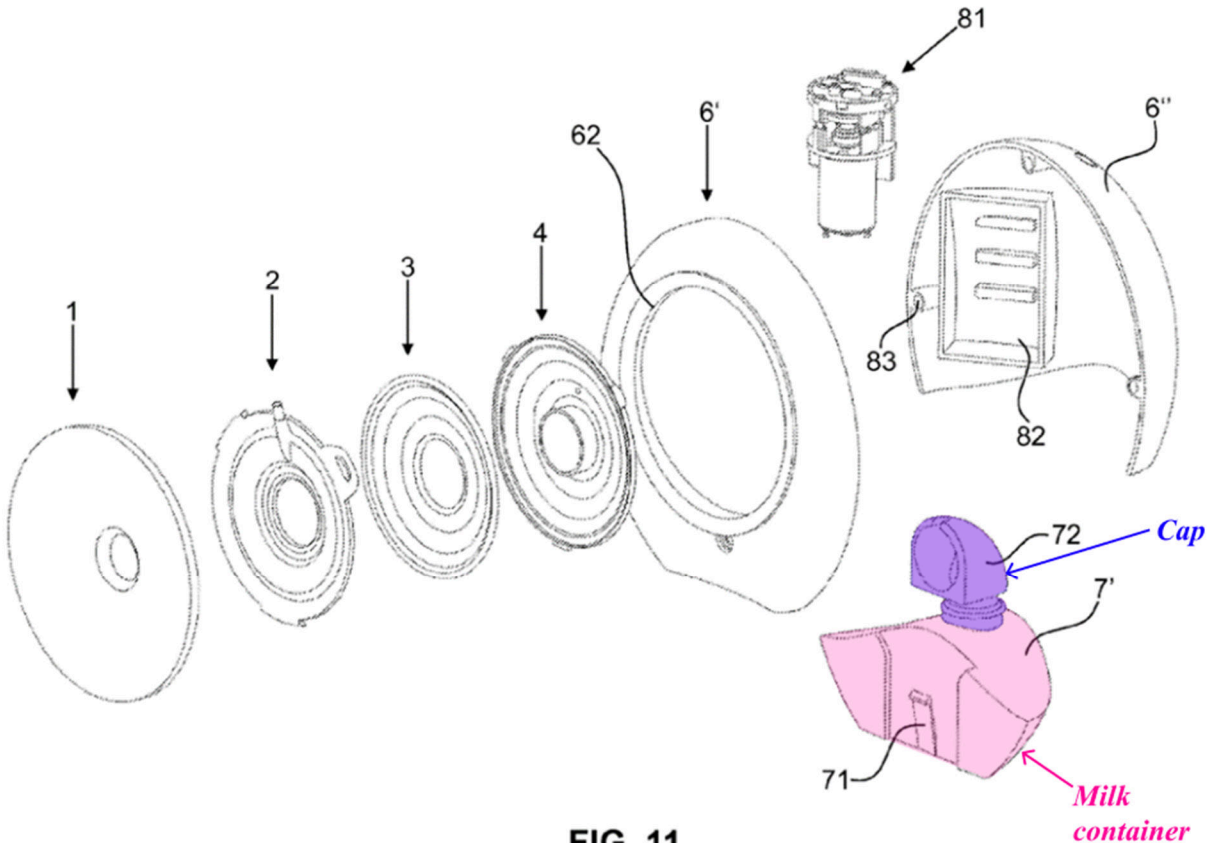
229. As I discussed for limitation 1[a][4], the Chang-Fang-Khalil device includes a *milk container*, e.g., Khalil's milk container. EX1010, [0050], [0067], [0069]. Further, the Chang-Fang-Khalil device includes a modified milk port (pointed downwards) to enable fluid connection between the *nipple tunnel* and the *milk container*. With this configuration, the *milk container* is configured to be attachable to the *housing* via the *milk container* with a *mechanical or magnetic*

mechanism, in accordance with the teachings of Chang and Khalil. EX1007, [0101]; EX1010, [0069].

r. Claim 18

- (i) The breast pump device of claim 1, wherein the milk container includes a cap that is removable from the milk container and a removable valve that enables milk to pass into the milk container in one direction.**

230. In the Chang-Fang-Khalil device, the milk container in the storing housing 700 is configured according to the suggestions of Khalil. As shown in the annotated version of Khalil's Figure 11 (below), Khalil's milk collection container 7' (which, like Park's breast pump device, is similarly arranged in a bottom portion of a device casing) has a "coupling part 72" that can be "plugged onto the milk port 34" and can act as a cap. EX1010, [0069].

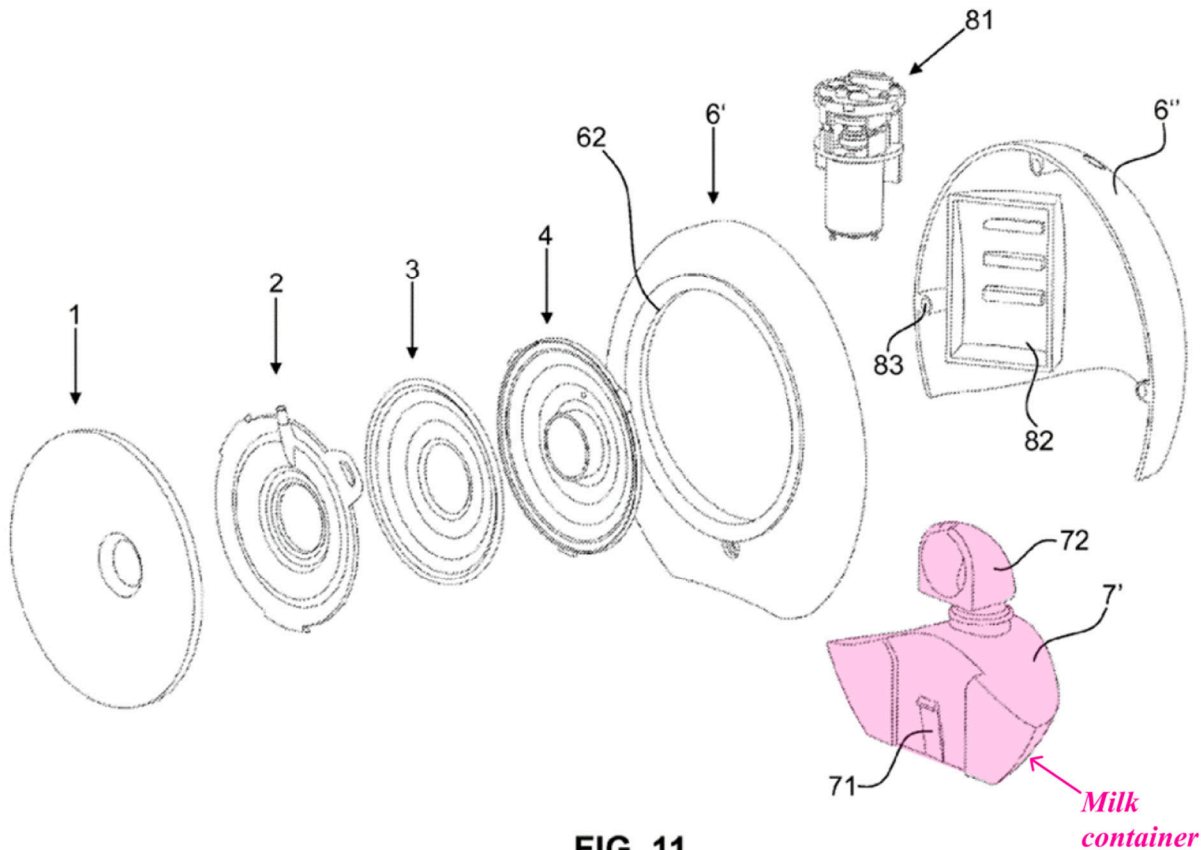


EX1010, FIG. 11 (annotated)

s. **Claim 20**

- (i) **The breast pump device of claim 1, wherein the milk container is wider than the milk container is tall.**

231. The Chang-Fang-Khalil device includes a milk container, e.g., Khalil's collection container 7' (*milk container*). EX1010, [0050], [0067], [0069]. As shown below in Khalil's Figure 3, collection container 7' is sized such that it is ***wider than...tall.***



EX1010, FIG. 11 (annotated)

The disclosures of Chang, Fang, and Khalil also render obvious that, in some implementations, collection container 7' is sized to satisfy the requirements of claim 20. Such a modification would be obvious to implement to accommodate the natural variation in breast sizes and shapes among users, ensuring a better fit and more efficient milk expression. Manufacturers of medical devices, particularly those intended for wearable use, typically design products in multiple sizes to enhance comfort, performance, and usability for a wide range of body types. Given the well-known variability in breast anatomy, a POSITA would recognize that offering

customizable breast pump components would meet the practical need for personalization and maximize the effectiveness of the device.

232. The size and shape of breast pump components (e.g., relative width of a milk container) also represented an obvious design choice based on the size and shape of the device. *Id.* The '381 patent specification confirms this through the lack of any discernible disclosure regarding how the specific design recited in claim 20 (i.e., a milk container that is wider than tall) conveys any meaningful advantage in the operation of a breast pump device. Additionally, a POSITA would have found it obvious that a variety of relative dimensions of collection container 7' may be implemented in the context of the Chang-Fang-Khalil device without necessarily changing its utility or effectiveness.

t. Claim 21

- (i) The breast pump device of claim 1, wherein the nipple tunnel includes on a lower surface the milk port through which the expressed milk flows under gravity into the milk container.**

233. As discussed in Section IX.F.1 (Chang-Fang-Khalil), in the combined device, Chang's breast shield is configured to have a milk port pointed downwards to enable connection with Khalil's milk container. This configuration enables milk flow from the *nipple tunnel* to the *milk container* via the *milk port*. See Analysis of Limitation 1[a][4], and Claim 16. Further, in this configuration, the *milk port* is positioned on the *lower surface* of the *nipple tunnel* such that the milk flow via the

milk port involves *the expressed milk flow[ing] under gravity into the milk container*. Further, 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, further enhancing the isolation of pump components from milk flow. EX1010, [0069].

u. Claim 22

- (i) The breast pump device of claim 1, wherein the housing includes a wireless data communication system powered by the battery.**

234. See Analysis of Claim 22 in Ground 1A. The device housing of the Chang-Fang-Khalil device would have included components that enable wireless communications (*wireless data communications system*) that are powered by a rechargeable battery (*battery*). EX1007, [0124].

v. Claim 23

- (i) The breast pump device of claim 1, wherein the housing has a front surface that is configured to fit inside a bra and to contact an inner surface of the bra, and a rear surface that is shaped to contact, at least in part, the breast shield.**

235. See Analysis of Claim 23 in Ground 1A. In the Chang-Fang-Khalil device, the *housing* includes a surface on the housing/outer shell 12 (*front surface*) that contacts an inner surface of the bra when worn (*configured to fit inside a bra and to contact an inner surface of the bra*), and a surface (*rear surface*) that contacts the *breast shield*. EX1007, [0071], [0073], FIGS. 1A, 4, 6A.

w. **Claim 27**

- (i) **The breast pump device of claim 1, wherein a total mass of the breast pump device, unfilled with milk, is less than 250 gm.**

236. *See* Analysis of Claim 27 in Ground 1A. A POSITA would have found it obvious that the Chang-Fang-Khalil device, when unfilled with milk, has a certain weight that provides comfort during use, rendering this claim obvious. EX1007, [0001]; EX1009, [0002]; EX1039, [0045], [0047], [0053], [0084]; EX1001, 7:18-24.

x. **Claim 29**

- (i) **The breast pump device of claim 1, wherein the air pump is configured to generate negative air pressure with a maximum suction of approximately 240 mmHg.**

237. *See* Analysis of Claim 29 in Ground 1A. A POSITA would have understood and found obvious that Chang's reference to "about 250 mmHg" corresponds to *a maximum suction of approximately 240 mmHg*. EX1007, [0012]; *id.*, [0087]-[0088]; EX1001, 33:47-34:38.

G. Ground 4A: Obviousness of Claims 1-18, 20-23, 26-29 Over Chang-Fang-Khalil-Kurihara

238. Based on my knowledge and experience in the field, a POSITA would have been motivated to combine Kurihara with Chang and Fang, as I discussed above regarding Ground 2A. *See* Section IX.E.1 (Chang-Fang-Kurihara). As previously discussed, based on my knowledge and experience in the field, a

piezoelectric system offers various advantages for the operation of a portable breast pump system. These types of systems enable precise control of the pumping action, which leads to more effective and comfortable milk expression. EX1016, [0093], [0123]. Based on my knowledge and experience in the field, replacing or augmenting the existing pump mechanism in the Chang-Fang-Khalil device with Kurihara's piezoelectric system is also a straightforward substitution that leverages the known benefits of piezoelectric actuation. For at least the same reasons, a POSITA would have likewise been prompted to combine Kurihara with Chang, Fang, and Khalil. The combination would have included each element, and rendered obvious, claims 1-18, 20-23, and 26-29, for the same reasons I discussed above.

3. Claim Analysis

a. Claim 26

- (i) The breast pump device of claim 1, wherein the air pump comprises a piezo air pump system.**

239. *See* Analysis of Claim 26 in Ground 1E. The Chang-Fang-Khalil-Kurihara device includes a pump, e.g., Kurihara's piezoelectric driving part 33, such that the device is configured as a *piezo air pump system* based on the teachings of Kurihara. EX1016, [0015], [0063], [0065].

b. Claim 28

- (i) The breast pump device of claim 1, wherein the breast pump device makes less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.**

240. See Analysis of Claim 28 in Ground 1E. The Chang-Fang-Khalil-Kurihara device would have been configured according to the suggestions of Kurihara to “configure a compact and silent breast-milk suction device,” thereby rendering this claim obvious. EX1016, [0093]; see EX1040, [0121]; EX1016.

H. Grounds 2B, 3B, 4B: Obviousness of Claim 19 Over Yuen629 in view of Chang-Fang-Kurihara (Ground 2B), Chang-Fang-Khalil (Ground 3B), and Chang-Fang-Khalil-Kurihara (Ground 4B)

1. Combination of Chang-Fang-Kurihara-Yuen629 (Ground 2B), Chang-Fang-Khalil-Yuen629 (Ground 3B), and Chang-Fang-Khalil-Kurihara-Yuen629 (Ground 4B)

241. See Section IX.B.1 (Chang-Fang-Yuen629). As previously discussed, and based on my knowledge and experience in the field, and my review of Chang, Fang, Khalil, Kurihara, and Yuen629, a POSITA would have recognized the benefits of combining these technologies to improve the overall functionality, hygiene, and user convenience of a breast pump system. EX1007, [0019]; EX1009, [0020]. Based on my knowledge and experience in the field, integrating Yuen629’s technology into Chang’s compact and wearable breast pump system would have been predictable. It would have also resulted in a highly convenient device that not only fits discreetly within a bra but also provides real-time feedback on the milk extraction process. EX1011, Abstract, 4:63-5:6, 6:9-23.

2. Claim Analysis

a. Claim 19

- (i) **The breast pump device of claim 1, wherein a top of the milk container includes an optically clear region that is aligned below one or more light emitters positioned in a base of the housing.**

242. See Analysis of Claim 19 in Ground 1B. The Chang-Fang-Kurihara-Yuen629 (Ground 2B), Chang-Fang-Khalil-Yuen629 (Ground 3B), and Chang-Fang-Khalil-Kurihara-Yuen629 (Ground 4B) devices include *one or more light emitters*, for example, Yuen629's IR units 38a and 38b. These emitters are positioned in a base of a pump housing (*base of the housing*), in accordance with Yuen629's suggestions. EX1011, 4:63-5:6, 5:7-28, 6:9-23, FIG. 14. In the Chang-Fang-Khalil-Yuen629 device, the *one or more light emitters* are also positioned near a bottom portion (*in a base*) of a pump housing (*housing*). Such a configuration is consistent with Yuen629's suggestions of IR units 38a, 38b being positioned in a bottom portion of "head portion 22" of the "breast pump 10," as shown in the annotated version of Yuen629's Figure 14 below. EX1011, 3:22-32.

I. Grounds 2C, 3C, 4C: Obviousness of Claim 24 Over Chang-Fang-Kurihara-Makower794 (Ground 2C), Chang-Fang-Khalil-Makower794 (Ground 3C), and Chang-Fang-Khalil-Kurihara-Makower794 (Ground 4C)

1. Combination of Chang-Fang-Kurihara-Makower794 (Ground 2C), Chang-Fang-Khalil-Makower794 (Ground 3C), and Chang-Fang-Khalil-Kurihara-Makower794 (Ground 4C)

243. *See* Section IX.C.1 (Chang-Fang-Makower794). As previously discussed, the teachings of Makower794 complement Chang-Fang-Kurihara, Chang-Fang-Khalil, and Chang-Fang-Khalil-Kurihara, by incorporating a display that provides real-time feedback on critical operational parameters, such as suction levels, milk volume, and flow rate. In the resulting system, the breast pump device would include a display to show this information.

2. Claim Analysis

a. Claim 24

- (i) The breast pump device of claim 1, wherein the housing includes at least one of a visual or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.**

244. *See* Analysis of Claim 24 in Ground 1C. The Chang-Fang-Kurihara-Makower794 device (Ground 2C), Chang-Fang-Khalil-Makower794 device (Ground 3C), and Chang-Fang-Khalil-Kurihara-Makower794 device (Ground 4C) includes a *display*, as suggested by Makower794's display 250, configured to display *at least one of a visual...indicator* relating to "approximate flow rate of

milk” (*whether milk is flowing or not flowing into the milk container*). EX1014, [0163], FIG. 57.

J. Ground 2D, 3D, 4D: Obviousness of Claim 25 Over Chang-Fang-Kurihara-Makower794-Guthrie002 (Ground 2D), Chang-Fang-Khalil-Makower794-Guthrie002 (Ground 3D), and Chang-Fang-Khalil-Kurihara-Makower794-Guthrie002 (Ground 4D)

1. Combination of Chang-Fang-Kurihara-Makower794-Guthrie002 (Ground 2D), Chang-Fang-Khalil-Makower794-Guthrie002 (Ground 3D), and Chang-Fang-Khalil-Kurihara-Makower794-Guthrie002 (Ground 4D)

245. *See* Section IX.D.1 (Chang-Fang-Makower794-Guthrie). As previously discussed, Guthrie002 supports Chang-Fang-Kurihara-Makower794 (Ground 2D), Chang-Fang-Khalil-Makower794 (Ground 3D), and Chang-Fang-Khalil-Kurihara-Makower794 (Ground 4C) by suggesting the use of embedded sensors within breast pump devices to monitor various operational metrics. In the resulting Chang-Fang-Khalil-Makower794-Guthrie002 device, a breast pump includes embedded sensors designed to monitor parameters related to its operation. Examples of these parameters include the rate of milk collection and the progression of the pumping session.

2. Claim Analysis

a. Claim 25

- (i) **The breast pump device of claim 1, wherein the housing includes at least one of a visual or haptic indicator that indicates if the air pump is operating correctly to pump milk, based on whether a quantity or a height of liquid in the milk container above a base of the milk container is increasing above a threshold rate of increase.**

246. See Analysis of Claim 25 in Ground 1D. The Over Chang-Fang-Kurihara-Makower794-Guthrie002 device (Ground 2D), Chang-Fang-Khalil-Makower794-Guthrie002 device (Ground 3D), and Chang-Fang-Khalil-Kurihara-Makower794-Guthrie002 device (Ground 4D) includes the sensing elements (e.g., Guthrie002's sensors 501, 502) and display elements (e.g., Makower794's display 250) to display indication information relating to breast pump device operation, e.g., *if the pump is operating correctly to pump milk*. EX1015, 10:39-60; EX1014, [0163]. Further, based on the sensing functions described in Makower794, such as flow rate and liquid level measurements based on various methodologies (e.g., optical, capacitive, ultrasonic, light/sound reflectivity), it would have been obvious that the combined devices are also configured to determine and assess whether *a quantity or a height of liquid in the milk container above a base of the milk container is increasing above a threshold rate of increase*.