

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EIS GMBH,
Petitioner,

v.

NOVOLUTO GMBH,
Patent Owner.

IPR2019-01302
Patent 9,937,097 B2

Before SUSAN L. C. MITCHELL, CHRISTOPHER G. PAULRAJ, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Challenged Claims Not Unpatentable
35 U.S.C. § 318(a)
Denying Petitioner's Motion to Exclude
37 C.F.R. § 42.64

I. INTRODUCTION

A. Background and Summary

EIS GmbH (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–30 of U.S. Patent No. 9,937,097 B2 (Ex. 1001, “the ’097 patent”). Paper 1. (“Pet.”). NOVOLUTO GmbH (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 14. On January 13, 2020 we issued our Decision Denying Institution. Paper 17 (“Dec”).

Petitioner filed a Request for Rehearing of our Decision Denying Institution under 37 C.F.R. § 42.71 (c) and (d). Paper 18 (“Req. Reh’g”).¹ Upon reconsideration of the arguments and evidence of record at the time, we granted the Request for Rehearing and instituted *inter partes* review on all grounds presented in the Petition. Paper 23. (“Reh’g Dec.” or “Rehearing Decision”).

Patent Owner then filed a Response on September 11, 2020. Paper 30 (“Resp.”). Petitioner filed a Reply on December 14, 2020. Paper 37 (“Reply”). Patent Owner filed a Sur-Reply on January 15, 2021. Paper 42 (“Sur-Reply”). On February 2, 2021, the parties jointly informed the Board that no oral hearing was needed in this case. Paper 44.

We have jurisdiction under 35 U.S.C. § 6. This Decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of the

¹ Petitioner also sought review of the Decision by the Precedential Opinion Panel. Ex. 3001. That request was denied on April 6, 2020. Paper 21. Following denial by the Precedential Opinion Panel, Petitioner brought an action in the United States District Court for the Eastern District of Virginia seeking review of denial by the Precedential Opinion Panel under the Administrative Procedure Act. Paper 22. The district court action was dismissed following our granting Petitioner’s Request for Rehearing. Paper 34, 2.

claims on which we instituted trial. Based on the complete record before us, we determine that Petitioner has not shown, by a preponderance of the evidence, that claims 1–30 are unpatentable. In addition, for the reasons explained below, we deny Petitioner’s Motion to Exclude evidence.

B. Real Parties in Interest

Petitioner identifies the following entities as real parties-in-interest: EIS GmbH, EIS Inc., Triple A Import GmbH, Triple A Marketing GmbH, Triple A Sales GmbH, and Triple A Internetshops GmbH (formerly known as “Internetsupport Bielefeld”). Paper 43.

Patent Owner identifies itself as the real party-in-interest and that WOW Tech International GmbH is the corporate parent of Novoluto GmbH. Paper 41.

C. Related Matters

Petitioner has stated that the ’097 patent is the subject of litigation in two district court actions: *EIS Inc. v. WOW Tech International GmbH et al.*, No. 1:19-cv01227-LPS, (D. Del.) and *Novoluto, GmbH v. Uccellini LLC d/b/a Lora DiCarlo*, C.A. No. DOR-6-20-cv-02284-MTK (D. Ore.). Paper 43, 3.

Petitioner also states that two related patents, US 9,763,851 B2 and US 9,849,061 B2 are the subject of IPR2019-01444 and IPR2020-00007 respectively. *Id.* Both of those proceedings are currently pending before the Board.

D. The ’097 Patent

The ’097 patent, titled Stimulation Device Having an Appendage, issued on April 10, 2018, from Application 15/487,123 filed on April 13, 2017. Ex. 1001, codes (10), (21), (22), (45)col. 3, , and (54). It claims

priority to German Patent Application No. 102015103694.0, filed March 13, 2015. Ex. 1001, col. 1, ll. 7–12.

The '097 patent relates to a sexual stimulation device which applies positive and negative pressure to a human body part, such as the clitoris. Ex. 1001, col. 3, ll. 21–22. The positive and negative pressures are created by changing the volume of a chamber in the device. *Id.* at col. 3, ll. 19–20. The volume of the chamber is changed by deflecting a flexible wall of the chamber. *Id.* at col. 3, ll. 16–19. Positive and negative pressures are determined relative to a “reference pressure.” *Id.* col. 4, l. 63– col. 5, l. 4. The device may also have an appendage which can be used as a handle. *Id.* at col. 4, ll. 27–28. The appendage may be in the form of a dildo. *Id.* at col. 8, ll. 24–31.

E. Illustrative Claims

Claims 1 and 12 are representative of the challenged claims and read as follows:

1. A stimulation device comprising:
 - a chamber having a flexible wall portion
 - a drive unit in physical communication with the flexible wall portion so as to cause deflections of the flexible wall portion in opposing direction, thereby resulting in a changing volume of the chamber,
 - the changing volume of the chamber resulting in modulating positive and negative pressures with respect to a reference pressure;
 - an opening for applying the modulated positive and negative pressures to a body part;
 - a control device for controlling the drive unit; and
 - an appendage, wherein the appendage is a dildo configured to be inserted into a vagina.
12. A method comprising:

causing deflections of a flexible wall portion of a chamber of a stimulation device in opposing directions, thereby resulting in a changing volume of the chamber, the changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference pressure; and applying the modulated positive and negative pressures to a body part through an opening, wherein the stimulation device is positioned by the user for applying the modulated positive and negative pressures using an appendage of the stimulation device, wherein the appendage is a dildo configured to be inserted into a vagina.

F. Evidence

Petitioner relies on the following references:

Taylor, US 5,725,473, issued March 10, 1998. (Ex. 1004) (“Taylor”).

Hovland et al., US 6,964,643 B2, issued November 15, 2005. (Ex. 1005) (“Hovland”).

Guan, CN2153351Y, issued December 11, 1993. (Ex. 1007) (“Guan”).

Lee, US 7,828,717 B2, issued November 9, 2010. (Ex. 1006) (“Lee”).

Petitioner also relies on the declarations of Michael R. Prisco, P.E., Ph.D., Exs. 1002 and 1018, and the declaration of Richard Meyst. Ex. 1020. Patent Owner relies on the declarations of Morton Olgaard Jensen, Ph. D., Dr. Med. (Exs. 2001 and 2026) and Debra Herbenick, Ph.D. (Ex. 2004 and 2028).

G. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–30 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–9, 12–24, 26–30	102	Taylor
1–30	103	Taylor, Hovland
1–30	103	Guan, Lee, Hovland

II. ANALYSIS

A. Legal Standards

1. Burden

In an *inter partes* review, the burden of proof is on the Petitioner to show that the challenged claims are unpatentable, and that burden never shifts to the patentee. 35 U.S.C. § 316(e); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016).

2. Anticipation

Section 102(a) provides that “[a] person shall be entitled to a patent unless . . . the claimed invention was patented [or] described in a printed publication . . . before the effective filing date of the claimed invention.” 35 U.S.C. § 102(a)(1) (2018).² Accordingly, unpatentability by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, arranged as in the claims. *See Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999); *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994).

3. Obviousness

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3)

² The provisions of the Leahy-Smith America Invents Act (“AIA”) regarding novelty and obviousness apply to patents containing at least one claim having an effective filing date on or after March 16, 2013. Pub L. 112–29, 125 Stat. 284 (2011). On its face, the ’097 patent has an effective filing date of July 24, 2015. Therefore, the AIA provisions of 35 U.S.C. §§ 102 and 103 apply to this decision.

the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). If the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains, the claim is unpatentable under 35 U.S.C. § 103. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

A proper § 103 analysis requires “a searching comparison of the claimed invention—including all its limitations—with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

“Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination.” *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). “Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Id.*

“[O]bjective evidence of nonobviousness includes copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention.” *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998) (citations omitted). “For objective [evidence of secondary considerations] to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention*.” *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010)

(alterations in original) (quoting *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995)).

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

In our Decision on Institution, we adopted Petitioner’s proposed definition of one skilled in the art as an individual with “a bachelor’s degree in mechanical engineering, biomechanical engineering, or the equivalent, and three or more years of experience in fluid mechanics and pump-based medical devices,” and Petitioner’s proposal that “practical experience could qualify one not having the aforementioned education as a [person of ordinary skill in the art], while a higher level of education could offset lesser experience.” Dec. 6–7.

Patent Owner renews its argument that in addition to the education level recited above, a person of ordinary skill in the art would have “three or more years of experience in research, development, or design of devices that interact with the human female body (and specifically the vulva).” Resp. 4. Patent Owner supports this contention by citing to the Technical Field discussion in the Specification where it states that field relates to “a stimulation device ... for erogenous zones, in particular for the clitoris.” *Id.* at 3 (citing Ex. 1001, col. 1, ll. 17–20). Patent Owner also contends that the claims support this definition as the claims

explicitly define a stimulation device with “an opening for applying the modulated positive and negative pressures to a body

part” and a dildo appendage “configured to be inserted into a vagina” and associated methods of applying the modulated pressures to a body part, by the user having positioned the device using the vaginal dildo.

Resp. 3–4 (citing Ex. 1001, claims 1, 12, 17, and 26).

We have considered Patent Owner’s argument and are not persuaded that our original definition of a person of ordinary skill in the art was in error. We do not agree that one of ordinary skill in the art requires such specific expertise for the subject matter set forth in the field of invention or the claims of the ’097 patent. A “hypothetical ‘person having ordinary skill in the art’ to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art.” *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (BPAI 1988). Although the device disclosed in the ’097 patent is a sexual stimulation device, the scientific and engineering principles applicable to the claimed device and method involve mechanical engineering and fluid flow that are not necessarily specific to the application of the device.

As we previously noted in our Decision on Institution:

While the invention generally relates to a device for stimulating female erogenous zones, as seen from the discussion below, the design and operation of the device largely relates to issues of mechanical engineering and fluid flow. Thus, we conclude that experience in developing devices that interact with the female body is not needed to define a person of ordinary skill in the art.

Dec. 7.

Based on the forgoing, we continue to apply the same definition of a person of ordinary skill in the art we used in our Decision Denying Institution.

C. Claim Construction

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.* Furthermore we need only construe the claims to the extent necessary to determine the patentability of the challenged claims. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

After considering all of the arguments presented by the parties we find that it is only necessary to construe the term “reference pressure.” Although the parties have also presented arguments concerning the construction of the term “pressure field generator,” we determine that it is not necessary to construe that term to determine the patentability of the challenged claims in light of the asserted grounds.³

1. Reference Pressure

In our Decision Denying Institution, we construed the term “reference pressure” to mean “a prevailing pressure within the device prior to placing

³ In section IX of its Reply, Petitioner presents argument that we were somehow misled by changes to the Specification of the ’097 patent relating to the term “pressure field generator.” Reply 27–28. As we declined to construe the term in our decision on institution and in this final decision, we do not address the arguments presented in Section IX of the Reply.

the stimulation device on the area of the skin to be stimulated.” Dec. 10. While Patent Owner agrees with this construction, Petitioner contends that we improperly limited the construction to one example in the Specification. Resp. 19; Reply 9.

In the Petition, Petitioner originally asserted that the “reference pressure” is “atmospheric pressure.” *See* Pet. 22 (stating “[w]hen the bellows 160 is neither compressed nor expanded, the air within the bellows 160 is at atmospheric pressure (i.e., the reference pressure)”). In its Reply, Petitioner presents a new interpretation of the term “reference pressure,” contending that the term should be construed to mean a “given” pressure around which higher or lower pressures are generated for stimulating the body, which may be determined prior to application or after application of the device to the target body part. Reply 10. In support of this construction, Petitioner points to the discussion in the Specification involving pressures above and below systolic pressure. *Id.* (citing Ex. 1001, col. 11–57.).

Patent Owner contends that Petitioner is presenting a new argument not raised in the initial petition. Sur-Reply 2. Patent Owner argues that Petitioner has improperly argued that the construction adopted by the Board is limited to atmospheric pressure. *Id.* at 4. Patent Owner also contends that Petitioner’s arguments with regard to systolic pressure are without merit and that the Board’s original construction is proper. *Id.* at 5–6.

We have considered the arguments advanced by the parties and the evidence of record, and conclude that our original construction was proper. Contrary to Petitioner’s contention, the construction is not limited to a single example, but is consistent with the overall teachings of the Specification. *See, e.g.*, Ex. 1001, col. 5, ll. 5–27; col. 15, ll. 34–37; Figure 14. The construction we adopted is not limited to atmospheric pressure (as originally

proposed in the Petition), but refers generally to the prevailing pressure in the device before it is applied to the body as described in the Specification of the '097 patent. This refers to the pressure within the device regardless of the environment in which it is used. For instance, the Specification of the '097 patent lists additional environments to include “a liquid medium, such as water or commercially available lubricant.” *Id.* at col. 5, ll. 5–27.

Even if we consider Petitioner’s new claim construction argument as being properly presented in its Reply, Petitioner’s argument regarding systolic pressure is unconvincing. The entire paragraph regarding systolic pressure reads

Assuming that in the first state the pressure in the chambers 3 and 4 corresponds to the currently prevailing external reference pressure (air pressure for example), the overall pressure that is present in the second state will be lower than the external reference pressure. This negative pressure is set such that it is preferably lower than the usual systolic blood pressure in the blood vessels of the body part 11. The blood circulation in this area thus increases, and the clitoris 12 is better supplied with blood in the second state.

Ex. 1001, col. 11, ll. 49–57. It is clear that, when read in context, the reference pressure referred to in this paragraph is the prevailing pressure in the device *before* the device is applied to the body part. Moreover, only the negative pressure is set with regard to systolic pressure, not the positive pressure. *Id.*

Based on the foregoing, we maintain our original construction of the term “reference pressure” as “a prevailing pressure within the device prior to placing the stimulation device on the area of the skin to be stimulated.”

D. Anticipation by Taylor

Petitioner contends that claims 1–9, 12–24, and 26–30 are anticipated by Taylor. Pet. 19.

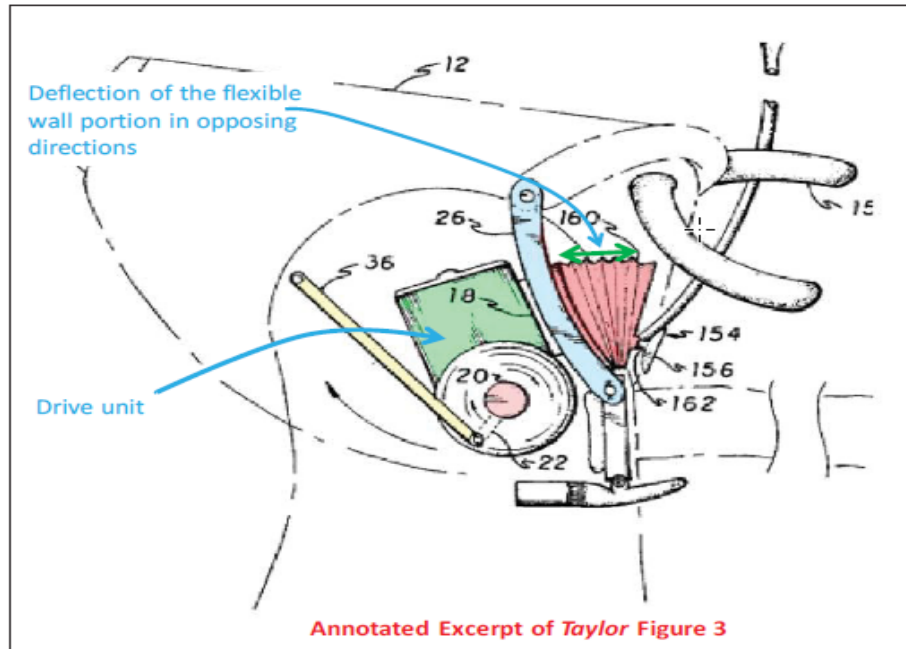
1. Taylor

Taylor discloses a sexual aid that includes a means for introducing a vacuum to stimulate the clitoris. Ex. 1004, Abst. In this embodiment, the device comprises a suction cup which engages the upper portion of the vulva. *Id.* at col. 5, ll. 28–30. The suction cup is in fluid communication with a bellows that cyclically introduces a vacuum within the suction cup. *Id.* at col. 5, ll. 32–38. The cyclical vacuum stimulates the clitoris. *Id.* at ll. 40–41.

Taylor discloses:

Referring to FIG. 3, an alternative embodiment of the drive mechanism is shown with the motor 18 mounted on the arm 26. As in the original embodiment the lever 22 mounted 55 on the output shaft 20 of the motor 18 is pivotally mounted on the connecting rod 36. The connecting rod 36 is pivotally mounted on the housing 12. As the output shaft 20 rotates, the lever 22 urges the connecting rod 36 against the housing 12 oscillating the arm 26 along with the motor 18.

Ex. 1004 col. 4, ll. 52–59. Petitioner’s annotated version of an excerpt of Taylor Figure 3 is reproduced below.



Excerpt of Figure 3 of Taylor as annotated by Petitioner to show the relationship of the drive unit to the bellows. Pet. 20.

Taylor goes on to disclose:

Referring only to FIG. 3, a second embodiment of the first stimulator 154 is shown. The first stimulator 154 includes a suction cup member 156 that conformingly and sealingly receives the upper portion of the vulva. The suction cup member 156 of the first stimulator 154 is more specifically directed at receiving the clitoris. The suction cup member 156 is in fluid communication with a bellows 160 or squeeze ball (not shown) via flexible conduit 162. As the arm 26 oscillates relative to the housing, the arm 26 compresses and expands the bellows 160 relative to the housing 12. The arm 26 and bellows 160 cyclically introduce a vacuum in the volume defined by the suction cup member 156 and the portion of the vulva received therein. The cyclical vacuum phenomenon stimulates the clitoris.

Ex. 1004, col. 5, ll. 28–41.

2. Analysis of Claim 1

Petitioner contends that each of the limitations of claim 1 is disclosed by Taylor. Pet. 19. Patent Owner contends that Taylor does not teach the

following limitations of claim 1: (1) the changing volume of the chamber resulting in modulating positive and negative pressures with respect to a reference pressure; (2) an opening for applying the modulated positive and negative pressures to a body part; and (3) a control device for controlling the drive unit. Because we agree with Patent Owner that Petitioner has failed to show that Taylor teaches these three limitations, we determine that Petitioner has failed to show by a preponderance of the evidence that Taylor anticipates claim 1 of the '097 patent. We focus only on these limitations in our analysis below.

a) The changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference pressure

Petitioner contends that the bellows of Taylor produces modulated positive and negative pressures with respect to a reference pressure, and thus satisfies this limitation. Pet. 22–23. In particular, Petitioner contends that when the bellows is in a position where it is neither contracted nor expanded, the air within the bellows is at atmospheric pressure—i.e., the reference pressure. *Id.* Petitioner contends that when the bellows expands, the pressure in the bellows falls below atmospheric pressure—a negative pressure. *Id.* Petitioner contends that as the bellows contracts past the midpoint, the air pressure increases above atmospheric pressure—i.e., a positive pressure. *Id.* Petitioner supports these contentions with the testimony of Dr. Prisco and Mr. Meyst. *Id.*; Reply 12–17; Ex. 1002 ¶¶ 58–74; Ex. 1020 ¶ 64.

Patent Owner contends that Taylor discloses a device that only provides suction, *i.e.*, negative pressure. Resp. 46. Patent Owner argues that Taylor does not disclose the use of positive pressure let alone modulating between positive and negative pressure. *Id.* Patent Owner contends that the

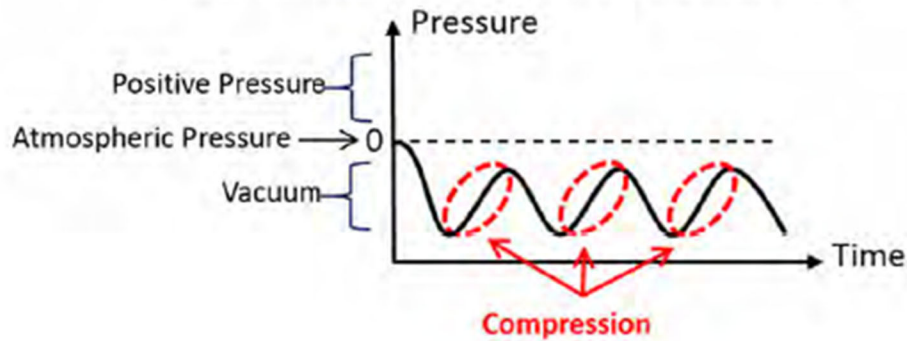
portions of Taylor cited by Petitioner do not disclose modulated positive and negative pressures with respect to a reference pressure, but are limited to varying negative pressure. *Id.* at 47.

Patent Owner further contends that Petitioner's argument is based on inherency and that Petitioner has failed to show that the mode of operation ascribed to Taylor by Petitioner's expert is necessarily present and that one skilled in the art would recognize that it is present. *Id.* at 47–48. Patent Owner also contends that Petitioner's argument relies on unsupported attorney argument and unsupported expert testimony. *Id.* at 48. Patent Owner contends that Petitioner's argument is premised on Taylor's bellows 160 at some point in operation being in a position that is neither fully open nor fully closed resulting in atmospheric pressure as the reference pressure. *Id.* Patent Owner contends that there is no basis for this assumption in Taylor as Taylor does not disclose such a point. Patent Owner contends that Taylor teaches that the bellows operates to provide a cyclic vacuum to the suction cups. *Id.* (citing Ex. 2026 ¶¶ 122, 128).

Patent Owner explains:

As the bellows expands it creates a vacuum pulling air flow into the bellows—*i.e.*, creating negative pressure with respect to the reference Pressure. *Id.* As the bellows compresses, the vacuum releases and pressure in the bellows returns toward the reference pressure, *i.e.*, the prevailing pressure of the sexual aid. *Id.* This cycle is illustrated below.

COMPRESSION OF AIR IN BELLOWS



Id. ¶ 123. Although pressure within the bellows during compression may increase in the negative pressure region and may approach or reach atmospheric pressure, pressure within the bellows is never positive *with respect to the reference pressure*, which is required by the claims of the '097 patent. *Id.*

Resp. 50.

In its Reply, Petitioner applies its construction for “reference pressure,” which we have rejected above, and contends that the reference pressure can be the pressure in the device shortly after it begins operation.

Reply 11. Petitioner states:

The claimed reference pressure could instead be a reference pressure prior to activating the device or after (e.g., immediately after) applying the device [to] the vulva. *Taylor* discloses compressing and then expanding the bellows after applying member 156 to the vulva, resulting in a positive and negative pressure relative to the pressure in bellows 160 (i.e., the reference pressure).

Reply 11 (citing Pet. 21; Ex. 1004, col. 5, ll. 29–40; Ex. 1002 ¶¶ 57–58, 74; Ex. 1018 ¶ 55; Ex. 1020 ¶¶ 55–56). Petitioner contends that using this definition of reference pressure, the cyclic vacuum of Taylor meets this limitation as the vacuum increases and decreases relative to the pressure shortly after activation. *Id.* at 11–12.

Petitioner also contends that when the suction cups are first applied, it creates a positive pressure with respect to the reference pressure and that the operation of the bellows would create a modulation of positive and negative pressure with respect to the reference pressure as it defines it as a “given pressure” during operation of the device. *Id.* at 12–16. Petitioner also contends that Taylor’s disclosure that the suction cups seal against the skin does not preclude the presence of a positive pressure with respect to the reference pressure. *Id.* at 15–16.

In sur-reply, Patent Owner contends that Petitioner’s argument is based on the incorrect assumption that the “reference pressure” can be any arbitrary “given pressure.” Sur-Reply 9. Patent Owner also contends that Petitioner’s argument with respect to the pressure in the suction cup being a positive pressure is unsupported by the record and is a new theory that should be disregarded. *Id.* at 10.

We have considered the arguments of the parties and the evidence of record and conclude that Petitioner has not demonstrated that Taylor discloses that the changing volume of the bellows results in modulation of positive and negative pressures with respect to a reference pressure.

First, Petitioner is basing its argument on a shifting and incorrect claim construction that “reference pressure” may include any “‘given’ pressure around which higher and lower pressures are generated for stimulating the body, which may be determined prior to application or after application of the device to the target body part.” *Compare* Reply 10, *with* Pet. 21–23 (stating “reference pressure” is “atmospheric pressure”). Based on such reliance on an incorrect claim construction alone, we find that Taylor does not disclose the changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference

pressure. But even if we were to adopt Petitioner’s erroneous claim construction, we find Petitioner’s substantive arguments concerning the teachings of Taylor are unavailing.

Petitioner’s contentions with respect to this limitation are also based on the erroneous premise that the bellows in Taylor must necessarily start in a position that is neither fully expanded nor fully compressed. Pet. 22 (stating “[w]hen bellows 160 is neither compressed nor expanded, the air within bellows 160 is at atmospheric pressure (i.e., the reference pressure)) (citing Ex. 1002 ¶¶ 58, 74; Ex. 1020 ¶ 64). Taylor, however is silent as to the starting position of the bellows. *See* Ex. 1004 col. 5, ll. 27–49; Ex. 2026 ¶ 121. Petitioner’s declarant, Mr. Meyst, confirms this silence by drawing a negative inference from such silence that does not meet the inherency test. In particular, Mr. Meyst testifies:

It is my opinion that pressures above and below the initial pressure would be generated by *Taylor*. This is at least because *there is no reason to assume* that an initially generated positive pressure in suction cup member 156 immediately after it is applied to the vulva would somehow be contrary to the operation of *Taylor*, and because there is no teaching that the device must begin operation with the bellows at its smallest volume.

Ex. 1020 ¶ 64 (emphasis added).

Thus, we agree with Patent Owner that Petitioner appears to argue that the starting position would inherently be neither fully compressed nor fully expanded, *see* Resp. 48–50, which is simply not supported by Taylor or the testimony of Petitioner’s declarants.

“A reference may anticipate inherently if a claim limitation that is not expressly disclosed ‘is necessarily present, or inherent, in the single anticipating reference.’ The inherent result must inevitably result from the

disclosed steps; “[i]nherency . . . may not be established by probabilities or possibilities.” *In re Montgomery*, 677 F.3d 1375, 1379–80 (Fed. Cir. 2012) (citations omitted, alterations in original).

We discern nothing in Taylor, the testimony of Dr. Prisco, or the testimony of Mr. Meyst to support the conclusion that the device in Taylor starts with the bellows in a position that is neither expanded nor compressed. *See* Ex. 1004, col. 5, ll. 27–49, Ex. 1002 ¶¶ 58; Ex. 1020 ¶ 64. In fact, given that Taylor explicitly teaches that the bellows acts to create a cyclic vacuum, one skilled in the art is just as likely to conclude that the bellows starts in the fully compressed position creating a stronger vacuum as the bellows is expanded. *See* Ex. 1004, col. 5, ll. 27–49; Ex. 2026 ¶¶ 121 (stating “Taylor describes a bellows for cyclically introducing only a **vacuum** . . . a POSITA would understand a bellows selected for purposes of creating a vacuum to provide unidirectional medium flow”).

For instance, as Dr. Jensen, Patent Owner’s declarant, explains:

[A] POSITA reading Taylor would want to maximize Taylor’s vacuum feature. As such, a POSITA might understand that the bellows is fully compressed initially. The way a POSITA would understand Taylor’s bellows to work is likely the following: As the bellows is expanded, a vacuum is created that allows for air flow to be pulled into bellows. As the bellows is compressed, the pressure in the bellows returns toward the starting pressure, *i.e.*, the prevailing pressure of the sexual aid. In other words, as the bellows is expanded, a negative pressure with respect to a reference pressure is created in the bellows that draws air into the bellows. As the bellows is compressed, the pressure in the bellows returns toward the prevailing pressure of the sexual aid as the vacuum is released. Regardless of the starting point of the bellows, a POSITA would understand that atmospheric pressure would be the “reference pressure” as understood in the context of the ’097 Patent. While the pressure within the bellows as the bellows is being compressed may increase, **the**

pressure within the bellows remains negative at all times and is never positive with respect to the reference pressure as claimed. This is also the only explanation based on the suction cups as described and disclosed in Taylor. Every other working principle generating positive pressures would lead to the cups disengaging from the body or falling off.

Ex. 2026 ¶ 122 (emphasis in original). As we find that Dr. Jensen’s analysis of the operation of Taylor’s device is more consistent with Taylor’s disclosure, we conclude that the evidence does not support Dr. Prisco’s contention that the bellows in Taylor must necessarily start in a position that is neither fully expanded nor fully compressed.

For all the reasons expressed above, we find that Petitioner has failed to show that Taylor discloses “the changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference pressure.”

b) An opening for applying the modulated positive and negative pressures to a body part

Petitioner contends that Taylor teaches this limitation based on the disclosure that one of the suction cups receives a portion of the vulva and that a cyclic vacuum is applied to the vulva through the suction cup. Pet. 23.

Patent Owner contends that Taylor does not teach this limitation as the suction cups of Taylor do not apply a positive pressure. Resp. 56–57. Patent Owner contends that if a positive pressure were applied through the suction cups, the cups would fall off, rendering Taylor inoperative. *Id.*

As discussed above, we do not find that Taylor discloses applying positive and negative pressure. Therefore we agree with Patent Owner that Taylor also does not disclose this limitation.

c) A control element for controlling the drive unit

Petitioner contends that Taylor meets this limitation in that Taylor discloses a power cord that supplies power to the electric motor. Pet. 24

Patent Owner contends that the power cord of Taylor is not a control element in that the cord does not control the function of the device, but merely provides power to the device. Resp. 57.

In its Reply, Petitioner argues that one skilled in the art would understand the power cord of Taylor to be a control device as it is the only element in Taylor that activates or deactivates the device. Reply 17–18. Petitioner contends that the Specification does not limit the term to a specific device. *Id.*

In Sur-Reply, Patent Owner contends that a power cord is not a control device as the term is used in the '097 patent in that it does not control the action of the device. Sur-Reply 12–13.

We have considered the arguments of the parties and the evidence of record and conclude that Petitioner has failed to establish that Taylor discloses this limitation.

While the Specification of the '097 patent does not specifically define the term control element, the Specification discloses that

the variation over time in the pressure field or the modulation of the pressure field by the control device is controlled largely automatically. Thus, the modulation of the pressure field, such as intensity, time profile or sequence, can be previously stored in the control device.

Ex. 1001, col. 7, ll. 18–22. The Specification also discloses

A control device 7 activates the drive unit 6, optional operating elements 71 and at least one optional display 72. Here, the control device 7 and the drive unit 6 are supplied with power

for example by the internal battery 76 and/or the external power supply 73.

Id. at col. 9, ll. 58–62. The Specification goes on to disclose “the control device controls the excitation of the drive unit such as the size of the deflection, the frequency, the modulation, etc.” *Id.* at col. 14, ll. 60–62.

Thus, the Specification makes it clear that the control unit does more than simply turn the device on and off, but controls the operation of the unit including the modulation of positive and negative pressures. *See* Ex. 2026 ¶ 137. Moreover, as shown above, the Specification makes it clear that the control unit is separate from the power source. *Id.* ¶ 138. We discern nothing in Taylor, nor does Petitioner point to any disclosure in Taylor that the power cord shown in Fig. 2 of Taylor does anything but provide power to the device. *See* Pet. 24; Ex. 2026 ¶ 139.

Based on the foregoing we conclude that Taylor does not disclose this limitation.

d) Conclusion

Based on the foregoing analysis, we conclude that Petitioner has failed to show by a preponderance of the evidence that claim 1 is anticipated by Taylor.

3. Claim 17

Claim 17 is an independent apparatus claim and like claim 1 includes the limitations calling for changing volume resulting in modulated positive and negative pressure, and for a control device. Ex. 1001, col. 18, ll. 1–13. The parties’ arguments with respect to claim 17 mirror those made with respect to claim 1. Pet. 36–38; Resp. 46–52.

For the reasons set forth with respect to claim 1 above, we find that Petitioner has not shown by a preponderance of the evidence that claim 17 is anticipated by Taylor.

4. Claims 2–6, 8, 9, and 18–24

Claim 2–6, 8, 9, and 18–24 are apparatus claims that depend from claim 1 or 17. Petitioner contends that each of the additional elements recited in claims 2–6, 8, 9 and 18–24 are disclosed in Taylor. Pet. 25–29; 39–41.

In addition to its arguments regarding claim 1, Patent Owner also contends that Taylor does not disclose the additional elements recited in claims 2, 9, 13, 14, 18 and 24. Resp. 57–58.

“A dependent claim shall be construed to incorporate by reference all the limitations of the claim to which it refers.” 35 U.S.C. § 112(d). Thus, the dependent claims include all of the limitations of claim 1 or claim 17. As discussed above, Petitioner has failed to show that all of the limitations recited in claim 1 and claim 17 are disclosed by Taylor; therefore, the same holds true for dependent claims 2–6, 8, 9, and 18–24.

5. Claims 12 and 26

Claim 12 is an independent claim and reads:

12. A method comprising:
 - causing deflections of a flexible wall portions of a chamber of a stimulation device in opposing directions, thereby resulting in a changing volume of the chamber, the changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference pressure; and
 - applying the modulated positive and negative pressures to a body part through an opening, wherein the stimulation device is positioned by the user for applying the modulated positive and negative pressures using an appendage of the stimulation device,

wherein the appendage is a dildo configured to be inserted into a vagina.

Ex. 1001, col. 7, ll. 40–53. Claim 26 is similar to claim 12. Compare *id.*, with *id.* at col. 18, ll. 33–46.

Like claim 1, claim 12 includes limitations calling for modulating positive and negative pressures with respect to a reference pressure. *Id.* Claim 26 is similar to claim 12 in that it also calls for producing such modulated positive and negative pressures. *Id.* at col. 18, ll. 33–46.

Petitioner presents the same arguments with respect to these elements of claims 12 and 26 that it presented with respect to claim 1. Pet. 31, 41–42.

Patent Owner’s arguments with respect to this element are also the same as those presented with respect to claim 1. *See* Resp. 46–52.

For the reasons set forth with respect to claim 1 above, we find that Petitioner has not shown by a preponderance of the evidence that claim 12 or claim 26 is anticipated by Taylor.

6. Claims 13–16 and 27–30

Claim 13–16 and 27–30 depend from claims 16 and 26. Ex. 1001, col. 17, ll. 53–62, col. 18, ll. 47–61. As they all include the limitation calling for modulated positive and negative pressures with respect to a reference pressure, we conclude that Petitioner has not shown that these claims are anticipated by Taylor.

E. Ground 2 – Obviousness based on Taylor Combined with Hovland

Petitioner contends that claims 1–30 are unpatentable as obvious over Taylor combined with Hovland.

1. Hovland

Hovland generally discloses a stimulation device wherein suction or a vacuum is applied to the clitoris to promote engorgement of the clitoris with

blood. Ex. 1005, Abst. An alternative embodiment of Hovland teaches the use of super-atmospheric pressure to massage the clitoris. *Id.* at col. 4, ll. 22–24.

2. Claim 1

Petitioner contends that Taylor combined with Hovland teaches all of the elements of claim 1. Pet. 45. As discussed with respect to the anticipation ground above, Petitioner contends that Taylor teaches or suggests all of the elements of claim 1. *Id.* Petitioner alternatively contends that to the extent Taylor does not teach modulated positive and negative pressures with respect to a reference pressure, Hovland teaches this limitation. *Id.* at 45–46.

Petitioner contends that Hovland teaches that both suction and increased pressure can be used to massage the clitoris, thereby increasing blood flow and engorgement of the clitoris. *Id.* Petitioner contends Hovland refers to creating a vacuum and/or using increased pressure to produce percussion and/or massage of the clitoris and that one skilled in the art would have interpreted this to teach the use of pressure below ambient and pressure above ambient—positive and negative pressures with respect to a reference pressure. *Id.* at 46–47. Petitioner contends that one skilled in the art would have been motivated to combine the teachings of Hovland and Taylor to produce a product that achieves improved and faster clitoral engorgement. *Id.* at 47–48.

Petitioner also contends that to the extent the power plug of Taylor is not a control device, Hovland teaches the use of a control device. Pet. 48.

Patent Owner contends that neither Hovland nor Taylor teach or suggest modulated positive and negative pressures with respect to a reference pressure. Resp. 52. Hovland teaches: “According to other

embodiments, pump/motor assembly 300 provides pneumatic and/or hydraulic actuation to create e.g. vibration, percussion, subatmospheric pressure and/or superatmospheric pressure, or modulation of these effects.” Ex. 1005, col. 13, ll. 20–24. Patent Owner contends that this passage in Hovland teaches the modulation of either a vacuum or super atmospheric pressure, but not modulating between them. Resp. 53. Patent Owner contends that while Hovland uses the term “and/or” with respect to certain embodiments, one skilled in the art would not have considered the term to refer to modulating between positive and negative pressures in the teachings of the ’097 patent. *Id.* at 53–54. Patent Owner contends that the use of the term and/or refers to a choice of effects and not modulating between them. *Id.* at 55. Patent Owner also argues that Hovland does not disclose any structure or means for modulating between positive and negative pressures. *Id.*

Patent Owner also contends that one skilled in the art would not have been motivated to combine the teachings of Taylor and Hovland. Resp. 58–59. Patent Owner argues that Petitioner has not adequately explained or supported its contention that it would have been obvious to modify Taylor with the teachings of Hovland to achieve the results stated in Hovland. *Id.*

Petitioner responds that the plain meaning of “and/or” supports its interpretation that Hovland teaches modulation between positive and negative pressures. Reply 8. Petitioner argues that Hovland specifically teaches modulation between various effects, including between positive and negative pressures. *Id.* Petitioner also contends that combining Taylor with Hovland is nothing more than modifying Taylor with a known method to produce a predictable result. *Id.* at 9.

In its Sur-Reply, Patent Owner contends that, when read in context, the term “and/or” as it appears in Hovland refers to a series of alternative modes, but not alternating between these modes to achieve modulation of positive and negative pressures with respect to a reference pressure. Sur-Reply 17–18. Patent Owner also contend that Petitioner misconstrues the teachings of Hovland with respect to using different pressures to stimulate the clitoris. *Id.* at 19–21.

As discussed above, we find that Taylor teaches all of the elements of claim 1 with the exception of the limitations calling for modulated positive and negative pressure, a control device, and an opening for applying positive and negative pressure. We now turn to the questions of whether those elements are taught by Hovland; whether Petitioner has shown that one skilled in the art would have been motivated to combine the teachings of Taylor and Hovland if Hovland teaches the missing limitations; and whether Patent Owner has offered sufficient evidence of objective indicia of patentability to overcome Petitioner’s arguments that the subject matter of claim 1 would have been obvious.

a) Modulated Positive and Negative Pressure

Petitioner contends that, to the extent the elements of modulated positive and negative pressure and control device are not taught by Taylor, those elements are taught by Hovland. Pet. 46–48.

Hovland teaches that in one embodiment, the device disclosed therein has a “pump/motor assembly [which] provides pneumatic and/or hydraulic actuation to create e.g. vibration, percussion, subatmospheric pressure and/or superatmospheric pressure, or modulation of these effects.” Ex. 1005, col. 13, ll. 21–24. Petitioner construes this passage as teaching that the device in Hovland can modulate both positive and negative pressures as required by

claim 1. Reply 6–9. Petitioner contends that the use of the term “and/or” would lead one skilled in the art to understand that the device of Hovland can modulate between subatmospheric and superatmospheric pressures. *Id.*

Patent Owner contends that although Hovland may teach a device that can produce positive (superatmospheric) or negative (subatmospheric) pressures, it does not teach modulating between those pressures. Resp. 53. Patent Owner contends that the recited paragraph only indicates that the individual effects can be modulated, but not that the device can modulate between the effects. *Id.* at 54.

We have considered the arguments advanced by the parties and the evidence of record and conclude that Patent Owner has the better argument. While we agree with Petitioner that Hovland teaches a device capable of producing positive and negative pressures individually, we do not find that Hovland discloses modulating between those effects. We agree with Patent Owner that, when read in context, the cited passage refers to modulation of the individual effects recited in the sentence, but not modulation between the effects. Resp. 54–55. As Patent Owner points out, this interpretation is consistent with the overall teachings of Hovland, which describe modulation of the vacuum or negative pressure effect. Resp. 55 (citing Ex. 2026 ¶161). For example, Hovland teaches the use of a vacuum modulator to vary the suction pressure applied by the device, in a manner similar to Taylor’s device. Ex. 1005, col. 12, ll. 42–59. Hovland also teaches that the vacuum modulator can be used to pulsate the vacuum level of the device. *Id.* at col. 14, ll. 21–22. Hovland goes on to teach:

When applied to the clitoris, the vacuum applied by device 200 will cause the clitoris to become engorged, i.e. filled with blood. Vacuum level and modulation can be adjusted by either the patient or her partner, as needed, to maintain engorgement.

Thus, embodiments of the invention provide the ability both to rapidly *modulate vacuum pressure* with modulator 290, in a manner akin to the modulation of alternating current, for example, and simultaneously to more evenly hold underlying vacuum pressure at a substantially constant level or gradually change it, e.g. with wheel 280, in a manner akin to direct current. This dual functionality provides substantial advantages over the prior art.

Id. at col. 14, ll. 27–39 (emphasis added). Thus when read in the context of the entire disclosure of Hovland, we find that the reference in Hovland to modulation refers to modulation of one specific effect, not modulation between two or more effects.

Petitioner contends that Patent Owner’s interpretation of Hovland limits the device to one which produces a vacuum or superatmospheric pressure. Reply 6–9. Petitioner contends that this ignores the use of the term “and/or” as it appears in Hovland, which calls for the device to create both effects. *Id.*; Ex. 1018 ¶¶ 42–55; Ex. 1020 ¶¶ 67–76.

While we agree with Petitioner that the term “and/or” calls for a device that can create both positive and negative pressures, as discussed above, we do not read Hovland as teaching modulating between effects, as required for claim 1. This is confirmed by the plain language of Hovland, which refers to “modulation of these effects” rather than “modulation between effects.” Ex. 1005, col. 13, ll. 20–24. Moreover, when the cited paragraph is read in the context of the other disclosures in Hovland discussed above, we find that the overall teachings of Hovland are focused on modulation of the individual effects, not modulating between the effects. Ex. 1005, col. 12, ll. 21–24; Ex. 2026 ¶¶ 161–163. While Hovland teaches a device that can produce positive and negative pressures we discern nothing in Hovland that teaches modulating between these effects.

Therefore, we conclude that neither Taylor nor Hovland teach the feature of modulating positive and negative pressures with respect to a reference pressure in a sexual stimulation device.

b) Motivation to Combine

As noted above, a determination of obviousness requires more than showing that all of the elements are present in the prior art. There must be a motivation to combine those elements to produce the claimed invention. *Unigene*, 655 F.3d at 1360. Because we have found that neither Taylor nor Hovland teach modulating between positive and negative pressures with respect to a reference pressure, we need not analyze whether Petitioner has failed to establish by a preponderance of the evidence that the combination of Taylor and Hovland renders obvious claim 1 of the '097 patent. Nonetheless, even assuming that the Hovland teaches this requirement based on its disclosure of “subatmospheric pressure and/or superatmospheric pressure, or modulation of these effects,” we further find that Petitioner has also failed to show a rationale as to why one of ordinary skill in the art would have combined the teachings of Taylor and Hovland to arrive at the claimed subject matter of the challenged claims.

In the present case, Petitioner contends that the motivation to combine the teaching of Taylor and Hovland arises from the teachings in Hovland that percussion and/or massage of the clitoris achieves improved and faster clitoral engorgement. Pet. 47 (citing Ex. 1005, col. 4, ll. 19–28; Ex. 1002 ¶ 105). Petitioner also contends that the combination of references is nothing more than using a known technique to improve a similar device. *Id.* at 47–48.

Patent Owner contends that Petitioner’s argument is factually unsupported in that Petitioner does not explain how one skilled in the art

would have modified the references or how the references teach modulation between positive and negative pressures. Resp. 58–59.

We have considered the arguments presented by the parties and the evidence of record and find that Petitioner has not adequately explained why one skilled in the art would have been motivated to combine the teachings of Taylor and Hovland to produce a stimulation device that modulates between positive and negative pressure.

The paragraph relied upon by Petitioner for establishing such a rationale reads:

A vacuum created over the clitoris, or suction applied to the clitoris, for example, creates a negative pressure in the clitoris that is or is likely to be lower than the systolic blood pressure. *Alternatively*, super-atmospheric pressure may be provided to produce massage or percussion of the clitoris and/or the surrounding area. *In either case*, the pressure differential tends to promote engorgement of the clitoris with blood and/or otherwise stimulate blood flow, providing the benefits described above while increasing the likelihood of short-term pleasurable effect and beneficial longer-term usage. Embodiments of the invention thus may encourage more regular and active compliance with a treatment program for urinary and/or fecal incontinence, while at the same time treating female sexual dysfunction if needed. Embodiments of the invention also are non-invasive, non-pharmacological, relatively inexpensive and easy to use.

Ex. 1005, col. 4, ll. 18–34 (emphasis added). It is clear from reading this paragraph that Hovland is talking about the benefits of using *either* negative or positive pressure, but not both. Thus, insofar as Hovland does not teach such modulation, Hovland does not provide the motivation to modify Taylor to modulate between positive and negative pressure.

Based on the foregoing we find that Petitioner has failed to establish a motivation to combine the teachings of Taylor with those of Hovland.

c) Objective Indicia

Before reaching an ultimate conclusion on obviousness, we must consider so-called objective indicia of non-obviousness when they are in evidence. *Graham*, 383 U.S. at 18. Objective indicia of non-obviousness, or “secondary considerations,” guard against hindsight reasoning in an obviousness analysis, and are often “the most probative and cogent evidence in the record.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016) (citations omitted). As such, objective indicia of non-obviousness must be considered in every case in which they are presented. *Id.* (citing *Transocean Offshore Deepwater Drilling Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012)). The secondary considerations evidence we must consider, if presented, include “copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention.” *Rouffet*, 149 F.3d at 1355. We must also determine if Patent Owner has shown a nexus between the evidence and the merits of the claimed invention. *Wyers*, 616 F.3d at 1246.

(1) Nexus

There must be a “nexus” between the merits of the claimed invention and the evidence of secondary considerations for such evidence to be accorded substantial weight. *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011). Nexus is presumed if a marketed product embodies the claimed features and is coextensive with them. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1372 (Fed. Cir. 2013). A patent owner is entitled to a presumption of a nexus if it shows that “the asserted objective evidence is

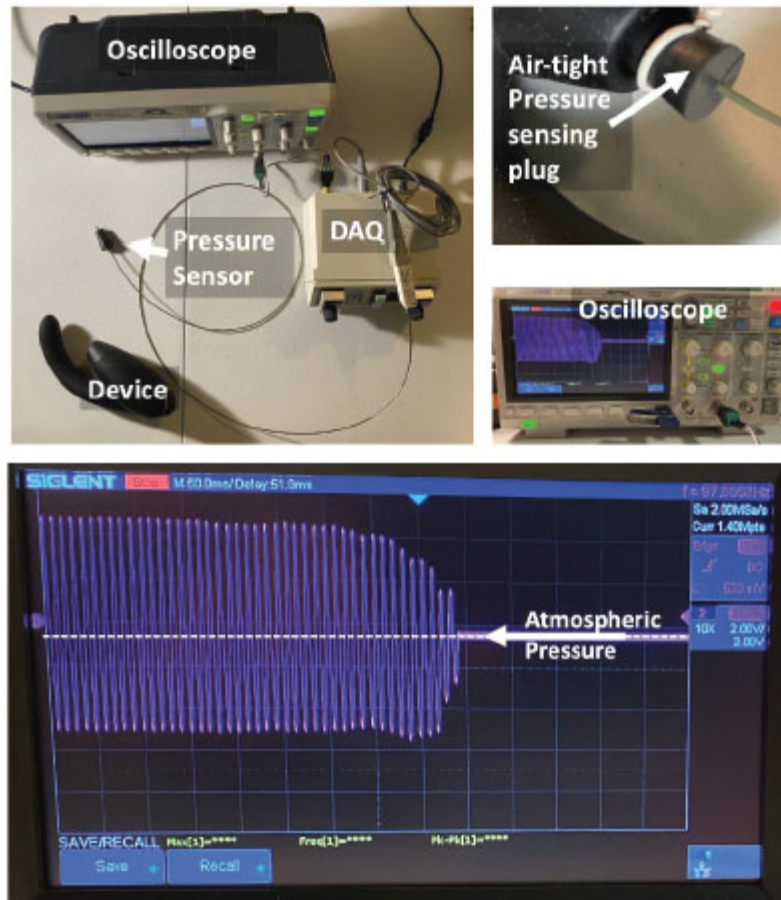
tied to a specific product and that product ‘is the invention disclosed and claimed in the patent.’” *WBIP*, 829 F. 3d at 1335.

Patent Owner contends that two of its commercial products, the Womanizer® InsideOut and Womanizer® Duo, “embody and are coextensive with” the claims of the ’097 patent. Resp. 67. In support of this contention Patent Owner relies on the testimony of its experts Drs. Jensen and Herbenick. Resp. 10 (citing Exs. 2006, 2026 and 2028).⁴

Both Dr. Herbenick and Dr. Jensen reviewed the Womanizer® InsideOut and concluded that the device was coextensive with at least claim 1 of the ’097 patent. Ex. 2026 ¶ 41; Ex. 2028 ¶ 39. Dr. Herbenick prepared a detailed claim chart tracking each element of the independent claims to specific components of the Womanizer® InsideOut, concluding that the device contained each of the structural elements recited in the independent claims. Ex. 2028 ¶¶ 41–47; Ex. 2006. Dr. Jensen reviewed the device and Dr. Herbenick’s claim charts and also concluded that all of the structural elements were present in the device. Ex. 2028 ¶ 41.

Dr. Jensen also conducted an experiment to determine whether the Womanizer® InsideOut produced modulated positive and negative pressures with respect to a reference pressure. Ex. 2028 ¶¶ 42–44. The following images from Dr. Jensen’s declaration shows the equipment used to test the pressure of the InsideOut, as well as the pressure graph generated as a result of the tests:

⁴ As both Dr. Herbenick and Jensen have testified, the Womanizer® InsideOut and Womanizer® Duo differ only in style features with the structure and mechanics of the two devices being the same. Ex. 2026 ¶ 41; Ex. 2028 ¶ 38. For this reason, Dr. Herbenick and Jensen focused their analyses on the Womanizer® InsideOut. Ex. 2026 ¶ 41; Ex. 2028 ¶ 38.



Ex. 2026 ¶ 42. As shown in the top images above, Dr. Jensen’s testing set-up included an oscilloscope, data acquisition equipment (“DAQ”), and a pressure sensor with an air-tight pressure sensing plug connected to the device. *Id.* In the pressure graph shown above, the y-axis indicates pressure (as a voltage measurement) relative to ambient or atmospheric pressure (zero line) and the x-axis indicates time (milliseconds). *Id.* Based on the results of that experiment and the product literature relating to the Womanizer® InsideOut, Dr. Jensen concluded that the commercial devices meet the limitations calling for modulated positive and negative pressures with respect to a reference pressure. Ex. 2028 ¶¶ 43–44.

Petitioner contends that Patent Owner has failed to establish a nexus between the commercial products and the challenged claims. Resp. 21. Petitioner contends that Patent Owner's arguments are largely based on the testimony of Dr. Herbenick, who Petitioner contends is not qualified to render such opinions. *Id.*

Petitioner contends that Patent Owner is not entitled to a presumption that the commercial devices embody the claimed invention as they include features not recited in the claims. *Id.* at 22. Petitioner also argues that Dr. Jensen's testing of the alleged commercial embodiment is unsound and does not establish a nexus between the device and the claims. *Id.*

We have considered the arguments presented by the parties and the evidence of record and find that Patent Owner has established a nexus between the claims of the '097 patent and its commercial products. The testimony of both Dr. Herbenick and Dr. Jensen demonstrate that the elements of the claims are present in the Womanizer® InsideOut and Womanizer® Duo products and that the products are essentially the claimed invention. Ex. 2026 ¶¶ 40–44; Ex. 2028 ¶¶ 36–47.

Petitioner contends that the presence of additional, unclaimed features precludes a presumption of a nexus between the commercial embodiments and the claims of the '097 patent. Reply 22. In support of this contention Petitioner cites to *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019). Petitioner's reliance on *Fox Factory* is misplaced. As the court in *Fox Factory* stated:

To be sure, we have never held that the existence of one or more unclaimed features, standing alone, means nexus may not be presumed. Indeed, there is rarely a perfect correspondence between the claimed invention and the product. As we explained, the purpose of the coextensiveness requirement is to ensure that

nexus is only presumed when the product tied to the evidence of secondary considerations “is the invention disclosed and claimed.” Thus, if the unclaimed features amount to nothing more than additional insignificant features, presuming nexus may nevertheless be appropriate.

Id. at 1375. The court went on to state: “Although we do not require the patentee to prove perfect correspondence to meet the coextensiveness requirement, what we do require is that the patentee demonstrate that the product is essentially the claimed invention.” *Id.*

In *Fox Factory*, the alleged commercial embodiment included unclaimed features that the patentee described as critical to the products’ performance. *Id.* at 1374–1375. It was the presence of these critical, unclaimed features that lead the court to hold: “A patent claim is not coextensive with a product that includes a ‘critical’ unclaimed feature that is claimed by a different patent and that materially impacts the product’s functionality.” *Id.*

The case before us is factually distinct from *Fox Factory*. While Petitioner has identified several features of the Womanizer® products that are not recited in the claims, Petitioner has not pointed to nor do we discern any evidence to suggest that these unclaimed features are critical to the products and impact the products’ functionality. *See* Reply 22. While Dr. Herbenick testified that additional features were present in the Womanizer® devices, Petitioner has not pointed to any testimony by Dr. Herbenick or other evidence to support the contention that these additional features significantly affect the functionality of the devices. *See* Reply 22–23; Ex. 1023, 115–116.

Petitioner also contends that Patent Owner’s evidence that the commercial products are coextensive with the claims of the patent is

unreliable. Reply 23. Petitioner contends that Dr. Herbenick did not perform a technical analysis of the devices herself and lacks the technical expertise to perform such an analysis. *Id.* With respect to Dr. Jensen's testimony, Petitioner contends that Dr. Jensen's testing technique is unsound and should not be relied upon. *Id.* at 23–24. We find both of these argument unpersuasive.

While we agree with Petitioner that Dr. Herbenick does not have a technical degree that would enable her to opine about the operation of various components in the commercial embodiments, we note that she has studied and tested various sexual stimulation devices. Ex. 2018 ¶¶ 12–13. Based on her experience with such devices we find that Dr. Herbenick is qualified to identify the various components of the commercial embodiments as she did in her declaration and claim chart. Ex. 2006; Ex. 2028 ¶¶ 39–47. Moreover, Dr. Jensen, who has a background in medical devices, examined the commercial embodiments and Dr. Herbenick's analysis and claim charts and concurred in Dr. Herbenick's findings. Ex. 2026 ¶¶ 41, 170.

We are similarly unpersuaded by Petitioner's critique of Dr. Jensen's testing methodology. In particular, Petitioner and Dr. Prisco point to Dr. Jensen's deposition testimony indicating that he used a rubber plug or bottle stopper with the pressure sensor for his testing. Ex. 1018 ¶¶ 77–78; Ex. 2022, 61:2–20. Petitioner contends that this technique is unreliable because the rubber stopper used by Dr. Jensen 'could be filling most of the chamber.'" Reply 23–24. In support of this contention Petitioner cites to Dr. Prisco's and Mr. Meyst's testimony concerning the use of the stopper by Dr. Jensen. *Id.* Dr. Prisco, however, never testified that the stopper might fill the chamber, but rather that the use of the stopper could affect the pressures generated. Ex. 1018 ¶ 78. Dr. Prisco offers no explanation why this might be

so or that it actually occurred when Dr. Jensen conducted his experiments. For this reason, we give little weight to Dr. Prisco's critique of Dr. Jensen's methodology. *Ebit Sys. Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1358 (Fed. Cir. 2018) ("The PTAB [i]s entitled to weigh the credibility of the witnesses") (internal citation omitted).

Mr. Meyst also testified that he had issues with how Dr. Jensen conducted his experiments. Ex. 1020 ¶¶ 91–95. As part of his critique, Mr. Meyst identified several potential issues with respect to Dr. Jensen's test method. *Id.* While Mr. Meyst opines that he would have conducted the experiments differently, Mr. Meyst does not explain how the alleged irregularities affected the results achieved by Dr. Jensen that the Womanizer® devices modulated positive and negative pressure with respect to a reference pressure. *Id.*

Dr. Prisco also testified that the data produced by Dr. Jensen shows that the pressure in the device modulated at a pressure greater than atmospheric pressure. Ex. 1018 ¶¶ 82–83. Petitioner contends that this further supports the conclusion that Dr. Jensen's test results are unreliable. *See* Reply 24. Again, we are not persuaded by this argument. Even if we were to accept Petitioner's argument that the reference pressure in Dr. Jensen's test was something other than atmospheric pressure, our construction of reference pressure does not limit the term to atmospheric pressure, but only the pressure in the device before it is placed in operation. Petitioner does not dispute that the data produced by Dr. Jensen show modulation of positive and negative pressure with respect to a reference pressure regardless of whether it is atmospheric pressure. *See id.*; Ex. 1018 ¶¶ 82–83.

Based on the foregoing we conclude that Patent Owner has established a nexus between the Womanizer® InsideOut and Womanizer® Duo products and the claims of the '097 patent.

(2) *Commercial Success*

The commercial response to an invention is significant to determinations of obviousness and is entitled to fair weight. *Demaco Corp. v. F.von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988).

Patent Owner contends that the Womanizer® products are “stand-out successes.” Resp. 67. In support of this contention, Patent Owner points to various consumer testimonials as well as Dr. Herbenick’s testimony regarding the sales of Womanizer® products. *Id.*

Petitioner contends that Dr. Herbenick’s testimony should be given little weight as Patent Owner did not produce the sales data referenced in Dr. Herbenick’s testimony. Reply 25.

Patent Owner responds that the failure to produce revenue data is irrelevant given the significant number of consumer reviews and Dr. Herbenick’s testimony. Sur-Reply 25.

We have considered the arguments presented by the parties and the testimony of Dr. Herbenick and evidence of record and find that Patent Owner has not shown that the Womanizer® products are commercially successful.

Commercial success in the context of secondary considerations is typically established by evidence of sales of the product embodying the claimed invention and relevant market share.⁵ *In re Applied Materials, Inc.*,

⁵ The analysis also requires a showing of a nexus between the claimed features and the sales of the relevant product. *Applied Materials*. 692 F.3d at 1299.

692 F.3d 1289, 1299 (Fed Cir. 2012). In the present case Patent Owner has only offered the testimony of Dr. Herbenick that the relevant products have achieved significant sales volumes and that sales continue to increase. Resp. 67 (citing Ex. 2028 ¶ 49). However, Patent Owner has not produced the sales data that served as the basis for Dr. Herbenick's conclusion, precluding an independent analysis of the data. *See* Reply 24; Sur-Reply 24; Ex. 2028 ¶ 49, n.11.⁶ Moreover, Dr. Herbenick did not offer any testimony regarding the market share for the relevant products. *See* Ex. 2028 ¶ 49.

Patent Owner contends Dr. Herbenick's testimony, coupled with the consumer reviews of the relevant products, is sufficient to establish commercial success. Sur-Reply 25. We are not persuaded by this argument. While the customer reviews may be relevant to showing a nexus between the commercial sales and the claimed features, the reviews do not provide any information regarding the actual sales and relevant market share.

Absent sales and market share information, we cannot determine if the relevant products enjoyed commercial success sufficient to support a finding of non-obviousness. *Applied Materials*, 692 F.3d at 1299.

(3) Long-Felt Need

"Evidence of a long felt but unsolved need that is met by the claimed invention is further evidence of non-obviousness." *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1369 (Fed. Cir. 2017). Evidence of a long felt

⁶ Dr. Herbenick states that the reason the underlying data was not produced was that the standard protective order did not provide sufficient protection for this highly confidential material. Ex. 2028 ¶ 49, n.11. We note that if Patent Owner had wished to rely on the sales data shown to Dr. Herbenick, Patent Owner could have requested a modification of the Protective Order to protect its highly confidential information. *See* 37 C.F.R. § 42.52(a)(7). Patent Owner did not avail itself of this option.

but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would have not persisted had the solution been obvious. *WBIP*, 829 F.3d at 1332.

Patent Owner contends that there was a long-felt but unmet need for a sexual stimulation device that provided sexual pleasure while minimizing potential side effects. Resp. 68 (citing Ex. 2028 ¶ 50). Patent Owner contends that the use of prior art stimulation devices could cause numbness or damage to genitalia creating a need for a device which avoided these effects. Resp. 68. Citing the testimony of Dr. Herbenick, Patent Owner contends that the Womanizer® products satisfied this need. *Id.* at 69 (citing Ex. 2028 ¶¶ 52–54).

In its Reply, Petitioner contends that indirect stimulation devices such as the claimed device were known in the art before the invention of the claimed device and that such devices would have avoided the side effects recited by Dr. Herbenick. Reply 25–26. Petitioner also contends that Patent Owner has not presented any empirical data to show that the commercial embodiments filled the long-felt need. *Id.* at 26.

In its Sur-Reply, Patent Owner contends that the testimony of Dr. Herbenick is sufficient to support a finding that the Womanizer® products satisfied a long-felt need. Sur-Reply 25.

We have considered the arguments presented by the parties and the evidence of record and conclude that Patent Owner has shown that there was a long-felt need that was satisfied by the Womanizer® products.

Dr. Herbenick testified that she led a study of women who used vibrators and found that 28.5% of women who used vibrators experienced one or more side effects including genital numbness, pain, irritation, inflammation/swelling, tears or cuts. Ex. 2028 ¶ 51 (citing Ex. 2008, 1861–

1863, Table 5). Dr. Herbenick testified that these injuries resulted in the need for a sexual stimulation device “that was effective at facilitating sexual pleasure and/or orgasm while minimizing the potential for side effects.” *Id.* Dr. Herbenick testified that the Womanizer® products satisfied this need by “providing alternating positive and negative pressures to the clitoris so as to provide indirect stimulation to the clitoris sufficient to facilitate female orgasm. This is important as physical contact has caused numbness or even tears or cuts in a subset of female vibrator users.” Dr. Herbenick also testified that the prior art devices, including the device disclosed in Taylor, failed to meet this need. *Id.* ¶ 53.

Petitioner contends that indirect stimulation devices were known in the art and that such devices could also cause unwanted effects. Reply 25–26. We find this argument unpersuasive. Petitioner cites to the testimony of Dr. Herbenick to support this contention. *Id.* However, a careful reading of the cited pages reveals that Dr. Herbenick testified that, in the study she conducted, women were merely asked what type of vibrator was used but not whether the vibrator was used directly or indirectly. Ex. 1023, 61–62. We also note that Dr. Herbenick testified that at the time she conducted her study most of the vibrators available in the market would have been direct vibration without a lot of indirect possibilities. Ex. 1023, 62–63. While she testified that there were some devices in the market that provided indirect stimulation, they were suction-only devices that were less popular. *Id.* Dr. Herbenick testified that these suction-only devices are not the same as the Womanizer® devices, which apply alternating positive and negative pressures. *Id.*

Petitioner also contends that Patent Owner has failed to present any empirical data to support show that the Womanizer® products fulfill the

alleged long-felt need. Reply, 26. Again we are unpersuaded by Petitioner’s argument. Petitioner has not stated what specific “empirical data” is needed to show that the Womanizer® products fulfill the need, nor has Petitioner cited any case law holding that such data is required. *Id.* Moreover, Petitioner has not presented any evidence to rebut Dr. Herbenick’s conclusion that the Womanizer® devices do fulfill the long-felt need.

In reaching our decision that the Womanizer® products fulfilled a long-felt need in the market for female sexual stimulation devices, we credit Dr. Herbenick’s extensive experience in studying sexual health and behavior, including vulvar and vaginal health, as well as the use of sexual enhancement products such as vibrators including her detailed studies reported in Exhibit 2008. Ex. 2028 ¶¶ 7, 12, 13, 16, 50–54. Petitioner did not offer any expert with a similar background to rebut Dr. Herbenick’s testimony.

(4) Failure of Others

Evidence that others tried but failed to develop a claimed invention may carry significant weight in an obviousness inquiry. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1081 (Fed. Cir. 2012). This objective indicia factor is closely tied to the long-felt need factor discussed above. *Id.* at 1082 (“Longfelt need is closely related to failure of others.”).

Patent Owner contends that prior to the development of the Womanizer® products, “experts in sexual health and behavior were well aware of the potential adverse side effects of using vibrators for sexual stimulation, yet no one had successfully designed a product that facilitated orgasm while physically contacting the clitoris without also having these potential side effects, despite numerous attempts.” Resp. 69. In support of

this contention, Patent Owner cites Dr. Herbenick's testimony that while experts in the field were aware of the issues of clitoral discomfort and numbness that arose from direct clitoral contact, none of the prior art devices accomplished the goal of providing a stimulation device without discomfort or numbness. *Id.*; Ex. 2028 ¶¶ 53–57.

Petitioner does not address Patent Owner's argument or evidence. *See* Reply 21–26.

We find that Patent Owner has persuasively shown that others in the field failed to develop a sexual stimulation device that avoided the issues of clitoral discomfort or numbness.

Dr. Herbenick testified based on her own experience in teaching the use of various stimulation devices and her work in developing such devices that no one had developed a product that achieved sexual stimulation in the same manner as the Womanizer® devices. Ex. 2012 ¶¶ 55–57. Dr. Herbenick testified that each prior device of which she was aware was limited to “either direct contact (such as vibrator or flicking) or was limited to providing suction.” *Id.* ¶ 57. Neither of these approaches solved the issue of clitoral discomfort or numbness. *See id.*

(5) *Skepticism*

Evidence of industry skepticism about whether or how a problem could be solved, or the workability of the claimed solution, weighs in favor of nonobviousness of the claimed invention. *United States v. Adams*, 383 U.S. 39, 52 (1966); *WBIP*, 829 F.3d at 1335.

Patent Owner contends that “industry experts and participants were skeptical about the commercial embodiments and, specifically, about how modulating between positive and negative air pressure might facilitate orgasm.” Resp. 70 citing Ex. 2028 ¶¶ 58–61.

Petitioner contends that skepticism must be evaluated from the viewpoint of industry experts and that, with the exception of Dr. Herbenick, the evidence submitted by Patent Owner is limited to consumer reviews. Reply 26 (citing *WBIP*, 829 F.3d at 1335; *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1365 (Fed. Cir. 2007)).

We have considered the arguments presented by the parties and the evidence of record and find that Patent Owner has shown industry skepticism relating to the Womanizer® products. Although we agree with Patent Owner that most of the reviews cited by Dr. Herbenick are consumer reviews and not experts in the field, the compilation of reviews cited by Dr. Herbenick include reviews from experts who expressed skepticism about the products. For example, there is a review by Dr. Emily Morse, “a sexologist with a doctorate in human sexuality,” who expressed skepticism about the product in her review. Ex. 2015, 1–2. Another expert is Vanessa Marin, a licensed psychotherapist specializing in sex therapy, who reviewed the product and expressed skepticism about it. Ex. 2016, 124–130. These reviews plus the testimony of Dr. Herbenick show industry skepticism about the Womanizer® products. Ex. 2028 ¶¶ 58–61.

(6) Praise by Others

Evidence of industry praise of the claimed invention weighs in favor of nonobviousness. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016). Evidence of industry praise may include evidence of industry awards given to commercial embodiments of the claimed invention. *See Henny Penny Corp. v. Frymaster, LLC*, 938 F.3d 1324, 1333–1334 (Fed. Cir. 2019) (finding evidence of industry praise, including industry awards for the patented product).

Patent Owner contends that, notwithstanding the industry skepticism discussed above, the industry has also praised the Womanizer® products extensively. Resp. 70. Patent Owner contends that reviews of the Womanizer® products have described them as “innovative, unique, and [in] other similar terms.” *Id.* at 71 (citing Ex. 2028 ¶¶ 62–69). Patent Owner also contends that the Womanizer® products have received at least 18 industry awards including the Most Innovative Product award at the 2018 ADULTEX Awards. *Id.*

Petitioner has not presented any arguments in response to Patent Owner’s showing. *See* Reply 23–26.

We find that Patent Owner has presented evidence showing praise in the industry favoring a finding of non-obviousness. As Dr. Herbenick testified, the Womanizer® InsideOut was named the most innovative Product at the 2018 ADULTEX Awards. Ex. 2028 ¶ 68; Ex. 2017, 1–4. The Womanizer® Duo was recognized and the Luxury Product/Range of the Year at the 13th annual StorErotica Awards in 2019 and was named the Sex Toy Product/Line of the Year – Powered (Vibrating) at the XBIZ Europa Awards. Ex. 2028 ¶ 68; Ex. 2017, 5–25. Dr. Herbenick also testified that the Womanizer® Duo was praised by Cosmopolitan magazine as having pressure waves that “gently suck the clitoris to give you an entirely different orgasmic sensation.” Ex. 2028 ¶ 65; Ex. 2016, 64. In addition, the Womanizer® products have received praise by both sex toy retailers and consumers. Ex. 2028 ¶¶ 62–69.

(7) *Copying*

“Copying may indeed be another form of flattering praise for inventive features.” *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1311 (Fed. Cir. 2010).

Patent Owner contends that Petitioner and others have copied that Womanizer® products and that this supports a finding on non-obviousness. Resp. 72–73. To support this contention, Patent Owner points to descriptions of competitors’ devices which describe the devices as offering “pleasure air technology” or “touchless air technology,” which Dr. Herbenick contends describes modulated positive and negative pressures with respect to a reference pressure. *Id.*; Ex. 2028 ¶ 71.

Petitioner contends that Patent Owner has not shown sufficient evidence of copying to support a finding of non-obviousness. Reply 25. Petitioner contends that Dr. Herbenick did not review tests of the competitors’ devices, nor could she describe how the products worked. *Id.*

In reply, Patent Owner contends that Petitioner mischaracterizes Dr. Herbenick’s testimony and fails to rebut the evidence of copying. Sur-Reply 25.

Copying in the context of objective indicia of non-obviousness can be demonstrated either through internal documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a virtually identical replica, or access to, and substantial similarity to, the patented product (as opposed to the patent). *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004). Marketing materials may also be used to show copying. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1368 (Fed. Cir. 2012).

We have considered the arguments presented by the parties and the evidence of record and find that Patent Owner has presented sufficient evidence of copying to support to finding of non-obviousness. Although Dr. Herbenick did not physically examine the competitors’ devices, she did

review various product descriptions which either compared the competitors' devices to the Womanizer® products or described the action of the products in a way that mirrored the actions of the Womanizer® products. Ex. 2028 ¶¶ 70–71. For example, a review of the Blowfish clitoral stimulator was described by Cosmopolitan magazine as “Mimicking the technology of the Cosmo-loved Womanizer.” Ex. 2034. Similarly the Satisfyer website described the Satisfyer Pro G-Spot Rabbit as offering a “rapid change between suction and pressure.” Ex. 2024, 4.

Given this evidence of the similarity of the competitive products to the Womanizer® products and Petitioner's failure to offer any evidence in rebuttal, we find that Patent Owner has presented persuasive evidence of copying to support a conclusion of non-obviousness.

(8) Conclusion

Based on the foregoing we conclude that Patent Owner has presented sufficient evidence relating to objective indicia to support a finding of non-obviousness. Although Patent Owner failed to present persuasive evidence relating to commercial success, Patent Owner has presented persuasive evidence relating to long-felt need, failure of others, praise by others, and copying. Patent Owner has also shown a nexus between its commercial products and the claimed invention. In sum, the objective indicia evidence in the record supports the non-obviousness of the challenged claims.

3. The Remaining Claims

As discussed above with respect to Ground 1, all of the remaining claims include a limitation calling for modulation of positive and negative pressures with respect to a reference pressure. Based on our analysis above, we find that Petitioner has not presented sufficient persuasive evidence that the subject matter of the remaining claims would have been obvious over

Taylor combined with Hovland and that Patent Owner has presented persuasive evidence regarding objective indicia of non-obviousness.

4. Conclusion

From the foregoing analysis we conclude that Petitioner has not demonstrated that the subject matter of claims 1–30 would have been obvious to one of ordinary skill in the art over Taylor combined with Hovland.

F. Ground 3 – Obviousness Based on Guan Combined with Lee and Hovland

Petitioner contends that claims 1–30 are unpatentable as obvious over Guan combined with Lee and Hovland. Pet. 53.

1. Guan

Guan discloses a gas health massager that generates pulsating air pressure to stimulate meridian points for therapeutic purposes. Ex. 1007, 3. Guan teaches the contraction of an air bag to produce the pulsating air pressure. *Id.*

2. Lee

Lee discloses a mechanized dildo having vibratory elements placed on the dildo so as to stimulate a clitoris. Ex. 1006, Abst.

3. Non-Analogous Art

Before we begin our analysis of the claims we first address Patent Owner’s contention that Guan cannot be properly combined with Lee as Guan is non-analogous art. Resp. 42–45.

“Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to

the particular problem with which the inventor is involved.” *In re Clay*, 966 F.2d 656, 658–59 (Fed. Cir. 1992).

Patent Owner argues that the field of endeavor for the present invention is sex toys whereas Guan is directed to medical treatment using a variation of acupuncture. Resp. 43. Patent Owner supports this argument by pointing to the teachings in the Specification that the claimed device is designed to be used to stimulate erogenous zones. *Id.* at 43–45. Patent Owner contends that Guan is directed to acupressure/acupuncture and is not relevant to sexual stimulation. *Id.*

Petitioner contends that acupressure can be used in the genital region. Reply 19. Petitioner also contends that Patent Owner’s contention that the device described in the ’097 patent is limited to stimulating erogenous zones is contradicted by the teachings of the ’097 patent and by Patent Owner’s experts. *Id.* at 20. Petitioner also argues that Patent Owner’s argument that Guan is not relevant because the invention is limited to sex toys fails. *Id.* at 21 (citing 21 C.F.R. § 884.5960 (categorizing genital vibrators as medical devices); Ex. 1034).

Patent Owner responds by contending that the presence of acupressure points in the genital region does not render Guan relevant prior art. Sur-Reply 21. In support of this contention Patent Owner points to the testimony of Dr. Herbenick that acupressure meridian theory is not concerned with sexual arousal and orgasms and that one skilled in the art would not look to meridian theory to aid in developing a sex toy. *Id.* (citing Ex. 2028 ¶ 78; Ex. 1023, 97).

Patent Owner also argues that Petitioner’s reliance on the location of meridians in the perineum or genitals is misplaced. *Id.* at 21–22. Petitioner contends that treatment for sexual dysfunction is different than sexual

stimulation and that they entail different approaches. *Id.* at 22. Patent Owner also contends that the regions where the meridians are located, e.g., the perineum, are significantly different than the vulva or the clitoris. *Id.*

In our Rehearing Decision, we addressed Patent Owner's contention that Guan is non-analogous art and held that although Guan is not directed to a sex toy, it is reasonably pertinent to the problem faced by the inventor. Reh'g Dec. 6. Having considered the arguments of the parties and the evidence of record, we affirm our original conclusion that Guan is analogous art.

Guan is directed to a device that uses pulses of air to massage or stimulate a body part. *See* Ex. 1007, 1; Ex. 1002 ¶ 70. Although we agree with Patent Owner that the principle use of the claimed device is stimulation of the clitoris, the '097 patent teaches its general applicability to stimulating a body part. Ex. 1001, Abst.; col. 1, ll. 19–20, col. 4, ll. 51–56, col. 10, l. 63 to col. 11, l. 4, claim 1.

Moreover, the Specification teaches that the disclosed device creates a massaging effect on the body part in an indirect way. Ex. 1001, col. 5, ll. 39–41. Guan also massages a body part indirectly. *See* Ex. 1007, 3. Thus, both the present invention and Guan address similar issues and Guan can be considered analogous art.

4. Analysis of Claim 1

Petitioner contends that the combination of Guan, Lee, and Hovland teaches each of the limitations recited in claim 1. Pet. 53–62. Because we find that Petitioner has not shown by a preponderance of the evidence that the challenged claims are unpatentable as obvious over the combination of Guan, Lee, and Hovland, we will concentrate our analysis on only the limitation that Petitioner has failed to show taught by the combination,

which is the requirement for “the changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference pressure.”

- a) *The changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference pressure*

Petitioner contends that Guan teaches this limitation. Pet. 55–56.

Petitioner contends that prior to starting any motion of the air bag, the pressure in the device is the reference pressure. *Id.* (citing Ex. 1002 ¶¶ 70, 128–129). Petitioner contends that as the lever in Guan compresses the air bag, it creates a positive pressure with respect to the reference pressure. *Id.* Petitioner contends that as the lever expands the airbag, it creates a negative pressure with respect to the reference pressure. *Id.* Petitioner contends that this results in modulated positive and negative pressures with respect to a reference pressure. *Id.*

In support of these arguments Petitioner initially relies on the following testimony of Dr. Prisco:

69. In *Guan*, when power is turned on to activate electromagnet 5, the electromagnet 5 will drive the magnet 4 and the lever 3 to oscillate about the pinned connection (as annotated using the curved arrow in the figure of *Guan* reproduced above), and cause the wall of air bag 2 marked A (in the figure above) to reciprocate towards and away from mouth 1 to cyclically expand and contract the air bag 2. (*Id.*)

70. Before wall A starts to reciprocate, the pressure of air in air bag 2 is at the prevailing atmospheric pressure. When mouth 1 is in contact with the body and air bag 2 contracts, the air in air bag 2 gets compressed, and its pressure increases to a value above the prevailing atmospheric pressure. Similarly, when mouth 1 is in contact with the body and air bag 2 expands, the air in air bag 2 also expands, and its pressure decreases below the prevailing atmospheric pressure. As the pressure inside air bag 2 increases above the prevailing atmospheric pressure, air

flows from the air bag 2 through the mouth 1 on to the body part that is in contact with the mouth 1. (*Id.*) And, when the pressure inside air bag 2 decreases below the prevailing atmospheric pressure, air flows from the mouth 1 into the air bag 2 and applies a suction force on the body part. In this manner, activation of the electromagnet 5 generates and applies a “pulsating air pressure” on the body for stimulation.

Ex. 1002 ¶¶ 69–70; *see also id.* ¶¶ 127–129. Dr. Prisco testified that the operation of Guan as he described would result in “modulated positive and negative pressures with respect to a reference pressure.” *Id.* ¶ 128.

Patent Owner responds that Guan does not disclose modulated positive and negative pressures, but is limited to pulsing positive pressure. Resp. 30–31. Patent Owner contends that Petitioner’s contentions with respect to Guan teaching modulated positive and negative pressures is not supported by the limited disclosure in Guan. Resp. 32–34.

Patent Owner supports these arguments with the testimony of Dr. Jensen who testified:

Guan fails to provide a complete or clear description of the device’s elements or the interactions and functioning of its elements. Guan fails to provide specific details of, for example, the coupling of lever (3) to other components, the orientations of the electromagnet and magnet (*e.g.*, orientations of the charges and poles), which are required to determine the movement of the lever (3) and the magnet (4), and details regarding how air enters and exits the air bag or even deformation of the airbag.

Ex. 2027 ¶ 103. Dr. Jensen goes on to note that Dr. Prisco’s analysis of Guan is not supported by the teachings of Guan, but are based on assumptions using information gleaned solely from the ’097 patent in an inappropriate hindsight analysis. *Id.* ¶ 104 (stating “[n]othing in Guan discloses an air-tight seal between the mouth (1) and the body. . . A POSITA

would not interpret Guan as Petitioner and Dr. Prisco have, without knowledge gleaned from the '097 Patent”).

Patent Owner also contends that the reciprocating motion of Guan only creates a variation in positive pressure and does not result in a negative pressure. Resp. 34–35. Patent Owner contends that one skilled in the art would have understood the device described in Guan to pulse air in only one direction and not between positive and negative pressures. *Id.*

Patent Owner contends that one skilled in the art would not have been motivated to modify Guan to modulate positive and negative pressures. Resp. 35–36. Patent Owner contends that Guan is directed to mimicking meridian-based therapies, which use either positive pressure or negative pressure, but not both. *Id.* Patent Owner contends that nothing in Guan would have led one skilled in the art to modify the device to produce both positive and negative pressures. *Id.* Patent Owner contends that Petitioner’s experts improperly used the '097 patent as a guide in their analyses. *Id.*

Petitioner contends that one skilled in the art would have understood that the air bag in Guan is in an intermediate position and that the action of the lever causes the air bag to expand and contract, thereby creating positive and negative pressures. Reply 2–3. Petitioner also contends that the plain meaning of the term pulsation supports the conclusion that the device in Guan produces positive and negative pressures. *Id.* at 4. Petitioner also contends that Guan’s teaching of both acupressure and cupping indicates that the device in Guan can create both positive and negative pressures. *Id.* at 5.

In addition to relying on the testimony of Dr. Prisco, Petitioner also cites to the testimony of Mr. Meyst. *Id.* Mr. Meyst testified that:

A person of skill in the art, prior to March 2015, would have understood, based on the figure of *Guan*, that because the lever 3 is described as reciprocating and driving the air bag 2, and because the lever 3 is depicted in an intermediate/neutral position (i.e., the lever 3 is expected to move both left and right of the depicted position in the figure), the resulting motion would generate modulated positive and negative pressures. Further, a person of ordinary skill in the art would have expected that, other than when a seal is created against mouth 1 when the air bag 2 is completely expanded or compressed, *Guan* would always generate modulated positive and negative pressures, relative to ambient air pressure, due to the electromagnet 5 driving the magnet 4, lever 3, and the wall of air bag 2 to have a reciprocating motion during operation.

Ex. 1020 ¶ 86.

Patent Owner responds that the teachings of *Guan* do not support Petitioner's analysis and that *Guan* is limited to producing only positive pressures. Sur-Reply 14.

We have considered the arguments presented by the parties and the evidence of record conclude that Petitioner has not demonstrated that *Guan* teaches the element “the changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference pressure.”

Both Dr. Prisco and Mr. Meyst based their opinions on the premise that the air bag of *Guan* is in an intermediate position that would allow it to expand creating a pressure below the reference pressure. Ex. 1002 ¶¶ 69–70; Ex. 1018 ¶ 34; *see* Ex. 1020 ¶ 87. *Guan*, however is silent with respect to the starting position of the airbag. As Mr. Meyst testified, if the airbag were in the fully expanded position or in the fully compressed position, the airbag would not create positive and negative pressures relative to a reference pressure. Ex. 1020 ¶¶ 86–87.

Given Guan's silence as to the starting position of the air bag, Petitioner and its experts appear to rely on an assumption that Guan inherently teaches that the air bag always starts in a position that is neither fully expanded nor fully compressed. Although inherency may supply a missing element in an obviousness analysis, the petitioner must show that it is a natural result flowing from the operation of the device. *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014). In the instant case, Petitioner has not established that the intermediate position would naturally result from the operation of the device.

Mr. Meyst testified that Guan shows the lever that drives the airbag in an intermediate position and that because the lever can reciprocate, the airbag must also must generate positive or negative pressures with respect to a reference pressure. Ex. 1020 ¶ 86. However, Mr. Meyst does not state, nor does Guan teach, that an intermediate position is always the starting position. *See id.* Thus it cannot be said that Guan inherently starts in the neutral position and invariably produces a positive and negative pressure with respect to a reference pressure without such a teaching.

Petitioner contends that the device of Guan can also be used for cupping, which in turn is a teaching that the device can be used to generate positive and negative pressures. Reply 5. We are not persuaded by this argument. The discussion of cupping in Guan appears as part of a discussion of prior art solutions. Ex. 1007, 3. We do not discern, nor does Petitioner point to, any specific teaching in Guan that the device of Guan can be used for cupping.⁷ Moreover, even if the device could be used for cupping,

⁷ Cupping is a traditional Chinese medical therapy that involves the application of negative pressure for therapeutic purposes. Ex. 1033, 8.

Petitioner has not pointed to any teaching that would have led one skilled in the art to combine cupping with acupressure. *See* Reply at 5.

Petitioner contends that Patent Owner has failed to identify any structure in Guan that would prevent the device from operating in the manner described by Petitioner's experts. Reply 4. Petitioner, however, inappropriately places the burden of persuasion on Patent Owner. It is Petitioner's burden to establish that the subject matter of the claims would have been obvious, not Patent Owner's burden to establish the negative, that such subject matter would not have been obvious. *See Magnum*, 829 F.3d at 1375.

b) Conclusion

For the reasons set forth above, Petitioner has not demonstrated that Guan teaches "the changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference pressure." Additionally, as discussed above with regard to Petitioner's Ground 2 contentions, we find that Hovland also fails to teach this limitation. Petitioner does not rely upon Lee to satisfy this limitation. Based on the foregoing, we conclude that Petitioner has not demonstrated that the combination of Guan, Lee, and Hovland teaches all of the elements of claim 1.

5. Claims 2–11

Claims 2–11 depend from claim 1 and therefore include all of the limitations of claim 1. 35 U.S.C. § 112 (d). As discussed above, Petitioner has not shown that Guan combined with Lee and Hovland teaches the claim element calling for the changing volume of the chamber resulting in modulated positive and negative pressures with respect to a reference

pressure. Therefore, we conclude that Petitioner has not demonstrated that Guan, Lee, and Hovland teach all of the elements of claims 2–11.

6. Claims 12–16 and 16–30

Claims 12 and 26 are independent method claims, which also include the limitation that the changing volume of the chamber or the pressure field generator results in modulated positive and negative pressure with respect to a reference pressure. Ex. 1001, col. 17, ll. 36–62; Col. 18, ll. 33–61. Claims 13–16 and 27–30 depend from claims 12 and 26, respectively.

As discussed above, the combination of Guan, Lee, and Hovland does not teach modulated positive and negative pressures with respect to a reference pressure. Therefore we find that Guan combined with Lee and Hovland does not teach all of the elements of claims 12–16 and 26–30.

7. Claims 17–25

Claim 17 is an independent apparatus claim, which also includes a claim element calling for the production of positive and negative pressures with respect to a reference pressure. Ex. 1001, col. 17, ll. 1–13. Claims 18–25 depend from claim 17. *Id.* at col. 17, ll. 14–31.

As discussed above, the combination of Guan, Lee, and Hovland does not teach modulated positive and negative pressures with respect to a reference pressure. Therefore we find that Guan combined with Lee and Hovland does not teach all of the elements of claims 17–25.

8. Motivation to Combine Guan, Lee, and Hovland

Having addressed the question of whether the combined teachings of Guan, Lee, and Hovland teach or suggest all of the elements of the claims, we now turn to the question of whether one skilled in the art would have been motivated to make such a combination.

“Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination.” *Unigene*, 655 F.3d at 1360. “Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Id.*

Petitioner contends that one skilled in the art would have been motivated to combine the teachings of Guan with those of Lee and Hovland because Guan teaches that the massager can be used to stimulate any region of the body including erogenous zones such as the clitoris. Pet. 58–59. Petitioner contends that one skilled in the art would have been aware of the disadvantages of direct stimulation of the clitoris and that indirect systems were better suited. *Id.* at 59 (citing Exs. 1001, 1005). Petitioner contends that it was well known in the art to provide a device such as Lee, which combines a dildo with a stimulation element for the clitoris. *Id.* at 60.

Petitioner goes on to contend:

Thus, a POSITA at the time of the alleged invention, recognizing the drawbacks of direct mechanical stimulation and the benefits of indirect stimulation via air pressure differential on the clitoris, would have had a reasonable expectation of success in replacing *Lee*’s mechanical vibrator with *Guan*’s massager to take advantage of the benefits of indirect stimulation discussed above. Ex. 1002 at ¶¶26-28, 134-137. Accordingly, the POSITA would have been motivated to incorporate *Guan*’s massager in *Lee*’s dildo so as to replace direct vibratory stimulation with pulsating air pressure during use of dildo 10. *Id.* Such a modification would have amounted to nothing more than a simple substitution of one known element for another to obtain predictable results. *See KSR*, 550 U.S. at 417. This is because at the time of the invention, a POSITA would have the requisite

skill level to replace *Lee*'s mechanical vibrator with *Guan*'s massager without any problem. In such a modified device, sleeve 16 would correspond to the claimed appendage in the form of a "dildo configured to be inserted into the vagina." Ex. 1002 at ¶137.

Id. at 61–62.

Patent Owner contends that one skilled in the art would not have been motivated to combine the teachings of Guan and Lee. Resp. 62–65. Patent Owner contends that one skilled in the art would not have viewed Guan as teaching stimulation of erogenous zones as Guan deals with acupressure, which relates to stimulating meridians that do not include erogenous zones.

Id. at 62.

Patent Owner also contends that although one skilled in the art may have known of the disadvantages of direct clitoral stimulation, one skilled in the art would not have looked to Guan for the solution insofar as Guan is not related to treating sexual dysfunction of clitoral engorgement. *Id.* at 63.

Patent Owner also contends that one skilled in the art would not have had a reasonable expectation of success in combining the device of Guan into the dildo of Lee. *Id.* at 63–64.

Patent Owner also contends that it would not have been a matter of simple substitution of the massager of Guan for the direct stimulator of Lee. *Id.* at 64. Patent Owner contend that such a modification would have required a complete redesign of the dildo and arm member. *Id.*

In response, Petitioner contends there are acupoints or meridians in the female genitalia, thus Guan would be applicable to stimulating these regions. Reply 19–20. Petitioner also points out that the broader claims are not limited to stimulating erogenous zones or the clitoris. *Id.*

In its Sur-Reply, Patent Owner contends that as

the un rebutted testimony of Dr. Herbenick makes clear, a POSITA looking to design a sex toy that enhances sexual arousal and orgasm by stimulating the clitoris with modulated positive and negative pressures relative to the reference pressure would not have looked to meridian-based therapies to do so because—unlike the '097 Patent—meridian theory is not concerned with enhancing sexual arousal and orgasm.

Sur-Reply 21 (citing Ex. 2028 ¶ 78); Ex. 1023. 97.

Patent Owner also contends that while references may teach applying acupressure to the perineum or genitalia, it is to treat sexual dysfunction. Sur-Reply 21–22. Patent Owner contends that treatment of sexual dysfunction is different from enhancing sexual arousal and that one would not look to a device for treating sexual dysfunction to enhance sexual arousal. *Id.*

We have considered the arguments presented by the parties and the evidence of record and find that Petitioner has not demonstrated that one skilled in the art would have been motivated to combine the teachings of Guan with Lee.

While Guan is silent as to which part of the body the device is to be applied, Guan teaches that the device “has good curative effect on blood pressure, heart disease, cerebral thrombosis, coronary heart disease, digestive system, nervous system and various pains.” Ex. 1007, Abst. Nothing in Guan suggests that it has any effect on sexual arousal or sexual dysfunction. *See id.* In addition, Dr. Herbenick, who has extensive experience in evaluating and developing sex toys, testified that:

As a POSITA myself, I do not recall conversations with design team colleagues in which anyone referenced meridian-based therapy devices, which makes sense because meridian-based therapy is not relevant to erogenous zones or sexual arousal. Additionally, even if a POSITA had come across Guan, I cannot

imagine why they would have been motivated to combine the device of Guan with other patents or devices to create something akin to the '097 Patent. This is because I do not think most POSITAs would be skilled in the arts of both meridian therapies and sexual stimulation, and would certainly not learn anything about pressures applied to genital parts from reading Guan. Also, I cannot imagine a POSITA reading Guan, which at most teaches pulsating pressures for purposes of treating illness and health problems associated with the meridian channels (which themselves have nothing to do with sexual arousal), and coming up with the modulation between positive and negative pressures with respect to a reference pressure, for purposes of sexual stimulation. In my opinion, a person of ordinary skill in the art would not and did not find that feature (the modulation of positive and negative pressures with respect to a reference pressure) obvious prior to the invention of the Womanizer products as claimed in the '097 Patent. In addition to the reasons already noted, it occurs to me that those skilled in the art often considered features that in some way mimicked common human forms of sexual stimulation (e.g., vibration mimicking rapid touch, vacuum suction mimicking mouth suction, dildos mimicking the penis, dildos with a thrusting motion mimicking intercourse). As a sexuality researcher, educator, and POSITA, I have never heard anyone describe using modulated pressures in rapid succession (such as from their mouth) and thus I cannot imagine that creating this style of stimulation would have been obvious to sexual stimulation device designers. Again, this is why the '097 Patent was truly inventive. I also cannot imagine why a POSITA would have read Guan and thought to add an appendage or dildo to it, again, because Guan is not a sexual stimulation device, and because there is nothing in the disclosure of Guan that would suggest to a POSITA that Guan could or should be combined with another device, let alone a dildo.

Ex. 2028 ¶ 78.

Although we acknowledge that Dr. Prisco testified that one skilled in the art would have been motivated to combine the teachings of Guan and Lee to take advantage of Guan's indirect stimulation, we note that Dr. Prisco

has no direct experience in developing sex toys. *See* Ex. 1002 ¶¶ 132–131; Ex. 1019. Dr. Herbenick, on the other hand, has extensive experience in evaluating and developing sex toys. Ex. 2028 ¶¶ 7–17; Ex. 2029. For this reason we give greater weight to Dr. Herbenick’s testimony on this issue.

Although we agree with Petitioner that acupressure and acupuncture have been used in the genital region, it has been used to relieve pain or to treat infections. *See* Exs. 1030, 1032, 1033. We do not see how the teaching of the use of acupressure for treating pain or illness would have led one skilled in the art to use the same methods to increase sexual arousal.

Petitioner also contends that Hovland provides a motivation to combine the teachings of Guan and Lee. Pet. 59. We are not persuaded. Petitioner argues that Hovland teaches that the advantage of indirect stimulation of the clitoris “may reduce the likelihood of fibrosis[] at the clitoris ... and consequent reduced clitoral and urethral physiological function.” *Id.* (quoting Ex. 1005 at 19:27–31). Like Guan and the acupressure references cited by Petitioner, Hovland is describing the use of indirect pressure to treat or prevent a medical condition. Like the acupressure references, Petitioner does not explain adequately why one skilled in the art would have combined a device used for sexual stimulation such as Lee with a device like Guan that is used to treat a medical condition.

Based on the foregoing we conclude that Petitioner has failed to show why one skilled in the art would have been motivated to combine the teachings of Guan with those of Lee and Hovland to produce the claimed invention.

9. Objective Indicia

Our analysis of Petitioner’s obviousness contention is not complete without considering Patent Owner’s evidence of objective indicia of non-

obviousness. *Graham*, 383 U.S. at 18. As discussed above in Section II.E.2.c), we find that Patent Owner has put forth sufficient evidence of objective indicia to establish that the claims of the '097 patent are not obvious.

10. Conclusion

Based on the foregoing, we conclude that Petitioner has not demonstrated that the subject matter of the challenged claims would have been obvious to one of ordinary skill in the art at the time the invention was made over Guan combined with Lee and Hovland.

III. PETITIONER'S MOTION TO EXCLUDE

Petitioner has moved to exclude Patent Owner's expert declarations (Exhibits 2026 and 2028), as well as Exhibit 2032. Paper 45 ("MTE"). For the reasons set forth below, Petitioner's Motion is denied.

A. Exhibit 2026 — Declaration of Dr. Herbenick

Petitioner contends that we should either exclude the testimony of Dr. Herbenick or afford it little weight for several reasons. First, Petitioner contends that Patent Owner failed to comply with 37 C.F.R. § 42.65(b) in that Patent Owner failed to provide an affidavit explaining how certain tests that Dr. Herbenick relied upon were performed. MTE 2–4. Second, Petitioner contends that Patent Owner failed to produce all documents relied upon by Dr. Herbenick in rendering her opinions. *Id.* at 5–8. Third, Petitioner contends that the testimony of Dr. Herbenick should be excluded because of allegedly improper objections made by counsel for Patent Owner during Dr. Herbenick's deposition. *Id.* at 9–12. Fourth, Petitioner contends that Dr. Herbenick is not qualified to testify as a technical expert. *Id.* at 14–15. Finally, Petitioner contends that we should strike Dr. Herbenick's

testimony as she did not disclose her work as a witness in other proceedings. MTE 7–8; Paper 47, 5 (“MTE Reply”).

We address each of these arguments in turn.

1. Failure to Comply with 37 C.F.R. § 42.65(b)

Petitioner contends that we should exclude or give little weight to all of Dr. Herbenick’s testimony because her declaration does not provide any information relating to the experiments that produced the graph discussed in paragraph 43 of her declaration. MTE 2–3. While Petitioner may be correct with respect to Dr. Herbenick’s failure to adequately describe what tests led to the graph on paragraph 43 of her declaration, we find this objection moot as we did not rely on that part of her testimony.

Petitioner also argues that we should exclude or give little weight to Dr. Herbenick’s testimony about the different components in the Womanizer® products as Patent Owner did not provide an affidavit concerning the deconstruction and observation of the devices. MTE 4–5. We do not find that this a sufficient reason to exclude or discount Dr. Herbenick’s testimony. Rule 42.65(b) refers to “technical” tests. We find that dismantling a device and identifying the components of the device does not constitute a “technical” test within the scope of the Rule. We therefore decline to exclude or give little weight to that portion of her testimony.

2. Withheld Documents and Information

Petitioner contends that we should exclude or give little weight to the testimony of Dr. Herbenick because Patent Owner failed to provide all the relevant facts and data that support Dr. Herbenick’s opinions. Specifically Petitioner contends that Patent Owner failed to produce sales data and research that supported Dr. Herbenick’s testimony relating commercial success to Patent Owner’s products; drafts of Dr. Jensen’s declaration that

Dr. Herbenick reviewed in connection with her declaration; and documents relating to the differences between the InsideOut and Duo products. MTE 5–7. Petitioner also points to Dr. Herbenick’s failure to disclose the fact that she has testified for Patent Owner in other matters as evidence that Patent Owner has withheld other information and documents. MTE 7–8. We address each of these issues in turn.⁸

a) Sales Data

Petitioner’s motion to exclude with respect to sales data is moot. As discussed above in Section II.E.2.c(2) above, we found that Patent Owner had failed to establish commercial success, in part, because Patent Owner failed to produce the relevant sales data.

b) Draft Declarations

We find that Petitioner’s objection to Dr. Herbenick’s declaration on the basis that Patent Owner did not produce the draft of Dr. Jensen’s declaration that Dr. Herbenick reviewed in connection with her declaration to be without merit. We agree with Patent Owner that the declarations of the other experts do not constitute facts or data as that term is used in 37 C.F.R. § 42.65(b). Paper 46, 5–6 (“MTE Reps.”) Documents relating to Patent Owner’s Products

Petitioner contends that Patent Owner failed to produce documents relating to the differences between the InsideOut and Duo products and that those difference show that there are technical differences between the products. MTE 7. Petitioner contends that this contradicts the testimony of

⁸ We note that at no time during this proceeding did Petitioner seek assistance from the panel to obtain the documents it now says warrant excluding Dr. Herbenick’s testimony.

Patent Owner's experts that the mechanics of the two products are the same.
Id.

We find that Petitioner's objection on this ground is without merit. To begin, Patent Owner's experts acknowledged that the InsideOut and Duo products were different but that the difference did not affect their analyses. Ex. 2026 ¶ 41; Ex. 2028 ¶ 38. Moreover, the first "technical difference" identified by Petitioner relates to the number and location of control buttons on the Duo device, a feature that does not appear to be related to the issue of whether the Duo device embodies the claimed invention. Ex. 1023, 117. The other "technical difference" identified by Petitioner is the addition of a light. Ex. 1053, 146. Again this is not a feature relevant to the issue of whether the commercial products embody the claimed invention.

3. Dr. Herbenick's Bias

Petitioner contends that Dr. Herbenick failed to disclose that she had testified for Patent Owner in other proceedings, which demonstrates Dr. Herbenick's bias and Patent Owner's withholding of relevant information. MTE 7–8; MTE Reply 5. We are not persuaded that this warrants excluding Dr. Herbenick's testimony. Although the testimony regarding Dr. Herbenick's work for Patent Owner may be relevant, it goes to the issue of credibility, not admissibility. *See, e.g., NuVasive, Inc. v. Iancu*, 752 F. App'x 986, 996 (Fed. Cir. 2018) ("While the Board can and should weigh the credibility of any expert testimony, it should not outright disregard expert testimony from a witness simply because that individual is compensated for his time and expense in testifying.").

4. Patent Owner's Alleged Misconduct

Petitioner contends that the testimony of Dr. Herbenick should be excluded because of alleged misconduct by Patent Owner's counsel during

the depositions Dr. Herbenick and Dr. Jensen. MTE 8–12. Petitioner contends that counsel for Patent Owner repeatedly made speaking objections which coached the witness and affected Petitioner’s ability to obtain discovery. *Id.*

Patent Owner contends that the objections were proper and necessitated by misrepresentations made by Petitioner’s counsel. MTE Resp. 10–13. Patent Owner also argues that even if the objections were improper, exclusion of the expert’s declarations is not the proper remedy. *Id.* at 13.

We begin by noting that several of the alleged speaking objections identified by Petitioner were from depositions in other proceedings and are not relevant to the issue of excluding testimony in this proceeding. Exhibits 1051 and 1052 are transcripts from IPR2019-01444 and Exhibits 1053 and 105 are from IPR2020-00007.

With respect to this proceeding, Petitioner has identified only three possible instances of speaking objections. We do not find this to be such egregious conduct as to warrant excluding Dr. Herbenick’s testimony. Moreover the testimony affected by the alleged improper objections has no bearing on our decision. For example, one objection related to the issue of the definition of a pressure field generator which does not play a part in our decision. *See* Ex. 1023, 149–151. The other concerned the operation of the device in Guan. *Id.* at 168. Dr. Herbenick offered no direct testimony concerning the operation of Guan nor do we rely on Dr. Herbenick’s testimony regarding Guan in reaching our decision. *See* Ex. 2028.

Given the limited number of alleged speaking objections and the fact that the affected testimony is not relevant to our decision, we decline to impose the sanction of excluding Dr. Herbenick’s testimony.

5. Dr. Herbenick's Expertise

Petitioner contends that Dr. Herbenick lacks the relevant technical expertise to testify about the validity of the '097 patent or whether Patent Owner's commercial products embody the claims of the '097 patent. MTE 14–15. We do not find that Petitioner has stated sufficient grounds to exclude Dr. Herbenick's testimony.

While Dr. Herbenick does not have a technical degree or an extensive technical background, her testimony was from the point of view of one with experience evaluating and designing sex toys. *See, e.g.*, Ex. 2028 ¶¶ 50–54 (evaluation of the long-felt need in the industry). It is in this context that Dr. Herbenick's testimony has been offered and relied upon by us in reaching our decision.

On the issue of validity, most of Dr. Herbenick's testimony has been with respect to objective indicia, an issue about which we find Dr. Herbenick well qualified to opine. The only “technical” testimony offered by Dr. Herbenick that we rely upon is her identification of the various components found in the Womanizer® devices. Ex. 2028 ¶¶ 39–47. With the exception of her opinion regarding modulation of positive and negative pressures, we find that her experience in evaluating and designing sex toys gives her the relevant experience to identify the various components of the devices. *See* Ex. 2028 ¶¶ 4–17.

With respect to Dr. Herbenick's testimony regarding modulation of positive and negative pressures, we have not relied on Dr. Herbenick's testimony in reaching our decision.

Dr. Herbenick did not offer any technical analysis of the prior art, therefore her lack of understanding regarding how the prior art operated is irrelevant to the question of whether her testimony should be excluded.

6. Conclusion

From the foregoing analysis we see no reason to exclude Dr. Herbenick's testimony or to give it little weight. For this reason, that portion of Petitioner's Motion to Exclude is denied.

B. Exhibit 2028 — Declaration of Dr. Jensen

Petitioner contends that the testimony of Dr. Jensen should be excluded or given little weight. MTE 1. As with Dr. Herbenick's testimony, Petitioner cites several reasons to exclude Dr. Jensen's testimony. First, Petitioner contends that Patent Owner violated 37 C.F.R. § 42.65(b) by not providing a proper affidavit describing Dr. Jensen's experiment. *Id.* at 2–3. Second, Petitioner contends that Patent Owner did not produce all documents Dr. Jensen relied upon in reaching his opinions. *Id.* at 5–8. Finally, Petitioner contends that the improper conduct by Patent Owner's counsel during the deposition of Dr. Jensen warrants exclusion of Dr. Jensen's testimony. *Id.* at 8–11.

1. Failure to Comply with 37 C.F.R. § 42.65(b)

While Petitioner contends that Dr. Jensen's declaration does not comply with 37 C.F.R. § 42.65(b), Petitioner does not state how the declaration fails to comply with the Rule. *See* MTE 2–4. Petitioner's arguments focus on alleged deficiencies in Dr. Jensen's methodology, which would go to the weight to be afforded such testimony, and do not address any failure to comply with our Rules.⁹ *Id.*

⁹ Petitioner contends that Dr. Jensen's procedure does not comply with the FDA's guidance for good laboratory practices found at 21 C.F.R. § 58. That section of the regulations relates to product safety testing and is irrelevant to any issue before us. *See* 21 C.F.R. § 58.1(a). Moreover, Petitioner's argument regarding compliance with the FDA rules and well as Petitioner's argument that Dr. Jensen's test is impossible to replicate is unsupported by

Moreover, failure to comply with 37 C.F.R. § 42.65(b) also goes to the weight given the evidence. *Emerson Elec. Co. v. IPCO, LLC*, IPR2017-00213, Paper 42, 25–26 (PTAB May 11, 2018) (affording expert testimony no weight for failure to comply with 37 C.F.R. § 42.65(b)); *Altair Pharm., Inc. v. Paragon Biotech, Inc.*, Paper 48, 16–17 (PTAB Nov. 14, 2016) (“Without the necessary information prescribed in §42.65(b), we cannot determine whether the evidence ... is credible.”). Therefore we decline to exclude Dr. Jensen’s for failure to comply with 37 C.F.R. § 42.65(b).

2. *Withheld Documents and Information*

Petitioner’s arguments with respect to this issue are the same as for Dr. Herbenick’s declaration discussed above. MTE 5–8. For the same reasons given above, we decline to exclude Dr. Jensen’s declaration.

3. *Patent Owner’s Alleged Misconduct*

Petitioner’s arguments with respect to this issue are the same as for Dr. Herbenick’s declaration discussed above. MTE 8–12.

We note that, with respect to Dr. Jensen’s deposition in this proceeding, Petitioner identified only one allegedly improper objection. MTE 11. A review of the testimony reveals that the questions relate to the issue of a pressure field generator, a term not in dispute in this proceeding. Ex. 1022, 74–75. We do not believe that a single alleged speaking objection about a term that is not in dispute warrants excluding Dr. Jensen’s declaration.

any evidence. “Attorneys’ argument is no substitute for evidence.” *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

4. Conclusion

Based on the foregoing we deny Petitioner's Motion to Exclude as it relates to Exhibit 2028.

C. Exhibit 2032

Petitioner contends that Exhibit 2032 should be excluded on the grounds of hearsay and lack of authenticity. MTE 12–14.

In reaching our decision we did not rely on Exhibit 2032. We therefore deny as moot Petitioner's motion with respect to Exhibit 2032.

D. Conclusion

For the reasons stated above, we deny Petitioner's Motion to Exclude in its entirety.

IV. CONCLUSION

Weighing the evidence of the disclosures of the references, the competing testimony, the reasoning to combine the references, and the evidence showing secondary indicia of non-obviousness, we determine that Petitioner has failed to show, by a preponderance of the evidence, that any of claims 1–30 of the '097 patent is unpatentable.

We also deny Petitioner's Motion to Exclude.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–30 of the '097 patent are not determined to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is denied; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–9, 12–24, 26–30	102	Taylor		1–9, 12–24, 26–30
1–30	103	Taylor, Hovland		1–30
1–30	103	Guan, Lee, Hovland		1–30
Overall Outcome				1–30

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