

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAGE PRODUCTS, LLC,
Petitioner,

v.

PUREWICK CORPORATION,
Patent Owner.

IPR2020-01426
Patent 8,287,508 B1

Before LYNNE H. BROWNE, KEVIN W. CHERRY, and
ERIC C. JESCHKE, *Administrative Patent Judges*.

CHERRY, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. BACKGROUND

Sage Products, LLC (“Petitioner”) filed a Petition for *inter partes* review of claims 1, 3–8, and 17–19 of U.S. Patent No. 8,287,508 B1 (Ex. 1001, “the ’508 patent”). Paper 1 (“Pet.”). PureWick Corporation (“Patent Owner”) filed a Preliminary Response. Paper 8.

On February 17, 2021, based on the record before us at the time, we instituted an *inter partes* review (Paper 10, “Dec.”) of claims 1, 3–8, and 17–19 of the ’508 patent on the following grounds (Pet. 2–3):

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1, 3–8, 17–19	102(b) ¹	Mahnensmith ²
4, 5, 19	103(a)	Mahnensmith, knowledge of one of ordinary skill in the art
1, 3–8, 17–19	102(b)	Keane ³
4, 5, 19	103(a)	Keane, knowledge of one of ordinary skill in the art
1, 3–8, 17–19	103(a)	Kuntz 166, ⁴ DesMarais, ⁵ knowledge of one of ordinary skill in the art
1, 3–8	102(b)	Kuntz EP355 ⁶
17–19	103(a)	Kuntz EP355, Mahnensmith, knowledge of one of ordinary skill in the art

¹ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. § 103. Because the ’508 patent has an effective filing date prior to the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of § 103.

² Mahnensmith, U.S. Pub. No. 2006/0015080 A1, published Jan. 19, 2006 (Ex. 1004, “Mahnensmith”).

³ Keane, U.S. Patent No. 3,349,768, issued Oct. 31, 1967 (Ex. 1005, “Keane”).

⁴ Kuntz, U.S. Patent No. 4,747,166, issued May 31, 1988 (Ex. 1006, “Kuntz 166”).

⁵ DesMarais, U.S. Patent No. 4,425,130, issued Jan. 10, 1984 (Ex. 1007, “DesMarais”).

⁶ Kuntz et al., European Patent Specification No. 0 613 355 B1, published Jan. 22, 1997 (Ex. 1008, “Kuntz EP355”).

Petitioner relies on the Declaration of Diane K. Newman, D.N.P., F.A.A.N. (Ex. 1002) in support of its unpatentability contentions.

Patent Owner filed a Response in opposition to the Petition (Paper 17, “PO Resp.”). Patent Owner supported its Patent Owner Response with the Declaration of Arrigo Jezzi (Ex. 2060). Petitioner filed a Reply in support of the Petition (Paper 20, “Reply”). Petitioner supported its Reply with the Second Declaration of Diane K. Newman, D.N.P., F.A.A.N. (Ex. 1017). Patent Owner filed a Sur-reply responding to the Reply (Paper 23, “Sur-Reply”).

Both parties requested an oral hearing. *See* Paper 26. A transcript of the oral hearing is entered in the record. Paper 29 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2020). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

B. REAL PARTIES IN INTEREST

Petitioner identifies Sage Products, LLC and Stryker Corporation as the real parties in interest for the Petition. Pet. 1. Patent Owner identifies PureWick Corporation, C.R. Bard, Inc., and Becton, Dickinson and Company as real parties in interest. Paper 6, 1 (Patent Owner’s Mandatory Notices).

C. RELATED PROCEEDINGS

The parties identified as a related proceeding the co-pending district court proceeding of *PureWick Corporation v. Sage Products LLC*, Case No. 1:19-cv-01508 (D. Del.). Pet. 1; Paper 6, 1.

D. THE '508 PATENT

The '508 patent, entitled “Using Moisture-Wicking Article Wrapped Over Openings In An Elongated Urine Collecting Container For Drawing Urine From A Region Surrounding An Urethral Opening,” is directed to “collecting and transporting urine away from the body of a person or an animal during various circumstances.” Ex. 1001, code (54), 1:10–12. The '508 patent describes its invention as particularly useful for circumstances that “include a condition such as incontinence or a disability that limits or impairs mobility,” “also include restricted travel conditions, such as sometimes experienced by pilots, drivers, workers in hazardous areas, etc.,” and “further include collection of urine for monitored purposes or clinical testing.” *Id.* at 2:46–53.

Figure 1 (reproduced below) shows an “embodiment of a urine collection device according to the present invention, with some of the container having been cut away to expose a portion of the chamber and the entry into the outlet port from the chamber.” *Id.* at 2:59–62.

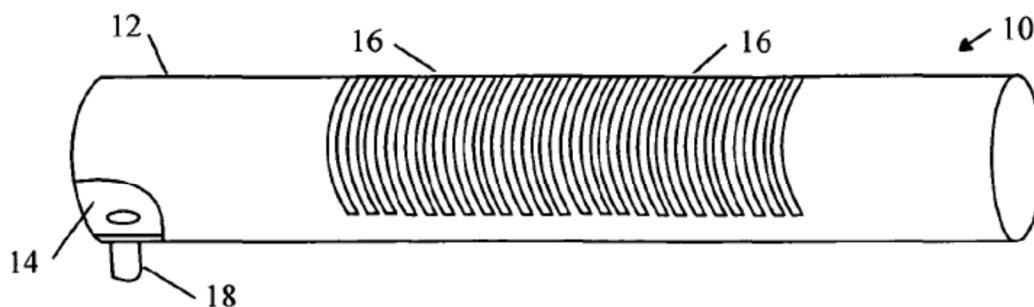


FIG. 1

Figure 1 of the '508 patent depicts a urine collection device. *Id.* at Fig. 1.

Figure 1's urine collection device 10 "includes a container 12, which defines a chamber 14 for collecting urine." *Id.* at 3:24–25. According to the '508 patent, "[t]he container 12 is closed, except for having an array of openings 16 through which urine can be drawn into the chamber 14 and at least one outlet port 18 through which urine can be drawn away from the chamber 14." *Id.* at 3:25–29.

The '508 patent describes that "[t]he exterior of the container 12 is configured for enabling a moisture-wicking article 20 to be secured over the array of openings 16 and for enabling the secured moisture-wicking article 20 to be disposed in contact with the region of a female body surrounding the urethral opening." *Id.* at 3:45–49. Figure 2 of the '508 patent is reproduced below.

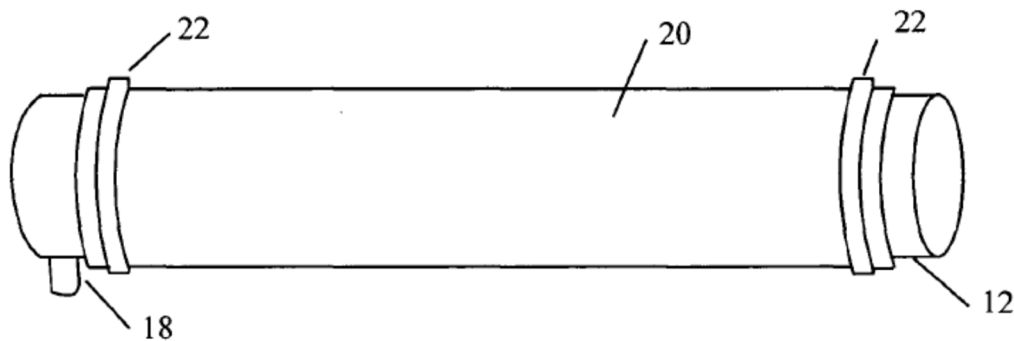


FIG. 2

Figure 2 of the '508 patent depicts a moisture-wicking article over a urine collection device. *Id.* at 2:63–65, Fig. 2.

The '508 patent explains that "the container 12 is configured for enabling the moisture-wicking article 20 to be secured over the array of openings 16 by applying elastic bands 22 about the moisture-wicking article 20 at positions that are adjacent opposite ends of the array of openings 16, as shown in FIG. 2." *Id.* at 3:59–64. The '508 patent describes other means for enabling a moisture-wicking article to be secured over a

container's array of openings, such as "spring clips, with water-resistant adhesive tape, Velcro fasteners, zippers, and snaps." *Id.* at 4:1–7. The '508 patent also describes a moisture-wicking article that "is in the form of a sock or sleeve that slips snugly over the container." *Id.* at 4:7–9.

The '508 patent discloses that the moisture-wicking article 20 can "include[] a rapidly permeable material such as gauze, felt, terrycloth, thick tissue paper, paper towel, etc." *Id.* at 4:10–12. The '508 patent also discloses that the urine collection device and moisture-wicking material may be "integrated in a unitary composite structure," such as by providing "a moisture-wicking felt layer [that] is bonded onto the surface of the container over the array of openings in the container" or using "a fritted wall of a porous glass container" to provide the moisture-wicking function. *Id.* at 6:32–40.

With regard to placement of the moisture-wicking article, the '508 patent states:

The urine collection device 10 having the secured moisture-wicking article 20 secured thereto is then disposed so that the secured moisture-wicking article 20 is in contact with the region of the body surrounding the urethral opening. For a female, the secured moisture-wicking article 20 is placed between the legs and held snugly against the external urethra by the pressure of the legs or by such means as an undergarment, elastic strips and/or adhesive tape. For a male, the secured moisture-wicking article is secured around the penis.

Id. at 5:10–19.

Figure 3 of the '508 patent (reproduced below) "is a block diagram showing the use of a urine collection device according to the present invention in one embodiment of a system for collecting and transporting urine away from the body of a person or an animal." *Id.* at 2:66–3:2.

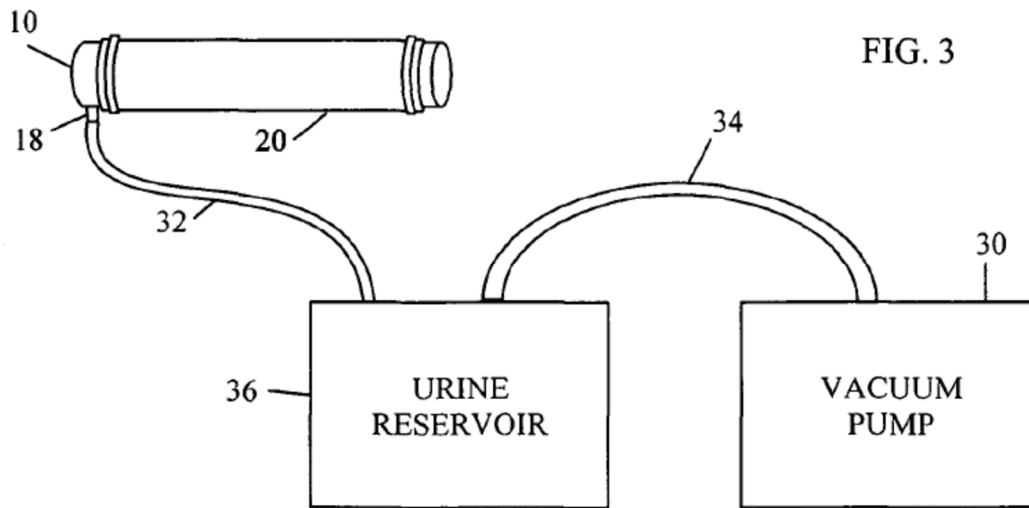


Figure 3 of the '508 patent depicts the use of a system including a urine collection device. *Id.* at Fig. 3.

Figure 3's system "includes a urine collection device 10, a moisture-wicking article 20, a vacuum pump 30, a first flexible tube 32, a second flexible tube 34 and a urine reservoir 36." *Id.* at 4:29–34. The '508 describes:

The vacuum pump 30 is adapted for applying a partial vacuum to the outlet port 18 of the urine collection device 10 via the second flexible tube 34, the urine reservoir 36 and the first flexible tube 32 to thereby cause urine collected in the moisture-wicking article 20 to be drawn through the array of openings 16 in the urine collection device 10 and into the chamber 14 of the urine collection device 10, and thence to be drawn away from the chamber 14 through the outlet port 18 and the first flexible tube 32 and into the urine reservoir 36.

Id. at 4:41–50.

Of the challenged claims, claims 1 and 17 are independent. Claims 3–8, 18, and 19 depend directly or indirectly from claim 1 or claim 17.

Claim 1 is illustrative and is reproduced below:

1. A urine collection device for use in a system for transporting urine voided from a person or an animal by drawing the urine into a moisture-wicking article that is disposed in

contact with a region of the person or animal surrounding an urethral opening, and further drawing the urine into the collection device from the moisture-wicking article, comprising:

a container defining a chamber for collecting urine,

wherein the container is closed, except for having an array of openings through which urine can be drawn into the chamber and at least one outlet port through which urine can be drawn away from the chamber; and

wherein an elongated exterior of the container is configured and dimensioned for enabling a moisture-wicking article to be secured over the array of openings of the container by wrapping the article over the array and securing the wrapped article, and for enabling said secured moisture-wicking article to be disposed in contact with the region of a female body surrounding the urethral opening.

Ex. 1001, 6:59–7:10.

II. ANALYSIS

A. CLAIM INTERPRETATION

We interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b), “including construing 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.” 37 C.F.R. § 42.100(b). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we give claim terms their ordinary and customary meaning as they would be understood by an ordinarily skilled artisan. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (“The ordinary and customary meaning ‘is the meaning that the term would have to a person of ordinary skill in the art in question.’” (quoting *Phillips v. AWH*

Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005))). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Petitioner argues the language “the moisture-wicking characteristic of a paper towel” of claims 4, 5, and 19 should be construed as “includ[ing] materials that can transport fluid via capillary action.” Pet. 14–15 (citing Ex. 1002 ¶¶ 81–83) (emphasis omitted).

Petitioner also asserts that the language “dimensioned for being secured over the array of openings by the application of elastic bands about the moisture-wicking article at opposite ends of the array of openings” of claim 18 should be construed as “dimensioned so that it is capable of being secured over the openings with elastic bands about the article at opposite ends of the openings.” *Id.* at 15 (citing Ex. 1002 ¶¶ 85–86) (emphasis omitted).

In its Response, Patent Owner proposed constructions for “moisture-wicking article” and “secured over the array of openings.” PO Resp. 10–18.

We discern no terms in need of express interpretation. Accordingly, we apply the legal standards set forth above when reading the claims.

B. THE PARTIES’ POST-INSTITUTION ARGUMENTS

In our Institution Decision, we concluded that the argument and evidence adduced by Petitioner demonstrated a reasonable likelihood that at least one challenged claim was unpatentable. Dec. 37. We must now determine whether Petitioner has established by a preponderance of the evidence that the challenged claims are unpatentable over the cited prior art.

35 U.S.C. § 316(e). “In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burdens of proof in *inter partes* review).

We previously instructed Patent Owner that “any arguments not raised in the [Patent Owner Response] may be deemed waived.” Paper 11, 8; *see also In re NuVasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (holding that patent owner’s failure to proffer argument at trial as instructed in scheduling order constitutes waiver). Additionally, the Board’s Trial Practice Guide states that the Patent Owner Response “should identify all the involved claims that are believed to be patentable and state the basis for that belief.” Consolidated TPG⁷ at 66.

C. LEGAL STANDARDS

Petitioner raises three grounds of unpatentability based on anticipation under 35 U.S.C. § 102(b). Dec. 8. Petitioner also raises four groups of unpatentability grounds based on obviousness. *Id.*

⁷ Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019), <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). To establish anticipation, “all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim.” *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001).

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) when in evidence, considering objective evidence indicating obviousness or nonobviousness.⁸ *KSR*, 550 U.S. at 406 (citing *Graham*, 383 U.S. at 17–18). In an *inter partes* review, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable. An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences

⁸ Patent Owner provides no objective evidence indicating nonobviousness. See PO Resp.

and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *accord Translogic*, 504 F.3d at 1259. Petitioner also must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *NuVasive*, 842 F.3d at 1382.

D. LEVEL OF ORDINARY SKILL

Petitioner contends that “a POSITA would be a clinical practitioner with an advanced medical degree, or an individual having a bachelor’s degree in engineering, knowledgeable in the field of normal micturition (voiding) and with experience in the field of urine management and incontinence care including devices for urine collection and management.” Pet. 14 (citing Ex. 1002 ¶ 23). Patent Owner argues that a POSITA “would have had a bachelor’s degree in engineering (e.g., chemical or material sciences), or an advanced medical degree, and at least 1–2 years of experience in designing products related to the biomedical application of material and chemical sciences.” PO Resp. 8 (citing Ex. 2060 ¶ 8).

We agree with Petitioner that the ’508 patent does not involve advances in “material or chemical sciences”; rather, it describes a vacuum urine collector using “moisture-wicking article,” which the patent describes as including paper towel, gauze, felt, and similar materials, secured over a perforated container using, e.g., elastic bands, clips, and snaps. Ex. 1001, Abstract, 4:1–15; Ex. 1017 ¶ 5. The ’508 patent does not focus on “principles of adhesion and cohesion” and “hydrophobic and hydrophilic materials,” as Patent Owner alleges. *See* PO Resp. 9–10. Instead, we agree with Petitioner that knowledge of urine collection devices is what is

necessary, rather than the more generalized field of “biomedical application of material and chemical sciences.” Ex. 1017 ¶¶ 5–7.

Accordingly, for purposes of this Decision, we adopt Petitioner’s proposed level of ordinary skill as it appears to be consistent with the level of skill reflected in the Specification and in the asserted prior art references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art). We note, however, that we reach the same decision under either definition of a person of ordinary skill in the art.

E. OVERVIEW OF THE PRIOR ART

1. Mahnensmith

Mahnensmith is a patent publication entitled “Fluid Collection And Aspiration Unit For Management Of Urinary Incontinence” and “relates to thin layer aspiration or perfusion units for collecting vapors or liquids and transferring such fluids to a receiving area.” Ex. 1004, code (54), ¶ 1. More specifically, Mahnensmith states its “invention comprises an aspiration unit for collecting and facilitating management of urinary excretions by individuals that are incontinent.” *Id.* ¶ 1.

Mahnensmith’s Figure 1 is reproduced below.

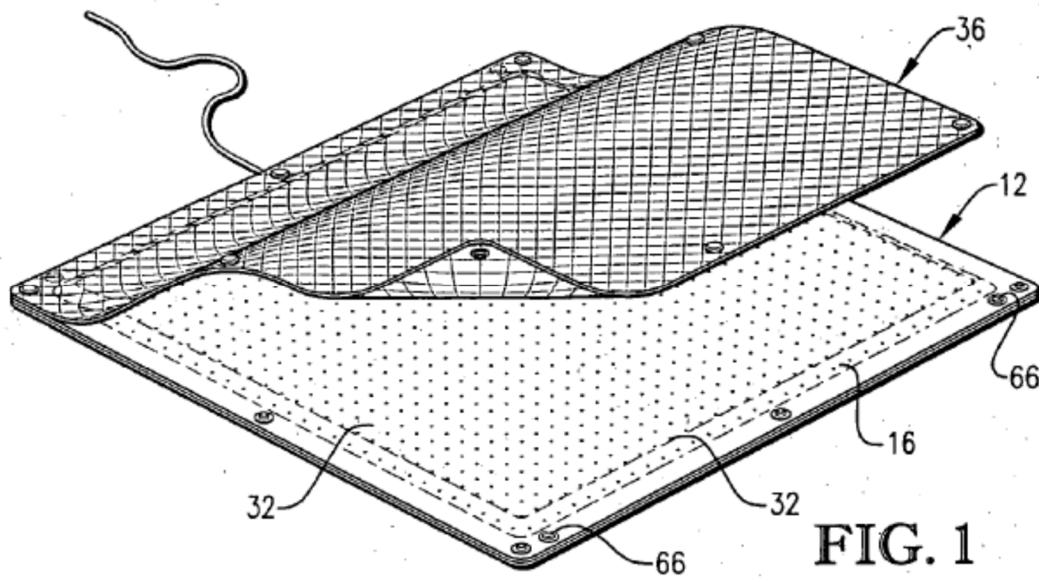


Figure 1 shows a thin layer vapor or liquid collection and aspiration unit for management of urinary incontinence. *Id.* ¶ 12.

Figure 1's unit 10 includes a flexible pad 12 having an outer liquid impermeable layer 14 and a liquid permeable layer 16 "in overlying relationship to layer 14." *Id.* ¶ 17.

Mahnensmith's Figure 2 depicting pad 12 is reproduced below.

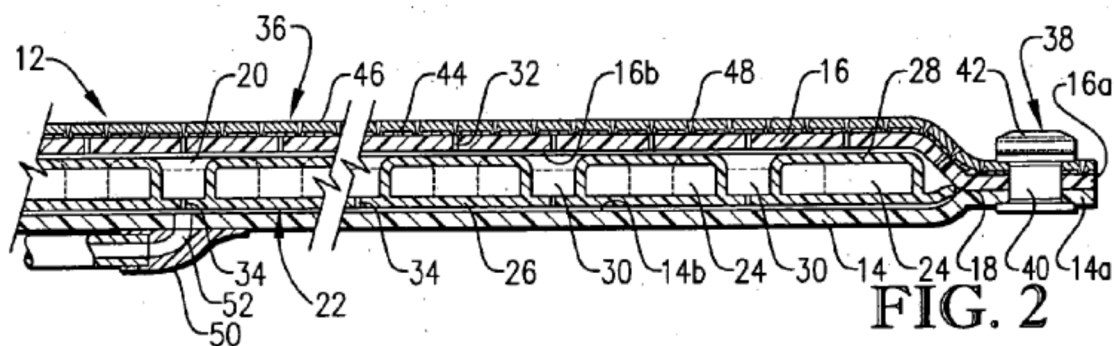


Figure 2 is a cross-sectional view of Figure 1. *Id.* ¶ 13.

Mahnensmith discloses that "[t]he peripheral margins 14a of layer 14 and 16a of layer 16 of layers 14 and 16 are joined by a liquid tight heat seal 18" and "[t]he innermost face 14b of layer 14 and the innermost face 16b of

layer 16 within the confines of the heat seal 18 joining layers 14 and 16 define an interior space 20.” *Id.* ¶ 17. Mahnensmith describes an intermediate cellular layer 22 within interior space 20 between the innermost faces 14b and 16b that includes “a series of individual, thin wall, liquid impermeable polymeric cells 24, which contain an entrapped fluid, such as air, and that are integral with a polymeric base sheet 26.” *Id.* ¶ 18.

Mahnensmith describes a porous sheet member 36 that “overlays the outermost face of permeable layer 16 and is releasably secured to pad 12 by a series of snap fasteners 38.” *Id.* ¶ 21. According to Mahnensmith, “[t]he resilient porous sheet member 36 desirably is of disposable material with Proctor & Gamble’s DryWeave® material being preferred because of its liquid wicking characteristics.” *Id.* ¶ 22.

Mahnensmith’s Figure 3 is reproduced below.

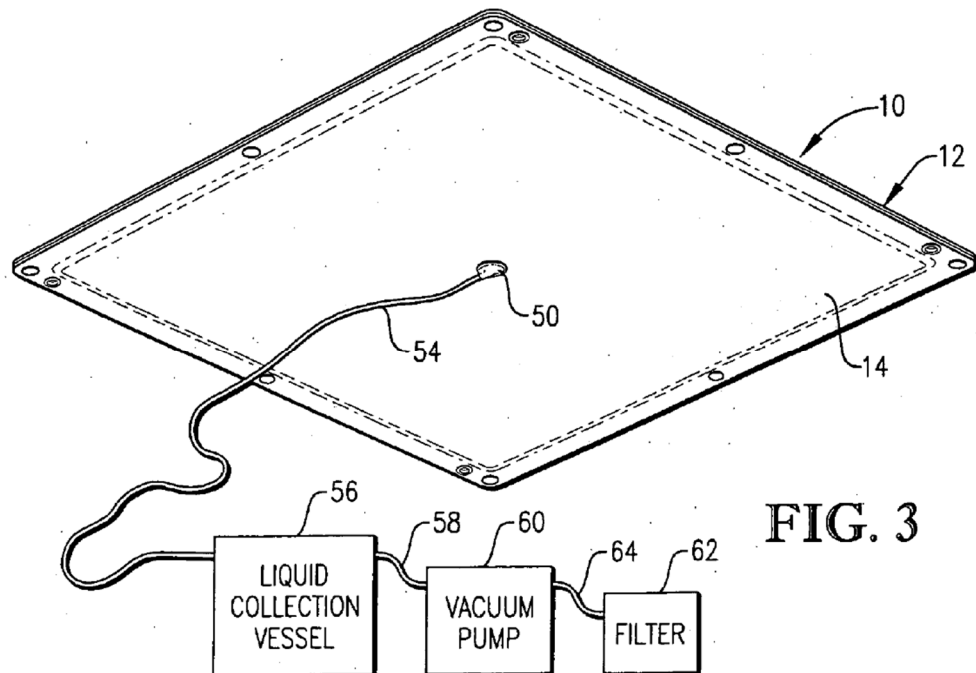


Figure 3 is a bottom view of a pad and aspiration assembly.
Id. ¶ 14.

Mahnensmith describes a fitting 50 that is heat-sealed to an outer face of the liquid impermeable layer 14, which has an L-shaped passage 52 (shown in Figure 2) communicating with the interior space 20. *Id.* ¶ 23. An elongated flexible conduit 54 is affixed to fitting 50 and leads to a liquid collection vessel 56. *Id.* A tubular line 58 in turn connects the interior of the liquid collection vessel 56 with an input port of a differential pressure device, such as a vacuum pump 60, which may be connected to a filter unit 62 via line 64. *Id.*

Mahnensmith discloses that “[i]n use, the pad 12 of unit 10 is placed beneath the patient on the surface of a bed or a chair or wheelchair seat, and preferably affixed in a desirable position with suitable fasteners such as bungee cords using the openings of grommet 66 for that purpose.” *Id.* ¶ 25.

Mahnensmith discloses another embodiment for a pad that can be worn by an ambulatory patient under their undergarment. *Id.* ¶ 30. Mahnensmith explains that this embodiment—pad 112—“is of construction similar to pad 12 except for its overall size and the manner of attachment of the porous sheet member 136 to the permeable layer 116 of pad 112.” *Id.* The operation and use of pad 112 is the same as described with respect to pad 12. *Id.* ¶ 31. Figure 4 depicting pad 112 is reproduced below.

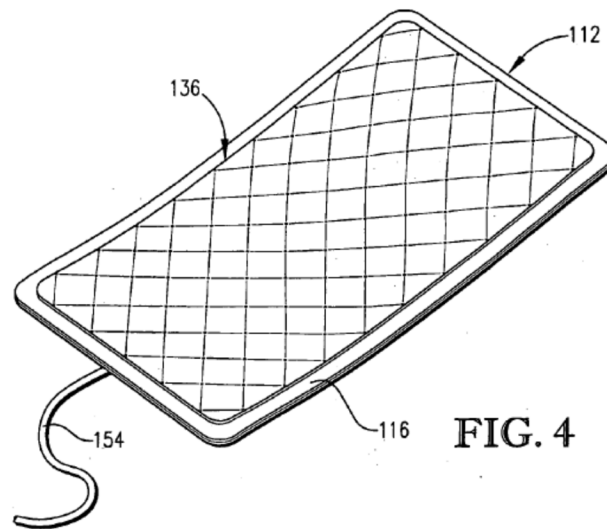


Figure 4 shows a smaller pad embodiment. *Id.* ¶ 15.

Figure 5 of Mahnensmith depicting pad 112 is reproduced below.

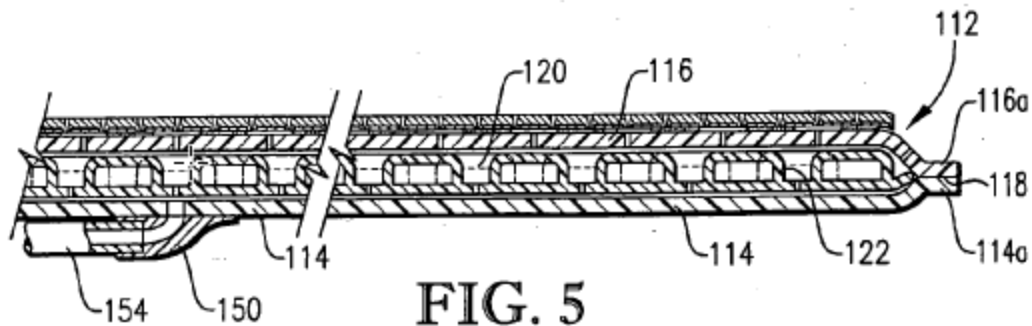


Figure 5 is a fragmentary enlarged vertical cross-sectional view of the pad as shown in Figure 4. *Id.* ¶ 16.

Mahnensmith's pad 112 includes a porous sheet member 136 that “may be removably affixed to the outermost face of permeable layer 116 by use of double-stick tape located around the perimeter of the porous sheet member 136, and at least at the corners of the sheet member 136.” *Id.* ¶ 30.

2. Keane

Keane is a patent entitled “Portable Urinal Provided With Suction Means For Use In Micturition,” which “relates to portable apparatus for use

in micturition, and more particularly to an apparatus adapted for collecting and conveying urine and other discharges from the region of the external genitalia.” Ex. 1005 at 1:3–4, 1:20–23.

Keane’s Figure 1 is reproduced below.

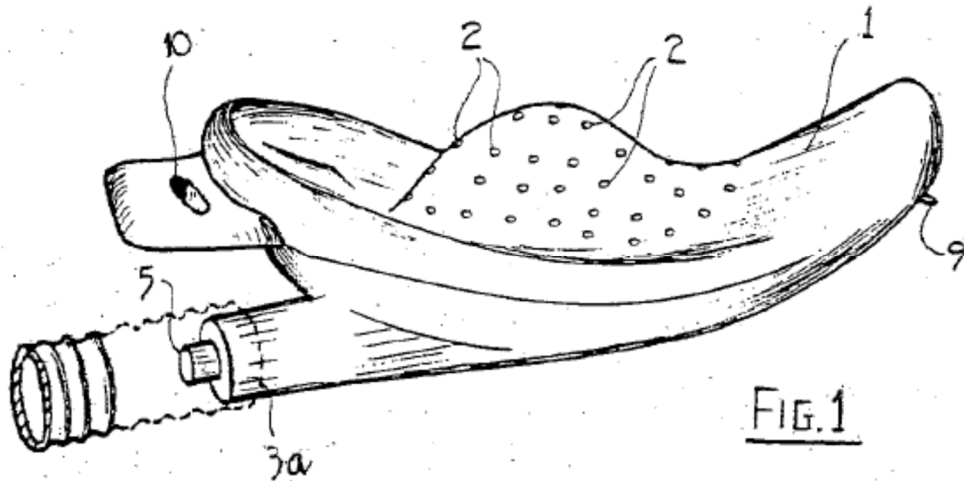


Figure 1 depicts an embodiment of the apparatus for female use.
Id. at 1:46–47.

Figure 1 shows an apparatus including “a suction head 1 being shaped as a modified cast of the external female genitalia.” *Id.* at 1:66–68. Keane explains that the suction head 1 “is made of a semi-rigid, non-irritant material, such as rubber, thermoplastic or the like.” *Id.* at 1:68–70. Keane states:

The suction head 1 is provided with a plurality of ducts 2 constituting inlet means from the surface of the suction head 1, which is in contacting apposition to the external genital organs (the vestibule of the vagina, the vaginal opening, the vestibular fossa, the posterior commissure, and the medial surfaces of the labia), to a central cavity 3 in communication with an outlet 3a at the anterior end of the suction head.

Id. at 1:70–2:5.

Keane's Figure 2 is reproduced below.

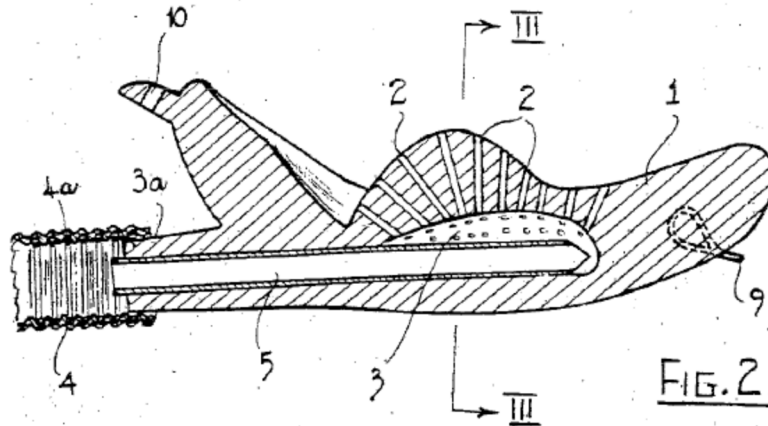


Figure 2 is a sectional view of Figure 1. *Id.* at 1:48–49.

An end of non-collapsible, flexible tubing 4 is connected to the outlet 3a and the tubing 4 leads to a urine container that “is subjected to a gentle partial vacuum by means of a suitable suction pump.” *Id.* at 2:5–10. A suction tube 5 also extends from outlet 3a into the cavity 3. *Id.* at 2:18–19. Keane discloses that “in use, any urine passed will drain through the ducts 2 towards the posterior end of the cavity 3 . . . and direct application of the vacuum through the tube 5 to the posterior end of the cavity 3 will serve to discharge any urine accumulating there quickly.” *Id.* at 2:23–30.

Keane's Figure 4 is reproduced below.

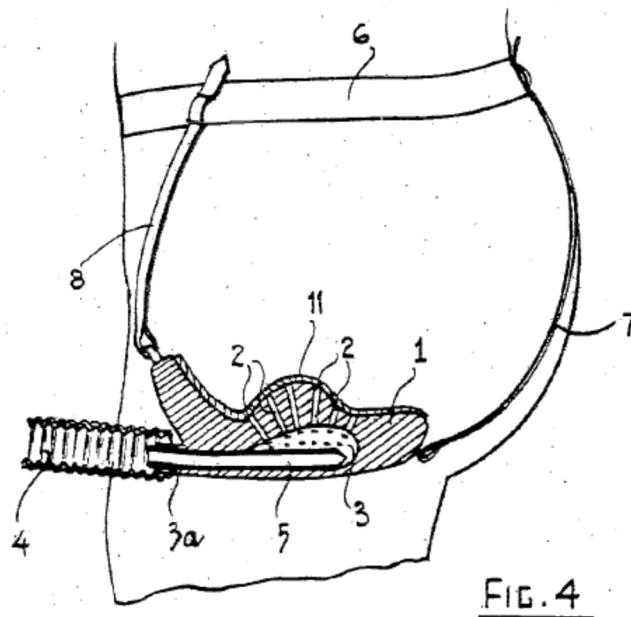


Figure 4 shows the apparatus in use. *Id.* at 1:52–53.

Keane discloses that “[t]he suction head 1 is held and maintained in position not only by virtue of its shape and the vacuum applied to its internal surface but also by means of a posterior elastic strap 7 and two anterior elastic straps 8 adjustably anchored to a waistbelt 6.” *Id.* at 2:34–38. Keane further discloses that “[i]f desired, a layer 11 (see FIG. 4) of absorbent open-cell porous material, such as foam plastic, may be interposed between the innermost contacting surface of the suction head 1 and the external genitalia to maintain uniformity of discharge and to assist prevention of leakage.” *Id.* at 2:47–51. Keane states that the layer 11 “will also serve to support the tissues of the genitalia and prevent them from being sucked into the openings of the ducts 2.” *Id.* at 2:52–55.

3. Kuntz 166

Kuntz 166 is a patent entitled “Fluid Aspiration System For The Management Of Urinary Incontinence,” which “relates to urine collection

and disposal systems, and more particularly, to such systems intended for use by and for incontinent patients.” Ex. 1006, code (54), 1:6–8.

Kuntz 166’s Figure 1 is reproduced below.

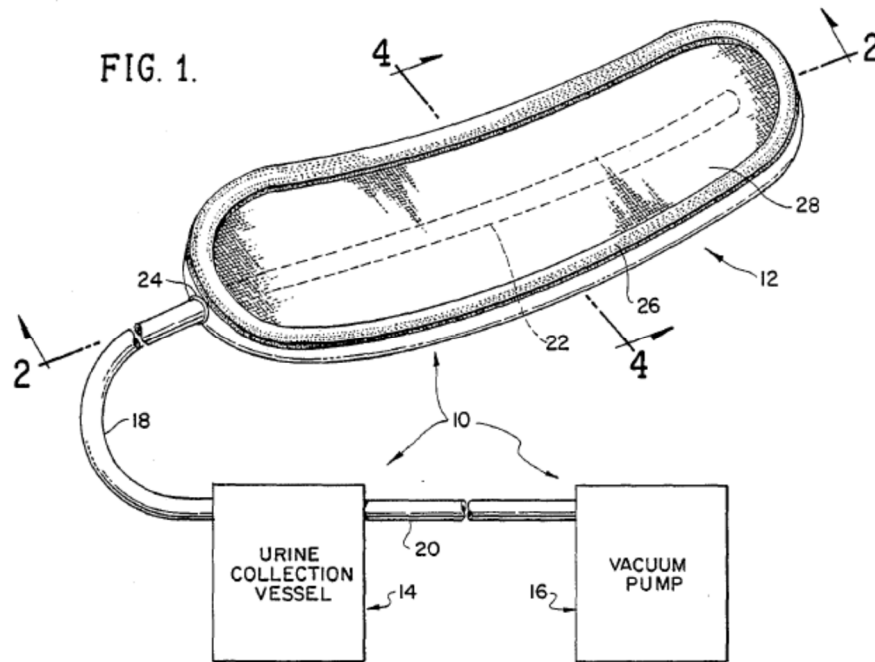


Figure 1 depicts a urine aspiration system. *Id.* at 3:14–16.

Figure 1’s fluid aspiration system 10 includes an absorbent pad 12, a urine collection vessel 14, and a vacuum source 16. *Id.* at 3:35–39. Kuntz 166 discloses vacuum tubing 18 to couple the pad 12 to the urine collection vessel 14 and tubing 20 extending from the urine collection vessel 14 to the vacuum source 16. *Id.* at 3:40–42. The pad 12 includes a central bore 22 extending along a longitudinal direction of the pad 12 from a tubing connector 24 to which the tube 18 is coupled. Kuntz 166 also describes “a peripheral cushioning ring 26 extending about the edge of the upper facing layer 28 of the pad” that “is intended to make direct contact with the patient’s body surrounding the urethral opening and facilitates the

positioning of the pad to the body surface so that all urine that is expelled by the patient is passed into and absorbed by the pad.” *Id.* at 3:48–52.

Kuntz 166’s Figure 2 is reproduced below.

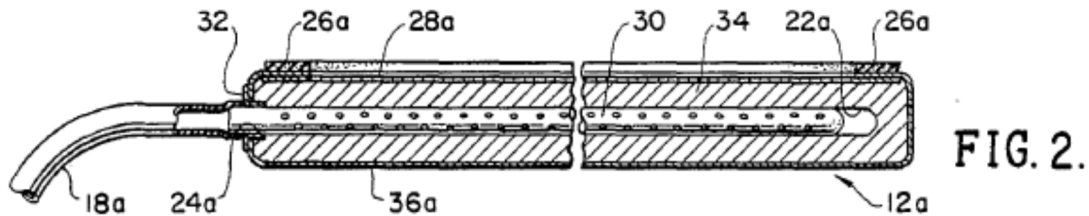


Figure 2 is a cross-sectional view of a pad. *Id.* at 3:17–19.

Kuntz 166 states that a “tube 18a is provided with an extended perforated end portion 30 which may be inserted within pad 12a to occupy substantially the entire extent of the hollow bore 22a of such pad.” *Id.* at 3:61–64. Kuntz 166 also discloses that a “pad 12a is comprised of a core 34 of urine absorptive material encased by an upper facing layer 28a and a lower backing layer 36a.” *Id.* at 4:9–11. Kuntz 166 describes the absorptive material as “highly absorbent cellulose tissue.” *Id.* at 2:48–51. Kuntz 166 also discloses an embodiment in which a core of the pad includes “a sponge formed of expanded cellulose microcellular material fabricated with an open cell construction.” *Id.* at 2:62–65. Kuntz 166 further states, “[i]n any event, the pad constitutes a manifold of capillary cells to which selective aspiration is applied when the pad is coupled to the urine receptacle and vacuum source of the overall system.” *Id.* at 2:65–68. In addition, Kuntz discloses that “[t]he pad 12 is positioned in place on a patient to surround the urethral opening” and “[i]t may be held in place by conventional means, such as adhesive, a sanitary belt, a panty garment or the like.” *Id.* at 5:62–65.

Kuntz 166's Figure 8 is reproduced below.

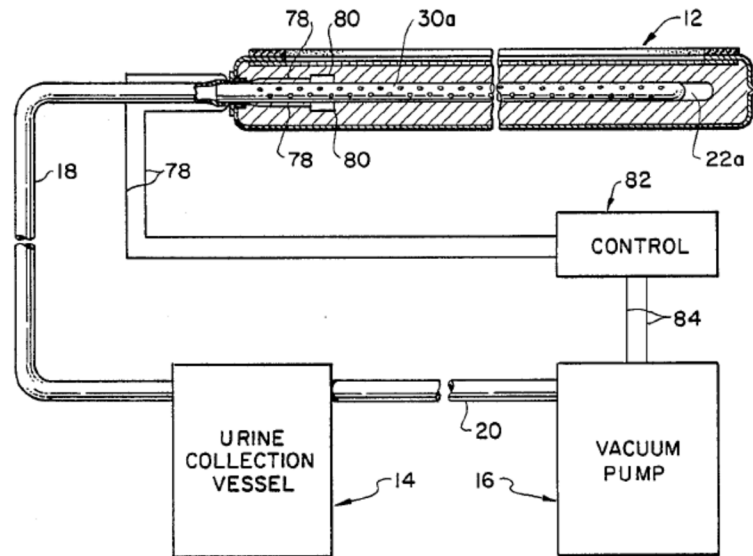


FIG. 8.

Figure 8 is a cross-sectional view of a pad. *Id.* at 3:29–31.

Kuntz 166 further discloses a fluid aspiration system that includes “a urine sensor and a control for the drive motor of the vacuum pump 16.” *Id.* at 6:44–47. Specifically, tube end portion 30a “is provided with a pair of leads 78 terminating in probe electrodes 80.” *Id.* at 6:49–51. Kuntz 166 discloses:

The leads 78 extend outside of the pad 12 to a control box 82 which is coupled via electrical leads 84 to control the actuation of the motor associated with the vacuum pump 16. When the pad 12 is devoid of urine, the vacuum pump 16 is not activated. However, when urine reaches the chamber (bore) 22a, its presence is sensed by the probe electrodes 80 which provide a signal to the control box 82, causing it to activate the motor associated with the vacuum pump 16 so that the pump begins operation to draw the urine out of the pad 12.

Id. at 6:51–61.

4. DesMarais

DesMarais is a patent entitled “Compound Sanitary Napkin,” which “concerns sanitary napkins” that “are considered to be absorbent devices designed to be worn externally of the body by women, usually during their menstrual periods, and to receive and contain menses and other vaginal discharges.” Ex. 1007, code (54), 1:7–11.

DesMarais’s Figure 1 is reproduced below.

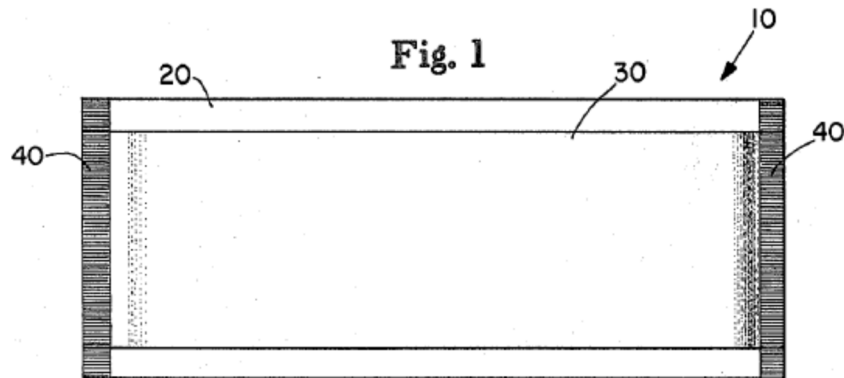


Figure 1 depicts a sanitary napkin. *Id.* at 2:34–35.

DesMarais’s sanitary napkin 10 includes a “primary menstrual pad 30, panty protector 20, and union means having limited extent 40.” *Id.* at 2:65–3:2.

DesMarais’s Figure 3 is reproduced below.

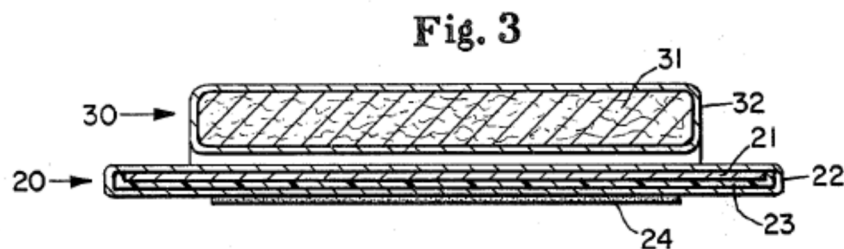


Figure 3 depicts a urine aspiration system. *Id.* at 3:14–16.

DesMarais describes a pad overwrap 32 that “can be any fluid permeable material commonly used as an overwrap in sanitary napkins or as a topsheet in disposable diapers.” *Id.* at 4:66–5:2. DesMarais further discloses that “[u]seful materials include carded, spun-bonded, melt blown web, air-laid webs, and other non-woven webs of natural or synthetic fibers.” *Id.* at 5:2–5. DesMarais states that a panty protector may be an “absorbent element comprised two sheets of a commercially available two-ply tissue paper towel product having a basis weight of approximately 26 grams per square meter so sold [sic] under the Bounty trademark by Procter & Gamble of Cincinnati, Ohio.” *Id.* at 10:60–65.

5. *Kuntz EP355*

Kuntz EP355 is a European patent specification entitled “Improved Pad And Pad Tube Connector For The Management Of Urinary Incontinence,” which “relates to absorptive aspiratable pads for use in urine collection and disposal systems and, more particularly, to an improved pad which is more efficient in the urine collection and disposal task.” Ex. 1008, code (54), 1:3–7.

Kuntz EP355's Figure 1 is reproduced below.

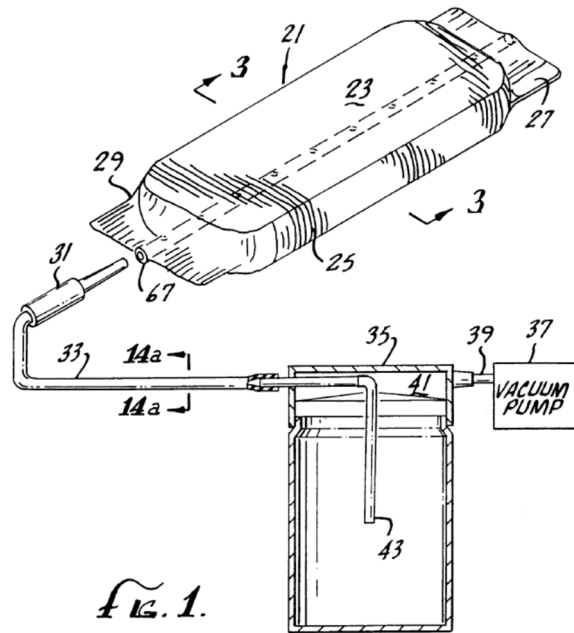


Figure 1 shows an aspiration system using an absorbent pad. *Id.* at 3:5–11.

Kuntz EP355 describes a generally rectangular absorptive pad 21 that “is intended to make direct contact with a patient’s body surrounding the urethral opening, and is easily positionable against the patient, especially between the patient’s body and garments.” *Id.* at 4:7–15. Kuntz EP355 discloses:

The exterior of the absorptive pad 21 is covered with an essentially non-wetting permeable material 25, which envelops the absorptive pad 21, along its length and is sealed at one end 27, hereafter referred to the closed end 27, and may be partially or totally closed at the other end 29, hereafter referred to as the tube end 29, resulting in the contents of the absorptive pad 21 being sealably surrounded by the essentially non-wetting permeable material 25.

Id. at 4:18–26.

Kuntz discloses an improved connector 31 that couples a tube 33 to a tube end 29 of the absorptive pad 21. *Id.* at 4:27–28. The tube 33 is also connected to a urine collection vessel 35, which is connected to a vacuum pump 37 via a tube 39. *Id.* at 4:28–32. Kuntz states:

Urine collection vessel 35 is configured to permit tube 39 to draw air from a space 41 at the upper portion of urine collection vessel 35, creating a reduced pressure, and causing delivery of a mixture of urine and air through tube 33, and through a downcomer tube 43 directed into the urine collection vessel 35.

Id. at 4:34–40.

Kuntz EP355's Figure 2 is reproduced below.

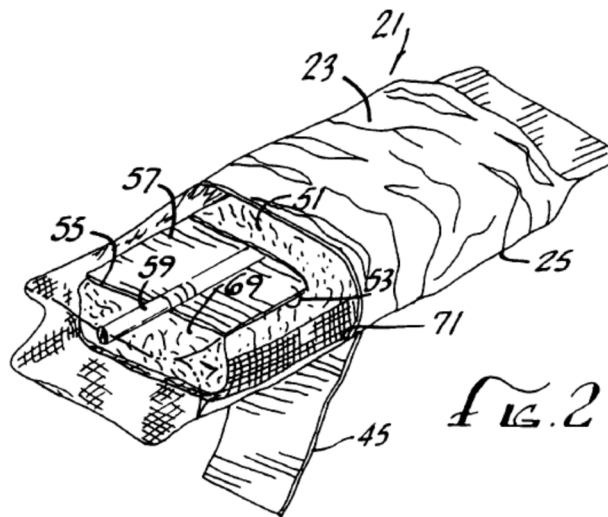


Figure 2 is a cutaway view of Figure 1's pad. *Id.* at 3:13–14.

Kuntz EP355 discloses:

At the bottom of pad 21 is an adhesive layer having a plastic or other non-sticking tear-away strip 45 which may be removed to expose the adhesive layer. The adhesive layer, to be shown later, is attached to the outer permeable non-wetting layer 25 and facilitates the fixation of the pad 21 to the inner surfaces of the user's garments, diaper or covering, when the pad 21 is utilized and held in place with a garment, diaper or covering. At the outer

periphery, the permeable non-wetting layer 25 is illustrated as surrounding all of the layers in absorbent pad 21. At the top 23 of the absorbent pad 21, and adjacent and inward of the permeable non-wetting layer 25, is a highly absorbent inner layer 51 which extends continuously enclosing an inner volume of the absorbent pad 21, and within the boundary of the permeable non-wetting layer 25.

Id. at 4:42–58. Kuntz EP355 further describes a wick tube assembly 53 including “a first layer of wicking material 55 and at least a second layer of wicking material 57 sandwiching a tube 59.” *Id.* at 5:3–5. Kuntz EP355 states that wicking materials 55, 57 are “planar, porous sheets of material,” “have a paper towel like consistency,” and “must be absorbent enough to attract liquid and transmit liquids through wicking action, but not retentive of liquid in a manner which would inhibit wicking.” *Id.* at 5:7–15.

Kuntz EP355’s Figure 3 is reproduced below.

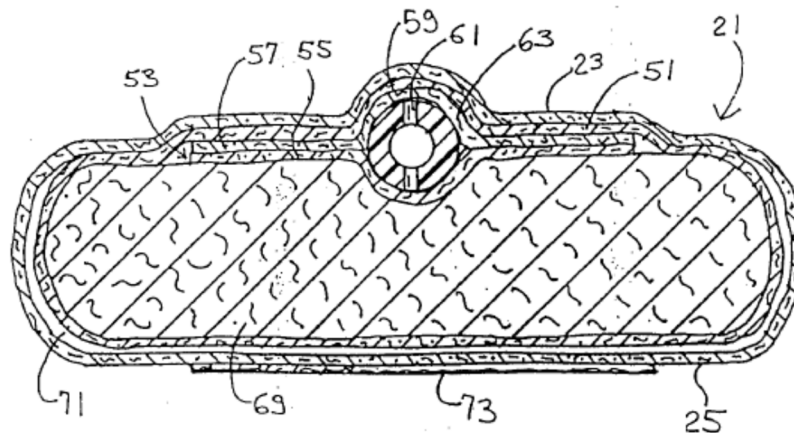


FIG. 3

Figure 3 is a cross-section of Figure 1’s pad along line 3–3. *Id.* at 2:34–35.

Kuntz EP355 describes tube 59 as perforated and includes upper apertures 61 and lower apertures 63 along its length within the pad 21. *Id.* at

5:5–6, 5:40–48. Kuntz EP355 further discloses a bulk absorbent material 69 underneath the wick tube assembly and adjacent the highly absorbent inner layer 51. *Id.* at 6:15–17. Kuntz EP355 describes the bulk absorbent material 69 as a material having “rapid absorption and release of urine, and acts as a temporary reservoir for increasing holding capacity.” *Id.* at 6:17–21. Kuntz EP355’s pad 21 further includes an impermeable lower liner 71 to prevent wetting of a patient’s garments or bedding. *Id.* at 6:30–34.

F. ANTICIPATION BY MAHNENSMITH: CLAIMS 1, 3–8, AND 17–19

Petitioner argues that Mahnensmith anticipates claims 1, 3–8, and 17–19. Pet. 16–26.

1. *Claim 1*

a. Petitioner’s Contentions

Petitioner submits that Mahnensmith discloses the following claim limitations of claim 1 of the ’508 patent:

urine collection device for use in a system for transporting urine voided from a person or an animal by drawing the urine into a moisture-wicking article that is disposed in contact with a region of the person or animal surrounding an urethral opening, and further drawing the urine into the collection device from the moisture-wicking article, comprising,

Pet. 18–19 (citing Ex. 1004, Abstract Fig. 1–5, ¶¶ 1, 22, 25, 30, 31; Ex. 1002 ¶¶ 131–133, 137, 138, 142, 144); “a container defining a chamber for collecting urine,” Pet. 19–20 (citing Ex. 1004 ¶¶ 8, 11, 17, 25, claim 1 Fig. 1–4; Ex. 1002 ¶¶ 134, 144); “wherein the container is closed, except for having an array of openings through which urine can be drawn into the chamber and at least one outlet port through which urine can be drawn away from the chamber,” Pet. 20–21 (citing Ex. 1004 ¶¶ 8, 20, 23, 25, 30, 31

Fig. 1, 3; Ex. 1002 ¶¶ 135–136, 144); “wherein an elongated exterior of the container is configured and dimensioned for enabling a moisture-wicking article to be secured over the array of openings of the container by wrapping the article over the array and securing the wrapped article,” Pet. 21–22 (citing Ex. 1004, Figs. 1, 2, 4, 5, ¶¶ 9, 21, 30, claims 7, 20; Ex. 1002 ¶¶ 137–141, 144); and “for enabling said secured moisture-wicking article to be disposed in contact with the region of a female body surrounding the urethral opening,” Pet. 22 (citing Ex. 1004, 24, 25, 30, 32; Ex. 1002 ¶¶ 142, 144).

b. Patent Owner’s Arguments

Patent Owner notes that there are two embodiments disclosed in Mahnensmith—pad 12 and pad 112. PO Resp. 41–43. Patent Owner raises several arguments against Pad 12, including that it is not elongated, and it is not “configured and dimensioned . . . for enabling said secured moisture-wicking article to be disposed in contact with . . . the region of a female body surrounding the urethral opening.” PO Resp. 43–46 (pad 12 elongated), 46–47 (no “configured and dimensioned” for pad 12 generally), 48–49 (no “region of a female body . . .” for pad 12), 49–52 (for the specific function of “for enabling said secured moisture-wicking article to be disposed in contact with . . . the region of a female body surrounding the urethral opening” for pad 12). Patent Owner also argues that neither pad 12 nor pad 112 meet the “region of a female body surrounding the urethral opening” limitation. *See id.* at 48–49 (pad 12), 60–63 (pad 112). As for pad 112, Patent Owner argues that “porous sheet member 136” is not “over the array” of openings, that it is not “configured and dimensioned” for “enabling contact with the region of a female body surrounding the urethral

opening,” and that it lacks an “elongated exterior . . . configured and dimensioned for . . . wrapping the article over the array.” *Id.* at 53–65. We consider each argument in turn.

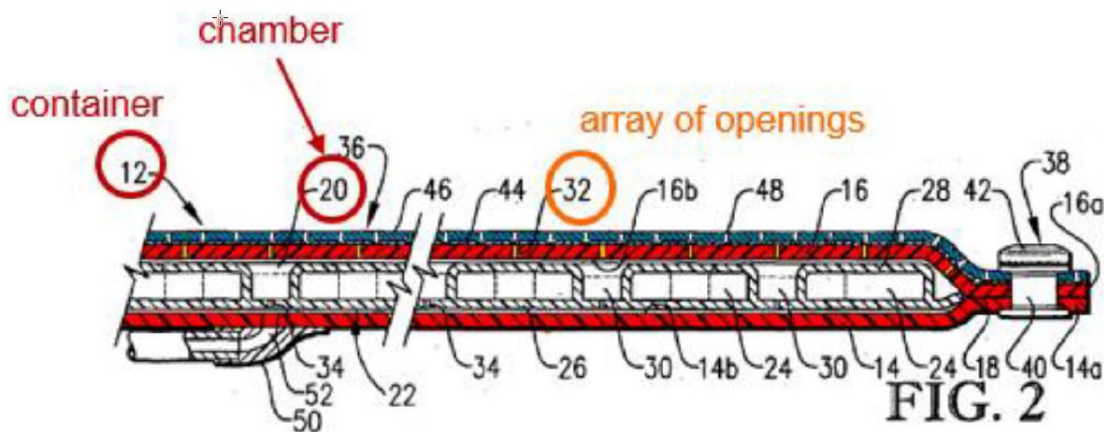
c. Analysis

Having review Petitioner’s evidence and argument, we find that Petitioner has shown by a preponderance of the evidence that pad 112 of Mahnensmith anticipates claim 1 of the ’508 patent. *See* Pet. 16–22; Ex. 1002 ¶¶ 131–144. We address Patent Owner’s arguments below.

Because we find that pad 112 anticipates claim 1 and for the sake of brevity, we do not address Patent Owner arguments directed to only pad 12. Instead, we focus our analysis on the embodiment shown in pad 112, and Patent Owner’s arguments corresponding to that embodiment. We note, however, Petitioner explains that Mahnensmith discloses that pad 112 “is of construction similar to pad 12 except for its overall size and the manner of attachment of the porous sheet member 136 to the permeable layer 116 of pad 112.” Reply 19 (citing Ex. 1004 ¶¶ 30, 31 (“The operation and use of pad 112 is the same as described with respect to pad 12”); Pet. 17 (showing pad 112, citing Ex. 1004 ¶¶ 30, 31)). Thus, in our discussion below, we do cite to pad 12 because Mahnensmith provides most of the explanation of how both the pads operate in the context of its discussion of pad 12. We also note that we include a lengthy discussion of Figure 2, which depicts a cross-sectional view of pad 12 because one of Patent Owner’s arguments depends heavily on an analysis of Figure 2.

Patent Owner’s first argument with respect to pad 112 is that the Petitioner failed to establish that pad 112 is “configured and dimensioned for enabling a moisture-wicking article to be secured over the array of openings

... by wrapping the article over the array.”⁹ PO Resp. 53–60. Patent Owner’s arguments (supported by similar testimony of Mr. Jezzi (Ex. 2060 ¶¶ 166–176) arise from Petitioner’s annotated version of Figure 2 of Mahnensmith depicting pad 12 (reproduced below).

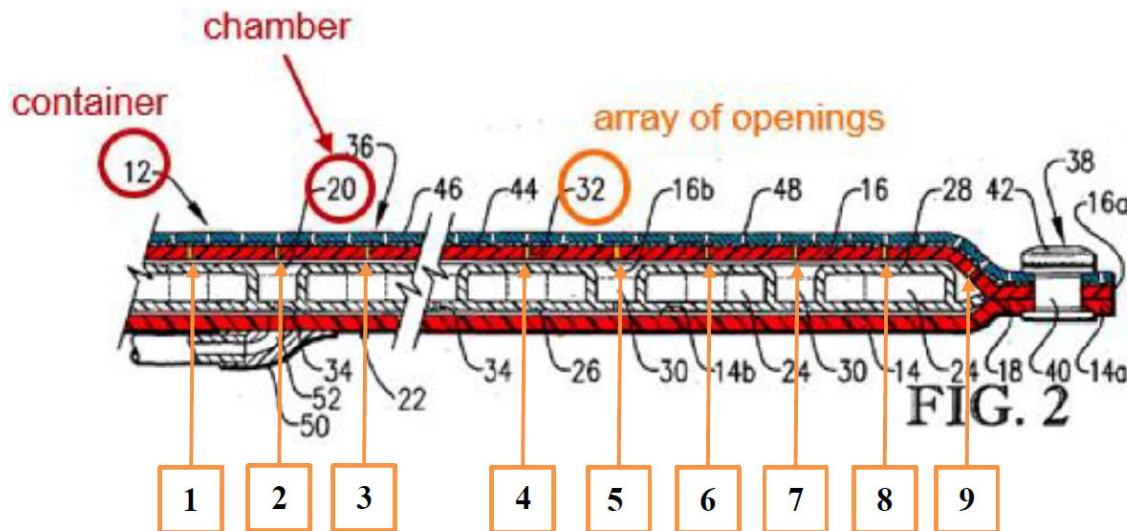


Petitioner’s annotated version of Figure 2 of Mahnensmith showing the container 12, chamber 20, and array of openings 32. Pet. 17.

In the Patent Owner Response and Mr. Jezzi’s Declaration, Patent Owner and Mr. Jezzi further annotate this figure, reproduced below, to include elements 1–9 depicting what Patent Owner asserts are nine openings

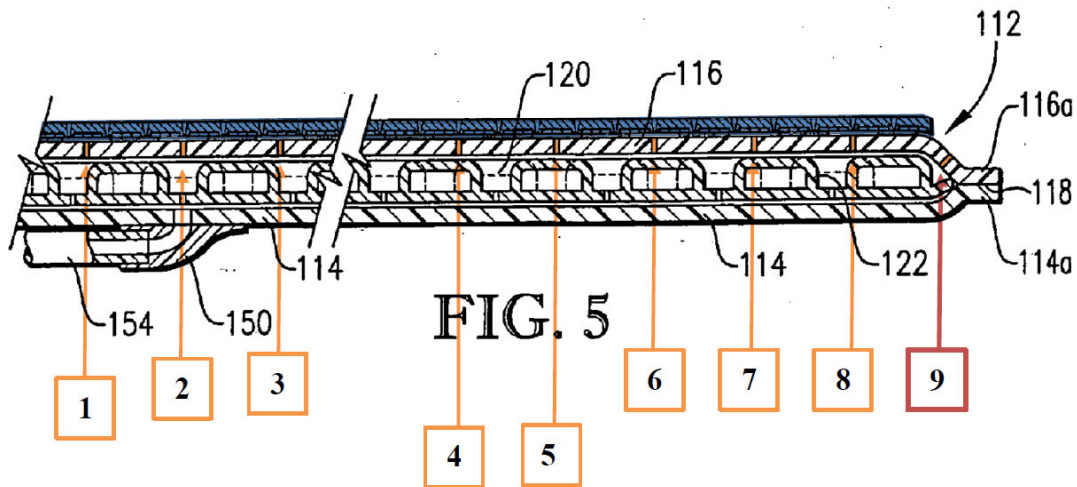
⁹ Patent Owner also argues that the Petition is insufficient because it never included a detailed analysis of pad 112 as depicted in Figures 4 and 5 of Mahnensmith. PO Resp. 55; Sur-Reply 21. In particular, Patent Owner complains that the Petition never included an annotated version of Figures 4 and 5 and never identified where the array of openings was in Pad 112. *Id.* Patent Owner contends that this renders the Petition insufficient under 37 C.F.R. § 42.104(b)(4). We disagree that the Petition fails to meet Rule 42.104(b)(4). There is no requirement of providing annotated version of every figure. Here, we find that Petitioner provides a detailed analysis of both embodiments with citations to Mahnensmith. Pet. 16–22. We find this is sufficient to comply with Rule 42.104(b)(4).

that Petitioner argues constitute an “array of openings.” PO Resp. 54;
Ex. 2060 ¶ 168.



Patent Owner’s Annotated version of Petitioner’s Annotated Figure 2 of Mahnensmith, showing alleged openings 1–9 in the drawing. PO Resp. 54.

Based on this annotation of the annotation of Figure 2 from the Petition, Patent Owner and Mr. Jezzi create an annotated version of Figure 5 (reproduced below) of Mahnensmith. PO Resp. 55–57; Ex. 2060 ¶ 169. Figure 5 is a “fragmentary enlarged vertical cross-sectional view of pad [112].” Ex. 1004 ¶ 16. Patent Owner maps what Patent Owner contends are openings of pad 12 shown in Figure 2 of Mahnensmith onto pad 112 shown Figure 5 of Mahnensmith, and alleging that one of the “openings” (i.e., element 9) of pad 112 identified in this annotated version of Figure 5 is not covered by the porous sheet, highlighted in blue. PO Resp. 56; Ex. 2060 ¶ 169.



Patent Owner's annotated version of Figure 5 of Mahnensmith showing what Patent Owner contends are nine openings in pad 112, including one (element 9) which is not covered by porous sheet 136 (highlighted in blue).
PO Resp. 56; Ex. 2060 ¶ 169.

Based on its interpretation of Figure 5 of Mahnensmith, Patent Owner and Mr. Jezzi argue that Petitioner has failed to show that Mahnensmith's porous sheet 136 covers the "array of openings" recited in claim 1. PO Resp. 57 (asserting that Petitioner identifies *all* openings, not a subset of openings, as "the array of openings"); Ex. 2060 ¶ 170. Patent Owner and Mr. Jezzi contend that Dr. Newman agreed that Patent Owner's annotated version of Figure 5 (reproduced above) "accurately depicts porous sheet 136 and layer 116's 'openings.'" *Id.* at 58 (citing Ex. 2039, 172:5–174:3); Ex. 2060 ¶ 172.

We disagree with Patent Owner's characterization of Figure 5 of Mahnensmith, in particular that there is an uncovered "hole 9" in Figure 5, because it represents an unreasonable and unsupported interpretation of the reference. To begin with, we agree with Petitioner (Reply 23 n.5) that Dr. Newman never conceded there was an uncovered hole or that Patent Owner's annotated Figure 5 "accurately" represented anything. A full review of her deposition testimony reveals she merely agreed the annotated

Figure 5 showed features labeled openings, but immediately disagreed with Patent Owner's interpretation of the annotation and offered theories why the drawing is not accurate . *See* Ex. 2039, 156:21–157:4, 172:5–174:3. We find that Patent Owner's characterizations of Dr. Newman's testimony to be inaccurate.

As for Patent Owner's and Mr. Jezzi's theory of an uncovered hole, we find it is inconsistent with Mahnensmith and that it is based entirely on speculation, inconsistent with how a person of ordinary skill would have understood Mahnensmith, and thus is not credible and give it little weight. Mahnensmith describes no uncovered openings. *See* Ex. 1017 ¶ 64. Indeed, Figure 4 of Mahnensmith, which also illustrates pad 112, does not show any uncovered openings. Ex. 1004, Fig. 4, ¶ 15 (explaining Fig. 4); Ex. 1017 ¶ 64. We further note that Mahnensmith only labels one feature in Figure 2 as an opening. *See* Ex. 1004, Fig. 2 (number 32). As for Figure 5, it labels *none* of its features as openings. *See id.* at Fig. 5. There is no textual description in Mahnensmith that most of the lines in the drawings the parties are now vigorously fighting over are even openings.

Patent Owner, understandably, wants to focus our attention almost entirely on the Petition and its coloring of certain features of Figure 2 orange. PO Resp. 54–60. From this launching point, already removed from Mahnensmith, Patent Owner and Mr. Jezzi make a further series of unsupported leaps. First, Patent Owner and Mr. Jezzi seem to assume that the drawings are to scale. However, it is well-established that patent drawings are not engineering drawings and are normally not to scale. *See Nystrom v. TREX Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005). Second, they seem to assume that Figure 2 and Figure 5 are essentially identical, but a

close examination of these drawings reveals they are not identical and have differences in the hatching and lines, particularly in the contested region where Patent Owner asserts there is an uncovered opening. Mahnensmith makes clear that although pad 12 and pad 112 are “similar” in construction, they are not identical. *Id.* ¶ 30. Given the number of subtle differences apparent on a careful examination of the two figures—including the differences in size and cross-hatching, we decline simply to follow Patent Owner and Mr. Jezzi in their speculative one-to-one mapping between Figures 2 and 5 without some justification beyond some similarity between the embodiments.

Here, we find the testimony of Dr. Newman of why pad 112 of Mahnensmith cannot have an uncovered opening credible, well-reasoned, and entitled to significant weight. *See* Ex. 1017 ¶¶ 64–68. We note that

In an anticipation analysis, the dispositive question is whether a skilled artisan would “reasonably understand or infer” from a prior art reference that every claim limitation is disclosed in that single reference. *Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1192 (Fed. Cir. 2003). Expert testimony may shed light on what a skilled artisan would reasonably understand or infer from a prior art reference. *Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336, 1345 (Fed. Cir. 2018).

Acoustic Tech., Inc. v. Itron Networked Sols., Inc., 949 F.3d 1366, 1373 (Fed. Cir. 2020).

Dr. Newman explains that Mr. Jezzi fails to adequately account for what Figure 4 depicting pad 112 would have disclosed to a person of ordinary skill in the art. Ex. 1017 ¶ 64. Moreover, Dr. Newman explains that a person of ordinary skill would understand that Mahnensmith’s pad 112 cannot have uncovered openings because

Mahnensmith states that its moisture-wicking article is “removably affixed to the outermost face of permeable layer 116 by use of double-stick tape located around the perimeter of the porous sheet member 136...” (Ex. 1004 at ¶30.) If there is an exposed opening at the perimeter, as Mr. Jezzi claims, that would mean that the double-sided tape would cover it, so it is not an “opening.” A POSA would not assemble a vacuum-assisted urine collection device like Mahnensmith’s just to cover its vacuum openings with tape, as that would defeat the purpose of having any inlet openings there in the first place. Moreover, the opening(s) would make it difficult for the tape to stay secure in that location.

Ex. 1017 ¶ 67. In addition, Dr. Newman testifies

a POSA would understand that it would be impractical to leave an uncovered opening in pad 12^[10]. Doing so would serve no functional purpose and would result in numerous drawbacks. For example, urine could leak back out the openings leading to incontinence-associated dermatitis, and the uncovered opening would result in an uncomfortable negative pressure against the patient’s skin, which could draw skin into the openings and could also lead to skin breakdown. Indeed, exposed openings would defeat one of the reasons for using a moisture-wicking article in the first place. I note that Keane, for example, discusses that concern with having uncovered openings. (Ex. 1005 at 2:47–56 (a soft layer over the suction openings “will also serve to support the tissues of the genitalia and prevent them from being sucked into the openings of the ducts”).) In addition, an uncovered opening could result in increased suction-generated noise.

¹⁰ We understand this to be a typographical error because this section of Dr. Newman’s declaration deals with only pad 112, and Patent Owner does not allege that there are any uncovered openings in pad 12. Indeed, Patent Owner recognizes this in its Sur-Reply. *See* Sur-Reply 24–25 (“In ¶68, she says holes in pad 112’s outer-perimeter could leak, but ignores they are where pad 112 ‘conform[s] to the surface of the patient’s body’ so urine cannot leak through them. Mahnensmith, [0032]; Jezzi-Decl., ¶174”).

Ex. 1017 ¶ 68. We agree with Dr. Newman and find that a person of ordinary skill reviewing Mahnensmith would reasonably understand or infer that there are no uncovered openings in pad 112 as Patent Owner contends. In contrast, Mr. Jezzi's testimony on this issue is not credible. Mr. Jezzi provides insufficient analysis of how a person of ordinary skill would look at these drawings in view of the state of the art, as Dr. Newman does, or recognition of the manifold problems identified by Dr. Newman, such as leaking urine, skin breakdown that his interpretation of Figure 5 would cause. *See* Ex. 2060 ¶¶ 167–171. Indeed, we agree with Dr. Newman's testimony that Mr. Jezzi's contention that urine would not leak because this part of pad 112 would conform to the woman's body (Sur-Reply 24–25; Ex. 2060 ¶ 174) would not make sense given the sensitivity of the area (genitalia region) involved. *See* Ex. 2063, 95:2–24. Instead, Mr. Jezzi's testimony focuses narrowly on the annotated version of Figure 2 and the coloring used in that annotation treating a person of ordinary skill like an automaton. We find this analysis not credible and entitled to little weight.

In its Sur-Reply, Patent Owner takes a new tack. Patent Owner now argues that Petitioner's arguments demonstrate that Mahnensmith is ambiguous and an ambiguous reference cannot form the basis of an anticipation reference. *See* Sur-Reply 21–25 (citing *Wasica Finance GmbH v. Cont'l Auto. System, Inc.*, 853 F.3d 1272, 1284 (Fed. Cir. 2017)). We disagree that Mahnensmith is ambiguous. As we explained above, Patent Owner's and Mr. Jezzi's theory of an uncovered opening is unreasonable and contrary to what a person of ordinary skill would understand Mahnensmith disclosing. *See supra* 35–37. Mahnensmith discloses that “[a] disposable porous sheet may be replaceably mounted in overlying

relationship to the permeable outer layer of the pad.” Ex. 1004 ¶ 9. And that “porous sheet member 36 overlays the outermost face of permeable layer 16 and is releasably secured to pad 12 by a series of snap fasteners 38.” *Id.* ¶ 21; claim 7. Mahnensmith describes that Pad 112 has a similar construction to pad 12, but “porous sheet member 136 . . . may be removably affixed . . . by use of double-stick tape...” *Id.* ¶ 30; claim 20 (“porous sheet in overlying relationship...[secured with] double-sided sticky tape”). Pad 12 and Pad 112 have “similar features” and Mahnensmith explains that “porous sheet member 136, which is also preferably Dry Weave® material may be removably affixed to the outermost face of permeable layer 116 by use of double-stick tape located around the perimeter of the porous sheet member 136” *Id.* ¶ 30. We find this sufficiently discloses that “porous sheet member 136” is over the array of openings in pad 112 of Mahnensmith. *See* Pet. 21–22 (citing Ex. 1002 ¶¶ 137–141).

Patent Owner’s second argument is that neither pad 12 nor pad 112 is not “configured and dimensioned” for enabling contact with the region “surrounding the urethral opening.” PO Resp. 48–49 (addressing pad 12), 60–63 (addressing pad 112, but referring back to the analysis of pad 12). In particular, Patent Owner contends that “‘the region of a female body surrounding the urethral opening’ is protected by the labia, which must be parted for this region to be accessed.” *Id.* at 60. Patent Owner asserts that “Dr. Newman testified in connection with the Keane ground that ‘the regions of the female body surrounding the urethral opening’ are ‘the vestibule of the vagina, the vaginal opening, the vestibular fossa, the posterior commissure, and the medial surfaces of the labia.’” *Id.* at 48

(citing Ex. 1002, p. 47). Patent Owner argues that “[f]or the ‘moisture-wicking article to be disposed in contact with’ the external female genital organs Dr. Newman identified, a typical woman’s labia must be spread apart because the labia covers and protects these anatomical features and the urethral opening.” *Id.* at 49 (citing Ex. 2060 ¶ 151; Ex. 2039, 88:12–22). Patent Owner argues that “[t]his is consistent with the specification’s disclosure that the secured moisture-wicking article is ‘held snugly against the external urethra.’” *Id.* (citing Ex. 1001, 5:13–18). Patent Owner asserts that “[t]he moisture-wicking article cannot be so held if the container to which it is secured is not ‘configured and dimensioned’ to be disposed between parted labia, because un-parted labia would prevent the article from being ‘held snugly against the external urethra.’” *Id.*

We disagree with Patent Owner that the claim limitation “enabling said secured moisture-wicking article to be disposed in contact with the region of a female body surrounding the urethral opening” requires intra-labial placement. Beginning with the claim language itself, there is no mention of the labia and the claim broadly recites a *region* surrounding the urethral opening, which does not indicate the claim is as narrowly limited as Patent Owner suggests. As for the Specification, Patent Owner points to a statement that the moisture-wicking article is “held snugly against the urethra,” but nothing in this statement requires intra-labial placement. *See* Ex. 1001, 5:15–16. More importantly, in our view, the ’508 patent states:

The [Kuntz 166] pad is *configured to make direct contact with the region of a female person’s body surrounding the urethral opening* and facilitates the positioning of the pad to the body surface so that urine that is expelled by the person is passed into and absorbed

Ex. 1001, 1:19–23 (emphasis added).

Dr. Newman testifies that “[a] POSA would understand that the Kuntz 166 is a pad, just like the Mahnensmith pad, and is not designed to be positioned intra-labially.” Ex. 1017 ¶ 51. Dr. Newman explains that a person of ordinary skill in the art “would understand Kuntz’s pad is disposed near the genitalia like a menstrual pad.” *Id.* We note that Mr. Jezzi agreed at his deposition that Kuntz 166’s pad is not positioned intra-labially, but rather is positioned near the external genitalia. Ex. 1018, 165:12–18, 185:8–20. Mr. Jezzi agreed that pad 112 of Mahnensmith is positioned similarly to the pad of Kuntz 166. Ex. 1018, 185:8–20. We find Dr. Newman’s testimony well-reasoned and supported and give it substantial weight. Given the ’508 patent’s statement regarding Kuntz 166 and our understanding of how the pad of Kuntz 166 is configured based on the testimony of Dr. Newman and Mr. Jezzi, we conclude that the intrinsic evidence does not support Patent Owner’s “intra-labial” requirement. We agree with and credit Dr. Newman’s testimony that the ’508 patent does not require intra-labial positioning. Ex. 1017 ¶ 52.

Patent Owner also contends that Dr. Newman admitted that intra-labial placement was required. PO Resp. 48; Sur-Reply 28. But we agree with Dr. Newman’s explanation that the statement cited by Patent Owner (Ex. 1002, p. 47) merely “was referring to how Keane’s device in particular was disposed against the female body, not saying that the claim term was limited to this one manner of positioning.” Ex. 1017 ¶ 53. We agree and credit Dr. Newman’s explanation that this understanding is consistent with the numerous statements in Dr. Newman’s declaration that do not require intra-labial placement. *Id.* ¶ 54.

Given this understanding of the claim scope, we find that Petitioner has shown sufficiently that Mahnensmith discloses this limitation.¹¹

Ex. 1004 ¶¶ 30, 32; Ex. 1002 ¶¶ 142, 144; Ex. 1017 ¶¶ 49–60.

Patent Owner’s third argument is that Mahnensmith does not anticipate because Mahnensmith’s porous sheet member 136 depicted in pad 112 is “overlayed” not “wrapped.” PO Resp. 63–65; Sur-Reply 28–29. Patent Owner asserts that “[t]he specification describes the container as configured and dimensioned for enabling the moisture-wicking article to be ‘wrapp[ed] **around** the device.’” PO Resp. 64 (quoting Ex. 1001, 5:3–9, Fig. 2). Patent Owner, pointing to a dictionary definition, argues that “‘overlaying’ refers to ‘lay[ing] or plac[ing] (one thing) over or upon another.’” *Id.* (quoting Ex. 2023).

We agree with Petitioner that Mahnensmith describes “wrapping the article over the array.” Reply 20 (citing Ex. 1002 ¶¶ 140, 144; Ex. 1017 ¶¶ 71, 72). The claims do not recite “wrapping around” the device. Our understanding of the claims is supported by the portion of the specification

¹¹ Patent Owner argues that Petitioner raises a new theory. Sur-Reply 27–28. We do not find this persuasive. The arguments in Petitioner’s Reply are consistent with its previous arguments. Patent Owner argued that the challenged claims required intra-labial placement and Dr. Newman and Petitioner responded directly to this argument indicating the actual scope of the claim and explaining clearly how Mahnensmith was consistent with the ’508 patent’s and Mr. Jezzi’s admissions and characterizations. We find that consistent with Petitioner’s prior arguments, and that, in any event, Patent Owner had adequate notice of arguments based on admissions in its own patent and by its own expert. *See Genzyme Therapeutic Prod. Ltd. P’ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016) (finding Board’s final written decision complied with Administrative Procedures Act because the patent owner had notice of “new evidence” supporting an existing obviousness theory).

cited by the Patent Owner, which explains that “*in one embodiment . . . the moisture-wicking article 20 is secured over the array of opening in the container . . . by wrapping the article 20 around the device.*” Ex. 1001, 5:3–6 (emphases added). Thus, it is clear that this description only describes one embodiment, and that the inventors were aware of how to describe “wrapping around the device” but chose a different, broader phrase—“wrapping . . . over the array”—for use in the claims. We decline to limit the broader language to require the moisture-wicking article to be wrapped “around” the container. *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) (“[P]articular embodiments appearing in the written description will not be used to limit claim language that has broader effect.”). With that clarification, we find that Petitioner’s evidence establishes that Mahnensmith discloses “wrapping . . . over the array” of openings. We find that Dr. Newman credibly testifies that Mahnensmith discloses “wrapping . . . over the array.” Ex. 1002 ¶¶ 140, 144; Ex. 1017 ¶¶ 71, 72. As Dr. Newman explains,

Mahnensmith states that its article is “replacably mounted in overlying relationship to the permeable outer layer of the pad” and that the article “overlays the outermost face of . . . layer 16” and is “releasably secured to” the pad. (Ex. 1004, ¶¶ 9, 21, 30–32.) That is exactly what “wrapping over” openings is. And Figure 1 shows the article being wrapped over the openings. Indeed, Mahnensmith described that feature as an improvement to Kuntz 166. (Ex. 1004, ¶¶ 6, 9.)

Ex. 1017 ¶ 72.

We find Dr. Newman’s testimony to be well-reasoned and consistent with the evidence and entitled to significant weight. Ex. 1002 ¶¶ 140, 144; Ex. 1017 ¶¶ 71, 72. Patent Owner and Mr. Jezzi cite to Exhibit 2023, which is a dictionary definition of “overlay.” *See* PO Resp. 64; Sur-Reply 28–29;

Ex. 2060 ¶ 187; Ex. 2023. However, we fail to see how a definition of “overlay” without a definition of “wrapping” informs much about this discussion. Although Mahnensmith uses “overlying,” the claims of the ’508 patent use “wrapping.” Dr. Newman credibly explains, with specific reference to the claim language and Mahnensmith, how Mahnensmith meets this limitation. We agree with Dr. Newman that, if anything, “Mr. Jezzi’s reference to a definition of ‘overlay’ (Ex. 2023) simply proves that it is a reference to wrapping ‘over.’” Ex. 1017 ¶ 72.

Finally, Patent Owner argues that Mahnensmith’s pad 112 does not have an “exterior” that is “configured and dimensioned for enabling” the porous sheet “to be secured over the array by wrapping” because “porous sheet 36/136 is laid on the flat pad 12/112 and secured via . . . ‘double-stick tape’ attached to porous sheet 136 (not pad 112).” PO Resp. 63. Patent Owner argues that “pad 112 is ‘configured and dimensioned’ to be larger than porous sheet 136 thereby preventing it from wrapping over the array of openings.”¹² *Id.* at 64 (citing Ex. 2060 ¶¶ 173–175). Patent Owner contends that “[u]nder Petitioner’s theory, a container’s exterior surface is ‘configured and dimensioned for’ enabling a moisture-wicking article to be secured over openings in the container by wrapping if snaps are added to the container, or if the moisture-wicking article includes double-sided tape to adhere to the container’s surface.” *Id.* at 65. Patent Owner asserts that “[t]his impermissibly renders the ‘configured and dimensioned for’ language

¹² Patent Owner also argues, based on its theory that pad 112 has uncovered holes, which we addressed *supra* at pp. 32–39, that pad 112 is not so “configured.” PO Resp. 64. We rejected that theory above, and so do not separately address this argument.

meaningless, because any container with an exterior surface would arguably be ‘configured and dimensioned for’ enabling such an article to be secured to it by double-sided tape.” *Id.*

We find that Petitioner has adequately shown that Mahnensmith is “configured and dimensioned for enabling” the porous sheet “to be secured over the array by wrapping.” *See* Ex. 1002 ¶ 140; Ex. 1017 ¶ 73. As Dr. Newman explains, Mahnensmith is “configured and enabled” exactly in the same way that the embodiment disclosed in the ’508 patent is. *See* Ex. 1017 ¶ 73. As Dr. Newman testifies, “several of the mechanisms used to secure the article in the 508 patent are external to the container, e.g., spring clips, adhesive tape, and elastic bands—just as in Mahnensmith’s ‘double-stick tape.’” *Id.* (citing Ex. 1001, 4:1–9).

We have reviewed Petitioner’s contentions and supporting evidence and considered Patent Owner’s arguments as discussed above. On the entire record, we find that Petitioner has shown by a preponderance of the evidence that pad 112 of Mahnensmith anticipates claim 1. *See* Pet. 16–26; Ex. 1002 ¶¶ 131–144.

2. Claims 3–8 and 17–19

a. Claims 3–8

Claim 3–8 depend directly or indirectly from claim 1. Ex. 1001, 7:13–34. Petitioner explains how those additional limitations are described by Mahnensmith. *See* Pet. 22–26. Patent Owner does not specifically argue whether Mahnensmith accounts for the additional limitations recited by claims 3–8 beyond those arguments addressed above for claim 1. Accordingly, Patent Owner has waived any argument directed to those limitations. *See* Paper 11, 8 (“Patent Owner is cautioned that any arguments

for patentability not raised in the response may be deemed waived.”). We have reviewed Petitioner’s evidence and argument. *See* Pet. 22–26. We agree with it and adopt it as our own. For the reasons provided therein, Petitioner demonstrates that claims 3–8 are anticipated by Mahnensmith.

b. Claim 17

Claim 17 is an independent claim and recites similar limitations to claim 1, except it includes a limitation that the elongated container is “closed at both ends.” Petitioner provides a mapping of the disclosure of Mahnensmith to the limitations of claim 17. *See* Pet. 24–25. Patent Owner does not specifically argue whether Mahnensmith accounts for the additional limitations recited by claim 17 beyond those arguments addressed above for claim 1. Accordingly, Patent Owner has waived any argument directed to those limitations. *See* Paper 11, 8 (“Patent Owner is cautioned that any arguments for patentability not raised in the response may be deemed waived.”). We have reviewed Petitioner’s evidence and argument. *See* Pet. 24–25. We agree with it and adopt it as our own. For the reasons provided therein, Petitioner demonstrates that claim 17 is anticipated by pad 112 of Mahnensmith.

c. Claims 18 and 19

Claims 18 and 19 depend from claim 17. Ex. 1001, 8:46–53. Claim 18 additionally recites “the article is dimensioned for being secured over the array of openings by the application of elastic bands about the moisture-wicking article at opposite ends of the array of openings.” *Id.* at 8:46–50. Claim 19 additionally recites that “the article has the moisture-wicking characteristic of a paper towel.” *Id.* at 8:52–53. Petitioner additionally accounts for the limitations of claims 18 and 19. *See* Pet. 25–26

(citing Ex. 1002 ¶¶ 150, 151, 156–164). Patent Owner does not specifically argue whether Mahnensmith accounts for the additional limitations recited by claims 18 and 19 beyond those arguments addressed above for claim 1. Accordingly, Patent Owner has waived any argument directed to those limitations. *See* Paper 11, 8 (“Patent Owner is cautioned that any arguments for patentability not raised in the response may be deemed waived.”). We have reviewed Petitioner’s evidence and argument. *See* Pet. 25–26. We agree with it and adopt it as our own. For the reasons provided therein, Petitioner demonstrates that claims 18 and 19 are anticipated by Mahnensmith.

G. OBVIOUSNESS OVER KUNTZ 166, DESMARAI, AND THE KNOWLEDGE OF PERSON OF ORDINARY SKILL IN THE ART: CLAIMS 1, 3–8, AND 17–19

Petitioner contends that the combination of Kuntz 166, DesMarais, and the knowledge of a person of ordinary skill in the art would have rendered claims 1, 3–8, and 17–19 unpatentable under 35 U.S.C. § 103(a). Pet. 39–56.

1. Claim 1

a. Petitioner’s Contentions

Petitioner argues that Kuntz 166 discloses

A urine collection device for use in a system for transporting urine voided from a person or an animal by drawing the urine into a moisture-wicking article that is disposed in contact with a region of the person or animal surrounding an urethral opening, and further drawing the urine into the collection device from the moisture-wicking article, comprising

Pet. 44–45 (citing Ex. 1002 ¶¶ 174–176, 190; Ex. 1006, Abstract, 5:59–6:9, 3:48–52, 2:38–43, 7:17–32, Figs. 1, 2, 8, Ex. 1003, PW55, Ex. 1001, 1:30–

33), “a container defining a chamber for collecting urine,” Pet. 45 (citing Ex. 1003, PW55; Ex. 1002 ¶¶ 179, 190; Ex. 1006, 7:60–65, 2:38–48, 3:58–64, 7:44–65, 4:29–32, 6:1–8), “wherein the container is closed, except for having an array of openings through which urine can be drawn into the chamber and at least one outlet port through which urine can be drawn away from the chamber,” Pet. 45–46 (citing Ex. 1003, PW55; Ex. 1006, Figs. 1, 2, 6:1–8, 3:58–64, 7:52–56; Ex. 1002 ¶ 190), and “and for enabling said secured moisture-wicking article to be disposed in contact with the region of a female body surrounding the urethral opening,” Pet. 47 (citing Ex. 1003, PW56, Ex. 1001, 1:19–24, Ex. 1005, 5:62–63, 3:48–57, 7:20–23, Ex. 1002 ¶¶ 179, 190).

Petitioner relies on the combination of Kuntz 166 and DesMarais as teaching “wherein an elongated exterior of the container is configured and dimensioned for enabling a moisture-wicking article to be secured over the array of openings of the container by wrapping the article over the array and securing the wrapped article.” *See* Pet. 46–47 (citing Ex. 1003, PW55, PW56; Ex. 1006, Fig. 2, 1:63–2:2, 2:62–68, 3:42–45, 3:58–4:16, 5:11–43, 5:53–57, 5:62–65, 6:1–7, 7:23–25, 7:44–65, 8:15–17; Ex. 1002 ¶¶ 178, 182, 183, 190–202; Ex. 1001, 1:33). Petitioner argues that Kuntz 166 describes pad 12 as including a moisture-wicking article. *Id.* at 46. In particular, Petitioner notes that Kuntz 166 states that “[u]rine is rapidly drawn . . . into the porous and absorptive core where it moves by capillary action,” *id.* at 46–47 (quoting Ex. 1006, 6:1–7), and that the ’508 patent admits that in Kuntz 166 “urine move to the central bore of the pad by capillary action,” *id.* at 47 (quoting Ex. 1001, 1:33). Petitioner submits that Kuntz 166 incorporates DesMarais by reference, and DesMarais discloses “an

‘overwrap’ formed of wicking articles including paper towel as discussed above.” *Id.* (citing Ex. 1007, Figs. 1–5, 3:3–11, 11:17–22, Abstract; Ex. 1002 ¶¶ 185–202)

Petitioner asserts that “wrapping and securing a wicking article as claimed was a well-known technique for applying a moisture-wicking article (as taught in DesMarais and other references) and would have improved Kuntz 166 in a predictable manner. *Id.* at 48 (citing Ex. 1002 ¶¶ 194, 195, 56–59). Petitioner notes that Kuntz 166 discloses inserting the container (tube) into a bore in the pad (rather than wrapping). *Id.* (Ex. 1006, 3:42–64, 2:45–48). Petitioner argues that this “creates a number of known problems . . . a gap is created between the pad materials and tube, allowing urine to collect [and] [i]t may also serve as a channel for airflow that will decrease the effectiveness of the vacuum.” *Id.* (Ex. 1002 ¶¶ 183, 192, 193). Petitioner contends that prior art such as Mahnensmith and Kuntz EP355 discloses “Kuntz’s bore technique was a known problem in the prior art at the time of the 508 alleged invention, and wrapping was a known solution.” *Id.* (citing Ex. 1002 ¶¶ 183, 192, 193; Ex. 1008, 2:12–29, 5:30–39; Ex. 1004 ¶¶ 5, 6).

b. Patent Owner’s Arguments

Patent Owner initially argues that this ground is procedurally improper because the extensive citation to Dr. Newman’s declaration amounts to improper incorporation by reference. PO Resp. 70–71; Sur-Reply 29. Patent Owner also raises several substantive arguments. First, Patent Owner argues that “DesMarais nowhere discloses a tube, never suggests its overwrap material is suitable for covering a tube, and would not have motivated the proposed modification,” and “Kuntz-166 already applies

DesMarais's teachings." PO Resp. 71–72; Sur-Reply 29–30. Second, Patent Owner argues that DesMarais's overwrap is not a moisture-wicking article, but is instead a hydrophobic material that repels water. PO Resp. 72–75. Third, Patent Owner argues that because DesMarais's overwrap is not moisture-wicking, the resulting combination has an outer layer that is hydrophobic, and not moisture-wicking. *Id.* at 75. Finally, Patent Owner argues that the pad in Kuntz-166 is not a moisture-wicking article, but rather is a "moisture-absorbent material." *Id.* at 75–77.

c. Analysis

We begin by addressing Patent Owner's procedural argument. We disagree with Patent Owner that the Petition is procedurally inadequate for this ground. The Petition contains a detailed mapping for the claims, and an explanation for the motivation to combine. *See* Pet. 39–56. This section of the Petition cites to Dr. Newman's declaration, but the Petition contains sufficient particularity to meet our requirements. Dr. Newman's declaration is more detailed, but nothing in our rules forbids the declaration from having more detail and reasoning to support the testimony of the declarant. *See Kinetic Techs., Inc. v. Skyworks Sols.*, IPR2014-00529, Paper 8 at 15–16 (PTAB Sept. 23, 2014).

Based on the entire record, we find that Petitioner has shown that the combination of Kuntz 166 and DesMarais accounts for the limitations of claim 1, that a person of ordinary skill in the art would have been motivated to combine the references in the manner proposed with a reasonable expectation of success. *See* Pet. 39–56. We address Patent Owner's arguments in detail below.

We do not find the alleged substantive defects Patent Owner alleges to be availing either. Patent Owner's arguments that a person of ordinary skill would not have made the proposed combination based on DesMarais or that the ground is really based on Kuntz EP355 mischaracterizes Petitioner's arguments. PO Resp. 72. Petitioner does not assert that DesMarais provides the motivation for the combination or changes, but merely the teachings about types of overwraps available. *See* Pet. 47–48. For the motivation, Petitioner points to Kuntz 166 as expressly mentioning DesMarais for the details of pad construction, and to Mahnensmith and Kuntz EP355 as demonstrating that overwrapping was a known solution to the problems of Kuntz 166. *Id.* at 48. Moreover, Dr. Newman provides additional reasoning to support relying on the teachings of DesMarais. *Id.* at 48–50 (citing Ex. 1002 ¶¶ 183, 192–201). Contrary to Patent Owner's assertions that they are not contained in the Petition, we find that the Petition contains several pages summarizing Dr. Newman's reasoning. *See* Pet. 47–50. Thus, the lack of motivation in DesMarais is irrelevant.

Patent Owner's second argument that DesMarais's overwrap is a hydrophobic material and Petitioner "simply got it wrong" is also unavailing. PO Resp. 72–75. Petitioner and Dr. Newman persuasively explain that DesMarais *does* disclose materials, which the '508 patent and Dr. Newman, identify as "moisture wicking." Reply 26–27 (citing Ex. 1002 ¶ 187; Ex. 1017 ¶¶ 123, 124). As Petitioner explains, DesMarais states that "hydrophobic" material is "one prefer[ence]," *id.* at 27 (citing Ex. 1007, 5:7), and DesMarais discloses

The pad overwrap material can be any fluid permeable material commonly used as an overwrap in sanitary napkins or as a topsheet in disposable diapers. Use materials include carded,

spun-bonded, melt blown web, airlaid webs, and other non-woven webs of natural or synthetic fibers.

Ex. 1007, 4:66–5:5. Dr. Newman testifies that this list from DesMarais includes materials described in the '508 patent as moisture wicking. *See* Ex.1002 ¶ 187; Ex. 1017 ¶¶ 123, 124. Mr. Jezzi acknowledged that “nonwoven web of natural fibers” includes paper towel. *See* Ex. 1018, 174:7–17 (“Q. Paper towel is a nonwoven web of natural fibers, right? A. Some people call paper nonwovens. Q. In particular, it’s nonwoven natural fiber material, right? A. It’s cellulosic, yeah.”).

In its Sur-Reply, Patent Owner argues that we should not consider this argument because it is a new argument. Sur-Reply 31–32. We disagree that this is a new argument. The Petition clearly states that the overwrap includes “moisture-wicking” materials. *See* Pet. 43 (“As Dr. Newman explained, options for the overwrap include wicking articles including ones referenced in the 508 patent). (Newman ¶¶ 169, 185-188, 198; Ex. 1007, 5:5-5:54, 7:26-35.) ‘This pad overwrap can be any fluid permeable material commonly used as an overwrap in sanitary napkins...[and can] include carded, spunbonded, melt blown web, airlaid webs, and other non-woven webs of natural or synthetic fibers.’ (4:66-5:6.)”). Patent Owner’s contentions that “Petitioner tries to re-write the Petition” (Sur-Reply 31) appears more to justify its own default in raising its new argument that Petitioner’s modification is inconsistent with Kuntz 166 and DesMarais, than any failure by Petitioner.

Patent Owner raises a new argument in the Sur-Reply that “POSAs would not have used paper-towel as a patient facing layer in the combination

because the design is inconsistent with **both** Kuntz-166 and DesMarais.”¹³ Sur-Reply 32. In particular, Patent Owner submits that “DesMarais teaches its overwrap should ‘present[] a drier feel to the user’ and not ‘caus[e] irritation,’” *id.* (citing Ex. 1007, 5:5–12, 1:21–25), and further contends that “these are two things paper-towel cannot do” (*id.* (citing Ex. 2060 ¶¶ 65, 200; Ex. 1018, 173:3–174:6). Patent Owner also contends Kuntz-166 likewise disparages using hydrophilic materials as the patient-facing layer. *Id.* (citing Ex. 1006, 2:14–17, 7:29–31; Ex. 2060 ¶¶ 64, 197, 200).

To begin with, we note that at best, the statements in Kuntz 166 and DesMarais merely express a general preference and do not “criticize, discredit, or otherwise discourage investigation into” the claimed invention. *See Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017). Indeed, as we found above, DesMarais expressly discloses that moisture-wicking materials can be used as overwrap. *See supra* at pp. 50–51. We further find that Kuntz 166 does not disparage moisture-wicking materials as the patient-facing layer, but express a preference for hydrophobic patient-facing layers. *See* Ex. 1006, 2:14–17, 7:29–31. Moreover, Kuntz 166 incorporates DesMarais and its disclosure that moisture-wicking materials may be used for overwrap materials “of some interest for its description of the structural details and fabrication techniques for liquid absorbent pads.” Ex. 1006, 1:63–2:1. Thus, we find that there is no teaching away from the

¹³ Patent Owner did not raise this argument in the context of this ground in its Patent Owner Response, but did raise a similar argument in the context of Ground 2—Mahnensmith and the knowledge of a person of ordinary skill in the art, which we addressed and rejected above. Thus, for completeness, we address this argument here as well.

proposed combination. *See* Ex. 1017 ¶ 85 (explaining why there is no teaching away).

Furthermore, we disagree with Mr. Jezzi’s underlying contentions that moisture-wicking overwrap—as used in the combination—necessarily will not present a drier feel to patient. Sur-Reply 32 (citing Ex. 2060 ¶¶ 64, 65, 197, 200; Ex. 1018, 173:3–174:6). As Dr. Newman explained at her first deposition and in her second declaration, that is not necessarily the case in vacuum-assisted urine collection systems. Ex. 2039, 283:3–9 (“[i]f it’s gonna pull the urine away, then that means . . . to the external region, it would be dry. Drier.”); Ex. 1017 ¶¶ 78 (explaining why a person of ordinary skill would select paper-towel like materials), 84 (explaining Mr. Jezzi’s lack of consideration of the fact that a vacuum is used in the devices and its effect on the feel of the material); *see also* Ex. 1002 ¶¶ 48–50 (explaining the benefits of vacuum assist); Ex. 1017 ¶¶ 13, 23, 24 (explaining the vacuum assist urine collection devices). This failure to consider how the moisture-wicking material would feel to the user in the combination leads us to find that Mr. Jezzi’s testimony in this regard is entitled to little weight.

Even if Mr. Jezzi is correct, we disagree with the contention that the fact that Kuntz 166 and DesMarais might express a preference for hydrophobic patient-facing materials would have led a person of ordinary skill away from the proposed combination, as Patent Owner contends. *See In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (holding that “a particular combination” need not “be the preferred, or the most desirable, combination described in the prior art in order to provide motivation”); *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (“A known or obvious composition does not become patentable simply because it has been

described as somewhat inferior to some other product for the same use.”). And, even if using a moisture-wicking material was known to have certain disadvantages, “a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). Here, we credit the well-reasoned testimony of Dr. Newman that a person of ordinary skill would recognize the benefits that such an overwrap would provide, including improved wicking, protection of the underlying pad, and low cost. Ex. 1002 ¶ 202; Ex. 1017 ¶¶ 85, 86.

Patent Owner’s argument that the combination would lack a moisture-wicking overwrap (PO Resp. 75) is based on its contentions regarding DesMarais’s disclosure that we addressed above. Patent Owner’s contention that Dr. Newman confirmed that the combination would have a hydrophobic layer like Kuntz EP355 does not accurately reflect her testimony. *See id.* (citing Ex. 2039, 220:3–7, 221:1–9, 224:10–13). In the portions cited, Dr. Newman was discussing the obviousness of using overwrap to solve the problems with Kuntz 166, not the nature of the outer layer. Indeed, contrary to Patent Owner’s contentions, in portions adjacent to the cited portions, Dr. Newman specifically mentions the outer layer in the combination would be moisture wicking and that the issue she was discussing was not the dryness of the overwrap but improving the device’s urine-sucking ability. *See* Ex. 2039, 222:2–223:9 (discussing DesMarais’s disclosure of moisture-wicking materials in overwrap), 223:10–224:9 (discussing the problem being device “not sucking well” and urine “collecting somewhere”).

Finally, Patent Owner argues that the pad in Kuntz-166 is not a moisture-wicking article, but rather is a “moisture-absorbent material.” *Id.*

at 75–77; Sur-Reply 32–33. We disagree. As Dr. Newman credibly and thoroughly explains, the pad of Kuntz 166 meets Patent Owner’s construction of the term “moisture-wicking article.” Ex. 1017 ¶ 126. Indeed, the ’508 patent admits (and Patent Owner agrees) that “urine is drawn through openings in an outer cover layer of the pad into the moisture adsorbent material core of the pad within which the urine moves to the central bore of the pad by capillary action.” Ex. 1001, 1:28–33; PO Resp. 75 (“Kuntz-166 absorbent core includes capillary cells . . . to move urine within the pad ‘by capillary action.’”); *see also* Ex. 1002 ¶¶ 177–182 (explaining that the pad of Kuntz 166 transports fluid by capillary action). As Dr. Newman credibly testifies, this is precisely what Patent Owner’s construction requires. *See* Ex. 1017 ¶ 126.

As for Patent Owner’s arguments that Kuntz’s pad retains moisture, and therefore, cannot be “moisture wicking,” we credit Dr. Newman’s explanation that Mr. Jezzi and Patent Owner ignore that Kuntz 166 states that it only “temporarily retains the urine,” Ex. 1006, 7:23–25, which, Dr. Newman credibly testifies, “is exactly what paper towel, gauze, felt, and other materials described in the 508 Patent ‘moisture-wicking articles’ do. . . .” Ex. 1017 ¶127. Indeed, Mr. Jezzi acknowledged at his deposition that paper towel also temporarily retains moisture. Ex. 1018, 40:9–42:19, 142:1–21. Thus, we agree with Petitioner that merely temporarily retaining moisture, as the pad in Kuntz-166 does, does not preclude Kuntz’s pad from being a moisture-wicking article.

Patent Owner also contends that Kuntz EP355 shows that Kuntz 166 is not a moisture-wicking article. PO Resp. 76 (citing Ex. 1008, 2:14–29). However, we agree with Dr. Newman that the improvement of Kuntz EP355

is not because it uses a moisture-wicking article for the first time, but because it uses an additional “wicking tube assembly (Ex. 1008, Fig. 5) where the wicking materials are wrapped over the openings of the tube, rather than inserted into a bore on the pad.” Ex. 1017 ¶ 129.

Patent Owner’s contends that the ’508 patent distinguished Kuntz 166’s pad as not moisture wicking. PO Resp. 76. However, nothing in the ’508 patent expressly says that Kuntz 166’s pad is not moisture wicking. Indeed, the ’508 patent acknowledges that Kuntz 166’s pad uses capillary action. We also note that it is difficult for us to understand why, if the ’508 patent distinguished Kuntz 166 as Patent Owner now claims, the Patent Owner never raised this point during the prosecution when the Examiner rejected the pending claims based on Kuntz 166.¹⁴ See Ex. 1003, PW56.

In its Sur-Reply, Patent Owner raises several new arguments why the pad of Kuntz 166 is not a moisture-wicking article. Sur-Reply 32–33. Patent Owner argues the Petition “provided no explanation of how POSAs would have successfully wrapped a multi-layered pad around tube 30 and that pads with hydrophobic patient-facing layers are not “moisture-wicking articles.” *Id.* In addition to both arguments being raised for the first time for this ground in the Sur-Reply, these arguments suffer from several problems. With respect to the apparent reasonable expectation of success argument, we credit Dr. Newman’s testimony that this modification was “straightforward”

¹⁴ We are not saying that the Examiner’s findings are binding now (*see* Reply 27), but saying that Patent Owner’s characterization of what the specification of the ’508 patent says is not consistent with its actions during prosecution, which suggests specification actually does not “distinguish[]” Kuntz 166 in the manner Patent Owner now contends.

and “within the level of knowledge of a POSA.” *See* Ex. 1002 ¶¶ 199–201; Ex. 1017 ¶¶ 117–119.

Dr. Newman’s testimony is well-reasoned and consistent with the art in the record, such as DesMarais and Mahnensmith that teach such overwrapping, and therefore, we give Dr. Newman’s testimony significant weight. As for Patent Owner’s argument that Kuntz 166 pad cannot be a moisture-wicking article because it has a hydrophobic outer layer, we note that the combination proposes using the moisture-wicking overwrap from DesMarais as the outer layer. Thus, Patent Owner argues the references separately, when the Petitioner is relying on the combination of the references. *See Bradium Techs. v. Iancu*, 923 F.3d 1032, 1050 (Fed. Cir. 2019) (obviousness combination cannot be overcome by attacking references individually).

Even considering the argument for only Kuntz 166, we find it unavailing. Nothing in the ’508 patent or Patent Owner’s proposed construction requires that the “moisture-wicking article” consists only of moisture-wicking materials. Indeed, the ’508 patent states that the “moisture-wicking article 20 *includes* a rapidly permeable material such as gauze, felt, terrycloth, thick tissue paper, paper towel, etc.,” which suggests that other materials may be included. Ex. 1001, 4:10–12 (emphasis added). Thus, we find that Petitioner has shown by a preponderance of the evidence that the combination of Kuntz 166 and DesMarais accounts for the claimed “moisture-wicking article.”

We have reviewed Petitioner’s contentions and supporting evidence and considered Patent Owner’s arguments as discussed above. On the entire record, we find that Petitioner has shown by a preponderance of the evidence

that the combination of Kuntz 166, DesMarais, and the knowledge of a person of ordinary skill in the art accounts for all the limitations of claim 1, that a person of ordinary skill would have been motivated at the time of the invention to make the combination in the manner proposed, and that a person ordinary skill would have had a reasonable expectation of success in doing so. *See* Pet. 39–50; Ex. 1002 ¶¶ 183–201. As explained in detail above, Petitioner demonstrates that claim 1 would have been obvious over the combination of Kuntz 166, DesMarais, and the knowledge of a person of ordinary skill in the art.

2. Claims 3–8

Claim 3–8 depend directly or indirectly from claim 1. Ex. 1001, 7:13–34. Petitioner accounts for the added limitations of these claims in the combination of Kuntz 166, DesMarais, and the knowledge of a person of ordinary skill in the art. *See* Pet. 50–53. Patent Owner does not specifically argue whether the combination of Kuntz 166 and DesMarais accounts for the additional limitations recited by claims 3–8 beyond the arguments considered above with respect to claim 1. Accordingly, Patent Owner has waived any argument directed to those limitations. *See* Paper 11, 8 (“Patent Owner is cautioned that any arguments for patentability not raised in the response may be deemed waived.”). We have reviewed Petitioner’s evidence and argument. *See* Pet. 50–53. We agree with it and adopt it as our own. For the reasons provided therein, Petitioner demonstrates that claims 3–8 would have been obvious over the combination of Kuntz 166, DesMarais, and the knowledge of a person of ordinary skill in the art.

3. *Claims 17–19*

a. Claim 17

Claim 17 is similar to claim 1 except it recites that the elongated container is “closed at both ends.” Pet. 53. Petitioner provides a mapping similar to that of claim 1, but additionally explains why having a chamber that is closed at both ends would have been obvious. *Id.* at 53–55. In particular, the Petition notes that Dr. Newman explains that “there are two known design choices or the location of an outlet port: on an end of the container or on its side.” *Id.* at 53–54 citing Ex. 1002 ¶¶ 204, 206). Petitioner notes that both Mahnensmith and Keane locate their outlets on the bottom side rather than an end, and it would be an obvious design choice with a number of advantages (*id.* at 54 (citing Ex. 1003, Fig. 3; Ex. 1005 at Fig. 2; Ex. 1002 ¶¶ 207–210). Petitioner notes that “placing an outlet port on the bottom side (rather than the anterior end) of Kuntz 166 facilitates lateral movement of the associated tube, better accommodates the patient’s garments, could improve vacuum efficiency, and would minimize layer separation.” *Id.* Petitioner argues that implementation of this design choice would be simple and predictable. *Id.* (citing Ex. 1002 ¶¶ 211–21).

In addition to the arguments considered above with respect to claim 1, Patent Owner argues that there is “*no* support for Petitioner’s assertion that a tube with a bottom-side outlet was a ‘known design’ choice for absorbent vacuum assisted urinary pads.” PO Resp. 38. Patent Owner asserts the references cited, Mahnensmith and Keane, differ structurally from the pads Kuntz 166 and DesMarais. PO Resp. 38–39. Patent Owner also asserts that Petitioner’s benefits are speculative and that the proposed modification is “anything but ‘routine.’” *Id.* at 39–40. Patent Owner also argues that

Petitioner cannot rely on the knowledge of a person of ordinary skill in the art for this limitation. *Id.* at 77 (citing *DSS Tech. Mgmt. v. Apple, Inc.*, 885 F.3d 1367, 1374–75 (Fed. Cir. 2018)).

We begin by noting that Patent Owner is incorrect that *DSS Technology Management* stands for the proposition that the knowledge of a person of ordinary skill “cannot be used to ‘supply a missing limitation.’” PO Resp. 77. As *DSS Technology Management* explains, the use of the knowledge of person of ordinary skill is not prohibited, but requires a reasoned basis. *See DSS Tech.*, 885 F.3d at 1374–75. Here, we find that Petitioner has provided a reasoned basis. As Dr. Newman explains, there are only limited options for placing the outlet on a urine collection device. Ex. 1002 ¶ 206. Dr. Newman demonstrated that these options are known in the art. *See id.* Although Mahnensmith may have differences, it still demonstrates that the ends may be closed and the outlet port may be located somewhere other than the end. *See Ex. 1004*, Figs. 1, 4, 5. We find Dr. Newman provided numerous reasons a person of ordinary skill would have been motivated to move the outlet port of Kuntz 166, including making the tube rotatable in several directions and avoiding pulling or snagging the cord. Ex. 1002 ¶¶ 208–210; Ex. 1017 ¶ 149. Finally, we find that Petitioner has shown sufficiently that the modifications were within the level of skill in the art. Ex. 1002 ¶¶ 211–212; Ex. 1017 ¶¶ 151–152. Accordingly, we find that Petitioner has shown by a preponderance of the evidence that claim 17 would have been obvious over the combination of Kuntz 166, DesMarais, and the knowledge of a person of ordinary skill in the art.

b. Claims 18 and 19

Claims 18 and 19 depend from claim 17. Ex. 1001, 8:46–53. Claim 18 additionally recites “the article is dimensioned for being secured over the array of openings by the application of elastic bands about the moisture-wicking article at opposite ends of the array of openings.” *Id.* at 8:46–50. Claim 19 additionally recites that “the article has the moisture-wicking characteristic of a paper towel.” *Id.* at 8:52–53. Petitioner additionally accounts for the limitations of claims 18 and 19. *See* Pet. 55–56 (citing Ex. 1002 ¶¶ 56, 59, 216–222, 230). Patent Owner does not specifically argue whether the combination of Kuntz 166 and DesMarais accounts for the additional limitations recited by claims 18 and 19, beyond those considered above with respect to claims 1 and 17. Accordingly, Patent Owner has waived any argument directed to those limitations. *See* Paper 11, 8 (“Patent Owner is cautioned that any arguments for patentability not raised in the response may be deemed waived.”). We have reviewed Petitioner’s evidence and argument. *See* Pet. 55–56. We agree with it and adopt it as our own. For the reasons provided therein, Petitioner demonstrates that claims 18 and 19 would have been obvious over the combination of Kuntz 166, DesMarais, and the knowledge of a person of ordinary skill in the art.

4. *Summary*

In sum, we determine that Petitioner has shown by a preponderance of the evidence that claims 1, 3–8, and 17–19 would have been obvious over the combination of Kuntz 166, DesMarais, and the knowledge of a person of ordinary skill in the art.

H. REMAINING GROUNDS

Having determined that Petitioner establishes by a preponderance of the evidence that claims 1, 3–8, and 17–19 are anticipated by Mahnensmith, and the subject matter of claims 1, 3–8, and 17–19 would have been obvious over the combination of Kuntz 166, DesMarais, and the knowledge of person of ordinary skill in the art, we do not address Petitioner’s additional anticipation grounds based on Keane and Kuntz EP355, and obviousness grounds based on Keane and the knowledge of a person of ordinary skill in the art and Kuntz EP355 and Mahnensmith. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App’x 984, 990 (Fed. Cir. 2020) (nonprecedential) (“We agree that the Board need not address [alternative grounds] that are not necessary to the resolution of the proceeding.”).

III. CONCLUSION¹⁵

In summary,

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1, 3–8, 17–19	102(b)	Mahnensmith	1, 3–8, 17–19	

¹⁵ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
4, 5, 19	103(a)	Mahnensmith, knowledge of one of ordinary skill in the art ¹⁶		
1, 3–8, 17–19	102(b)	Keane ¹⁷		
4, 5, 19	103(a)	Keane, knowledge of one of ordinary skill in the art ¹⁸		
1, 3–8, 17–19	103(a)	Kuntz 166, DesMarais, knowledge of one of ordinary skill in the art	1, 3–8, 17–19	
1, 3–8	102(b)	Kuntz EP355 ¹⁹		

or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

¹⁶ This ground was not reached. *See supra* § II.H.

¹⁷ This ground was not reached. *See supra* § II.H.

¹⁸ This ground was not reached. *See supra* § II.H.

¹⁹ This ground was not reached. *See supra* § II.H.

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
17–19	103(a)	Kuntz EP355, Mahnensmith, knowledge of ordinary skill in the art ²⁰		
Overall Outcome			1, 3–8, 17–19	

IV. ORDER

For the reasons given, it is:

ORDERED that Petitioner *has shown* based on a preponderance of evidence that claims 1, 3–8, and 17–19 of U.S. Patent No. 9,399,531 B2 are unpatentable; and

FURTHER ORDERED because this is a final written decision, the 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.

²⁰ This ground was not reached. *See supra* § II.H.

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