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Paper 30
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ULTHERA, INC.,
Petitioner,

v.

DERMAFOCUS LLC,
Patent Owner.

Case IPR2016-01459
Patent 6,113,559

Before MEREDITH C. PETRAVICK, FRANCES L. IPPOLITO, and JAMES A. WORTH, *Administrative Patent Judges.*

WORTH, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

On July 19, 2016, Petitioner Ulthera, Inc. ("Ulthera") filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–18 of U.S. Patent No. 6,113,559 (the '559 patent, Ex. 1001). Patent Owner DermaFocus LLC ("DermaFocus") waived a Preliminary Response by notice on October 27, 2016. Paper 10, 1. We determined that the information presented in the Petition demonstrated a reasonable likelihood that Petitioner would prevail with respect to claims 1–4, 6–9, and 11–18 of the '559 patent. Pursuant to 35 U.S.C. § 314, we instituted trial as to those claims. Paper 11 ("Dec. Inst." or "Dec.").

After institution of trial, Patent Owner filed a Patent Owner Response to the Petition (Paper 18, "PO Resp."). Petitioner filed a Reply to Patent Owner's Response (Paper 21, "Pet. Reply").

An oral hearing was held on October 4, 2017, a transcript of which has been entered in the record. Paper 29 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1–4, 6–9, and 11–18 of the '559 patent are unpatentable.

A. Related Matters

According to the parties, the '559 patent is the subject of the following related matter: *DermaFocus LLC v. Ulthera, Inc.*, No. 1:15-cv-654-SLR (D. Del., filed July 29, 2015). Pet. 11; Paper 8, 1.

B. The ’559 Patent (Ex. 1001)

The ’559 patent is titled “Method and Apparatus for Therapeutic Treatment of Skin with Ultrasound,” and relates to the therapeutic use of ultrasound for treatment of the skin, in order to reduce wrinkles (rhytides), especially on the face. Ex. 1001, 1:7–10, 1:56–61. In particular, the invention relates to the controlled application of ultrasound energy into the dermis layer of the skin without causing significant damage to the epidermis layer of the skin. *Id.* at 1:58–65. The ’559 patent hypothesizes that the mechanism for skin rejuvenation is the triggering of a biological response that causes synthesis of new connective tissue in the dermis through activation of fibroblasts. *Id.* at 1:58–65, 3:55–4:2. The ’559 patent states that another mechanism for the stimulation of a biological response is hyperthermia in the range of 47 °C to 75 °C, which will denature a relatively small fraction of the proteins in the dermis. *Id.* at 8:40–48. The ’559 patent explains that the amount of protein denaturation depends on the temperature and the amount of time of the treatment. *See id.* at 8:48–61.

The ’559 patent states that prior art methods for reduction of wrinkles generally resulted in damage to the epidermis and dermis layers, made the patient susceptible to infection, and involved a prolonged recovery. *Id.* at 1:37–47. Such prior art methods included cryo-peeling, chemical-peeling, dermabrasion and laser ablation methods. *Id.* According to the ’559 patent, these prior art methods could cause the patient significant discomfort and pain, and make the skin appear raw or damaged for significant periods of time, on the order of weeks or months. *Id.* The ’559 patent states that embodiments of the claimed invention can produce a smoother appearance

of the skin without adversely damaging the epidermis layer of the skin. *Id.* at 1:52–54, 2:33–37.

Figure 1 of the ’559 patent is depicted below:

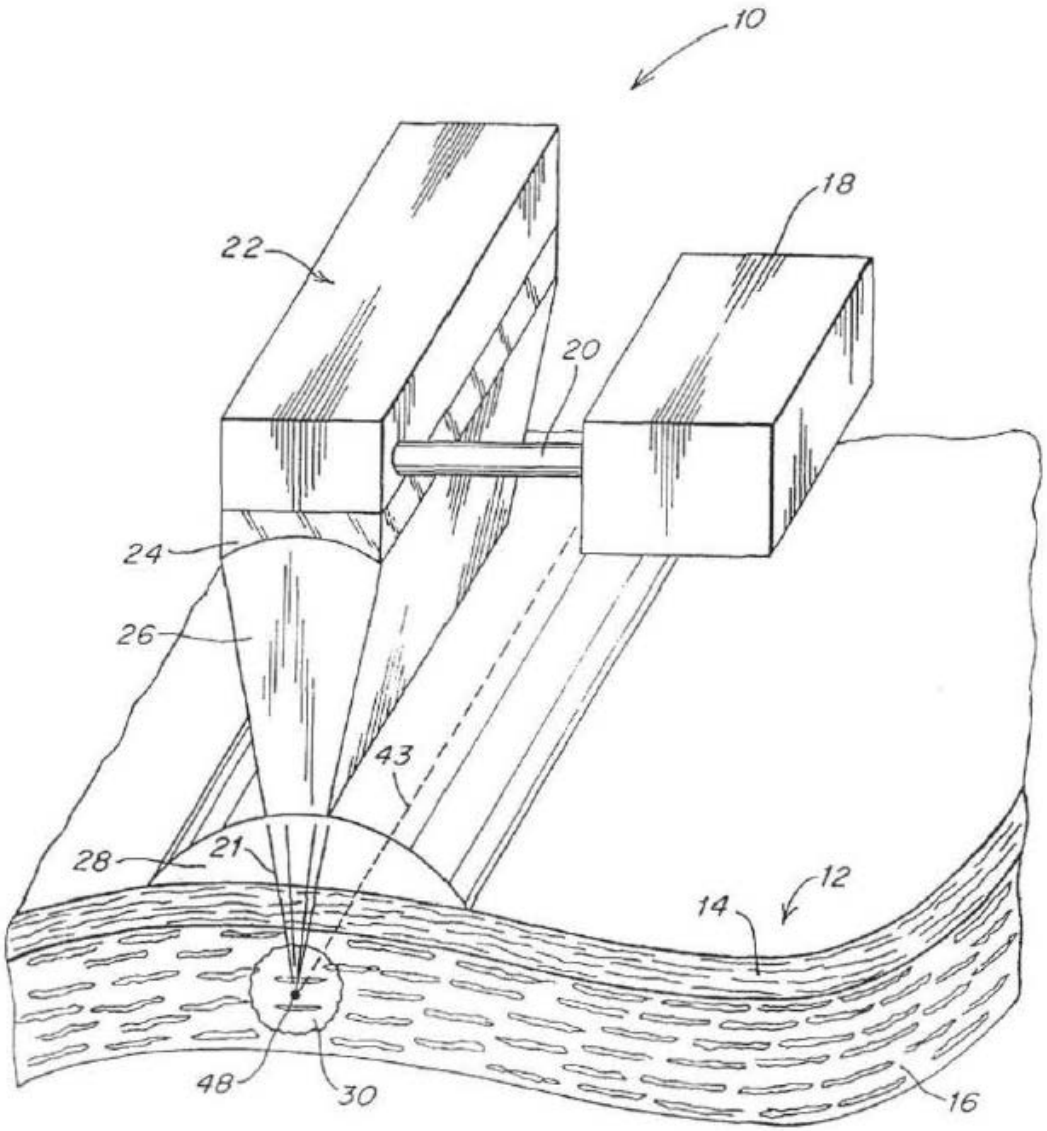

Fig. 1

Figure 1 illustrates an embodiment in which ultrasound beams are focused into the dermis layer of the skin. *See id.* at 3:13–20, 3:38–42.

C. Illustrative Claim

Claims 1–4, 6–9, 11–18 are subject to review. Independent claim 1, reproduced below, is the sole independent claim and is illustrative of the subject matter:

> 1. A method of rejuvenating human skin, the method comprising
>
> identifying a region of skin to be treated;
>
> focusing ultrasound energy in a dermis layer of the region of skin; and
>
> depositing energy in the dermis layer sufficient to heat tissue within the layer to a temperature ranging from about 47° C. to about 75° C. to stimulate or irritate a dermis layer in the region of the skin so as to cause a change in the dermis layer of the skin that results in a change in a smoothness of an epidermis layer of the skin.

Ex. 1001, 10:21–32.

D. Grounds of Unpatentability Instituted for Trial

We instituted a trial based on the following grounds of unpatentability:

References	Basis	Claims challenged
Knowlton[1] and the Technomed patent publication[2]	§ 103	1–4, 6, 7, and 12–16

[1] Knowlton, WO 96/34568, pub. Nov. 7, 1996 (Ex. 1005).

[2] Cathignol et al., FR Pub. No. 2,672,486, pub. Aug. 14, 1992 (Ex. 1006). We will refer herein to the translation (Ex. 1007) (hereinafter, "Technomed patent publication"). This reference is referred to in the Petition as "the Technomed patent." However, the Petitioner states that it is not relying on an issued patent but rather on a printed publication as prior art under

References	Basis	Claims challenged
Knowlton, the Technomed patent publication, and Technomed PCT[3]	§ 103	8, 9, 11, 17, and 18

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016). Under that standard, and absent any special definitions provided in the specification, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner asserts that no terms require construction. Pet. 14. Patent Owner requests construction of the limitation "to stimulate or irritate a dermis layer in the region of the skin so as to cause a change in the dermis layer of the skin," as recited in claim 1. For the reasons that follow, we do not provide an express construction of any terms.

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35 U.S.C. § 102(b). *See* Pet. 13. Therefore, for clarity, we refer to it as "the Technomed patent publication."

[3] Chapelon et al., WO 93/12742, pub. July 8, 1993 (Ex. 1008). We will refer herein to the translation (Ex. 1009) (hereinafter, "Technomed PCT").

Patent Owner argues that "to stimulate" or "irritate" means "to increase the functional, biological activity of the dermis." PO Resp. 10. Petitioner argues that it is not necessary to construe this limitation because it is undisputed that Knowlton, relied upon by Petitioner to teach or suggest this limitation, discloses heating the dermis to produce a biological response. Reply 3 (citing Ex. 1005, 1:9–22, 5:20–26). At the oral argument, counsel for Patent Owner agreed that Knowlton discloses this limitation. Tr. 24:10–21. Accordingly, we do not provide an express construction of this limitation. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (claim terms require construction only as relevant and only to the extent necessary to resolve the issues in dispute).

As set forth in more detail below, the dispute in this proceeding centers on the term "focusing ultrasound energy in a dermis layer of the region of the skin." Ex. 1001, 10:24–25. The parties have not requested construction of this limitation nor provided proposed constructions thereof. We do not provide an express construction because, although the limitation is central to our analysis, the construction does not appear to be in dispute and there appears to be agreement among the parties and experts that the term "focused ultrasound," at least includes a type of ultrasound that has a focal point or focal region. *See Vivid Techs., Inc.*, 200 F.3d at 803 (construing terms to resolve issues in dispute). We note that focused ultrasound is depicted, *inter alia*, in Figure 1 of the '559 patent. Ex. 1001, 5:20–30; Tr. 18:16–25 (Counsel for Petitioner: "There's basically a lens. You have an ultrasound source and you have a lens and the lens concentrates the sound waves at a desired point."); Ex. 1003 (Schafer Decl.) ¶ 18 (focus line); Ex. 2002 (Palmeri Decl.) ¶¶ 17, 20 (focused ultrasound has a focal

region); Ex. 2003 (Schafer Depo.), 23:20–24 (focal point), 24:14–17 (focal region).

B. Person of Ordinary Skill in the Art

According to Petitioner, a person having ordinary skill in the field of the subject matter described in the '559 patent would have at least a bachelor's degree in electrical, mechanical, or biomedical engineering with at least 4–5 years of work experience designing and/or working with medical devices using energy for the treatment of tissue, with at least some experience with focused ultrasound, and would be familiar with the anatomy/biology of the areas that the medical devices are intended to treat, or a master's degree in electrical, mechanical, or biomedical engineering with at least 2–3 years of work experience and other knowledge as discussed above. Pet. 22 (citing Ex. 1003 ¶¶ 42–44). Patent Owner does not offer a counter-definition with respect thereto. *See* PO Resp. 10–12. On this record, and given the general lack of dispute, we agree with Petitioner that a person of ordinary skill in the art would have at least a bachelor's degree in electrical, mechanical, or biomedical engineering with at least 4–5 years of work experience designing and/or working with medical devices using energy for the treatment of tissue, with at least some experience with focused ultrasound, and would be familiar with the anatomy/biology of the areas that the medical devices are intended to treat, or a master's degree in electrical, mechanical, or biomedical engineering with at least 2–3 years of work experience. *See* Ex. 1003 ¶ 44. As such, a person of ordinary skill would be an engineer with experience designing medical devices intended to focus ultrasound energy into patients, or experience working with such devices.

C. Principles of Law

To prevail in its challenges to the patentability of the claims, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

D. Obviousness over Knowlton (Ex. 1005) and the Technomed patent publication (Ex. 1007)

Relying on the Declaration of Dr. Mark Schafer (Ex. 1003), Petitioner contends that Knowlton and the Technomed patent publication render obvious claims 1–4, 6, 7, and 12–16. Pet. 29–49. We have reviewed Petitioner's explanation identifying where each limitation allegedly appears in Knowlton and the Technomed patent publication, along with the testimony of Petitioner's declarant, Mark E. Schafer, Ph.D. *Id.*; Ex. 1003 ¶¶ 45–75. We have also reviewed Patent Owner's assertions and evidence as to why Petitioner's explanations and evidence are deficient, as well as the testimony of Patent Owner's declarant, Mark L. Palmeri, Ph.D. PO Resp. 12–59; Ex. 2002 ¶¶ 43–88.

1. Overview of Knowlton

Knowlton, titled "Apparatus for Skin Resurfacing," relates to a method and apparatus for shrinking collagen containing tissue, while creating no more than a first degree burn on an external surface. Ex. 1005, at [54], 1:4–7. Knowlton discloses the use of energy sources including "RF, microwave, ultrasound, laser and the like."[4] *Id.* at 11:4–7. Knowlton discloses applications including:

> tightening and firming soft tissue, unstable joints due to collateral ligament laxity, the treatment of unstable spinal column disorders, treatment of weaknesses of the abdominal wall, treatment of other connective tissues, esophageal hernia with reflux, urinary incontinence in women, dysdynamic segments of the myrocardium [sic] and other aneurysmal dilatations of the vessel, sleep apnea, laxity and wrinkling of the skin, and the like.

Id. at 5:14–19. Knowlton states a mechanism of thermal shrinkage of collagen, e.g., in a dermis underlying the epidermis of the skin, denaturation of the triple helix of the collagen molecule, followed forty-eight hours later by the proliferation of fibroblasts at the injured site, producing scar collagen. *Id.* at 1:19–25, 2:8–11, 11:25–27. Knowlton describes a "reverse thermal

[4] Knowlton includes ultrasound in a list of "electromagnetic energy sources." Ex. 1005, 11:6–7; *see also id.* at 6:25–26. Dr. Schafer states that a person of ordinary skill in the art would understand that ultrasound is not electromagnetic energy but is instead mechanical energy. Ex. 1003 ¶ 47. Nevertheless, Dr. Schafer declares that in his opinion, the error is "editorial rather than substantive" because "Knowlton is clear that his invention teaches the use of ultrasound as a means for tissue heating." *Id.* On the basis of this record, we agree with Dr. Schafer that Knowlton discloses ultrasound as a modality for heating. We explore in more detail below which types of ultrasound would have been understood to be included in various embodiments (i.e., focused ultrasound or unfocused ultrasound).

gradient from the skin layer to the underlying collagen tissue," e.g., to heat the dermis "above 65 degrees" while avoiding blistering on the surface of the skin. *Id.* at 4:17–27, 5:30–6:7.

2. Overview of the Technomed patent publication

The Technomed patent publication, titled "Ultrasound apparatus for extracorporeal therapeutic treatment of varicosities and superficial varicose veins," relates to an ultrasound apparatus for the extracorporeal therapeutic treatment of varicosities and superficial varicose veins. Ex. 1007, [54], 1:3–4. The Technomed patent publication describes transmitting ultrasonic waves capable of producing in a focal region an ultrasonic intensity of between about 100 W/cm^2 and about 2 kW/cm^2, and preferably between 100 W/cm^2 and 500 W/cm^2. *Id.* at 2:19–21, 5:1–10. The Technomed patent publication states a mechanism in which the target veins close due to thermal destruction of the vein's epithelium. *See id.* at 5:8–10.

3. Analysis

Petitioner sets forth how each limitation of claims 1–4, 6, 7, and 12–16 would be understood to be disclosed by Knowlton and the Technomed patent publication, and its assertions as to why it would have been obvious to a person of ordinary skill to combine the references to arrive at the invention of claims 1–4, 6, 7, and 12–16. Pet. 29–49. Patent Owner disagrees. PO Resp. 12–59.

a. Claim 1

In the Petition, Petitioner alleges how each limitation of claim 1 would be understood to be disclosed by Knowlton and the Technomed patent publication, and why such a combination would have been obvious. Pet. 33–41. Patent Owner disputes whether Knowlton or the Technomed

patent publication discloses "focusing ultrasound energy in a dermis layer of the region of skin," as recited by claim 1, and whether a person of ordinary skill in the art would have combined the references as asserted. PO Resp. 12–59. However, Patent Owner does not dispute whether the prior art discloses the other limitations of claim 1.

Petitioner bears the burden of proof on each limitation. 35 U.S.C. §316(e). We analyze first the undisputed limitations and then the disputed limitation and issues.

i. Undisputed limitations

As a preliminary matter, we first address the undisputed limitations. With respect to the limitation "to stimulate or irritate a dermis layer in the region of the skin . . . so as to cause a change in the dermis layer of the skin that results in a change in a smoothness of an epidermis layer of the skin," we find that Knowlton discloses tightening skin, and in certain embodiments treating wrinkles, by inducing the formation and contraction of scar collagen. Ex. 1005, 3:16–18, 5:13–21; *see* Pet. 37–38, 40–41.

With respect to the limitations "identifying a region of skin to be treated" and "depositing energy in the dermis layer sufficient to heat tissue within the layer to a temperature ranging from about 47º C. to about 75º C.," we find that Knowlton discloses heating the dermis to 40°C to 80°C. *See* Ex. 1005, 11:3–7, 11:25–27, 14:8–11, claim 49; *see also* Pet. 38–39.[5] We find that the overlapping temperature range of Knowlton satisfies, or in the alternative renders obvious, the recited temperature limitation. *See*

[5] As discussed *supra*, Petitioner asserts, and Patent Owner concedes, that Knowlton disclose heating the dermis to produce a biological response. Pet. 36; Reply 3 (citing Ex. 1005, 1:9–22, 5:20–26); Tr. 24:10–21.

ClearValue, Inc. v. Pearl River Polymers, Inc., 668 F.3d 1340, 1345 (Fed. Cir. 2012) (overlapping prior art range meets limitation, e.g., where there is no argument that there is criticality to the claimed range or that the system works differently over a range of values); *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006).

ii. Disputed Limitation

"focusing ultrasound energy in a dermis layer of the skin"

We turn now to the disputed limitation, "focusing ultrasound energy in a dermis layer of the region of skin." Petitioner essentially presents two theories of the case. First, Petitioner asserts that Knowlton itself discloses the "focusing" limitation. Pet. 34. Under this theory, the Technomed patent publication is not being relied upon for any particular limitation and is merely relied on for assistance to a person of ordinary skill in enabling the invention, if at all. Petitioner still argues this ground as based on obviousness rather than anticipation by Knowlton. Second, and in the alternative, Petitioner argues that the Technomed patent publication discloses "focusing ultrasound energy in a dermis layer of the region of skin." *Id.* at 31–35. Patent Owner disagrees in each case. PO Resp. 12–59.

A. Knowlton's treatment of collagen

Petitioner asserts that Knowlton discloses "focusing ultrasound energy in a dermis layer." Pet. 24, 29, 34, 38 (citing, e.g., Ex. 1005, 1:9–14, 5:20–26, 11:3–7, 11:25–27, 14:29–15:8; Ex. 1003 ¶ 62). The Petition sets forth its contentions with respect to Knowlton as follows:

> Knowlton also discloses "focusing ultrasound energy in a dermis layer of the region of skin." Ex. 1003 ¶ 62. Knowlton teaches that the dermis is composed primarily of collagen and that the dermis provides the main structural support for the skin.

> Ex. 1005 at 1:9-14. Knowlton further teaches that wrinkling of the skin occurs as a consequence of inadequate support of epidermis. *Id.* at 5:20-21. Knowlton describes using energy to heat and denature collagen beneath the skin surface, including in the dermis layer. *Id.* at 11:25-27. Knowlton also describes that ultrasound is one of the energy sources that can be used and describes the use of focused ultrasound. *Id.* at 11:3-7, 15:1-8.

Pet. 34; *see also* Pet. 39 (claim chart).

Patent Owner asserts that Knowlton teaches two distinct methods and devices, one for treating the dermis and a second for treating subcutaneous and deeper tissue. PO Resp. 14–15 (citing Ex. 2002 ¶ 45; Ex. 2003, 73:18–21). Patent Owner states that the first method heated the dermis, e.g., by creating a reverse thermal gradient, to induce scar collagen deposition and contraction of collagen to tighten skin and reduce wrinkles (the embodiment of Knowlton Figure 1). *Id.* at 15 (citing Ex. 1005, 5:20–6:17; 10:3–11:30, Fig. 2; Ex. 2002 ¶ 45). Patent Owner states that the second device and method was for applying energy "through the skin" to sculpt fat in the "underlying subcutaneous layer," i.e., for liposculpture. *Id.* at 15–16 (citing Ex. 1005, 3:3–6, 4:15–26, 6:18–24, 12:7–10, 14:16–15:8, 16:16–26, Ex. 2002 ¶ 46). Patent Owner asserts that the second device was directed to the fibers of collagen that package fat cells in the subcutaneous layer. *Id.* Patent Owner insists that this liposculpture device contains a focusing element which was not found in the first device. *Id.* at 16, 20 (citing, e.g., Ex. 1005, 7:4–6, 14:19–15:8, 15:22–27, Fig. 4; Ex. 2002 ¶¶ 52–53; Ex. 2003, 57:2–8, 74:22–75:21).

Of the portions of Knowlton on which Petitioner relies, only one expressly discloses focused ultrasound, i.e., Ex. 1005, 14:29–15:8.[6] Petitioner thus primarily relies on Knowlton's disclosure of using focusing element 62 to heat collagen tissue 14, in arguing that Knowlton discloses focusing ultrasound into the dermis. *See* Ex. 1005, 15:1–8, *cited in* Pet. 34, 39 (claim chart). This is the embodiment of Figure 4 of Knowlton. *See* Ex. 1005, 14:23–15:9. However, this portion of Knowlton begins with a discussion of the "underlying subcutaneous layers" and "deeper soft tissue layers": "Referring now to Fig. 4, an apparatus 58 for creating a desired contour effect of underlying subcutaneous layers or deeper soft tissue layers which include loculations of fat with fibrous septae made of collagen tissue is illustrated." Ex. 1005, 14:23–25. This discussion is consistent with the preceding paragraph of Knowlton, which explains that "[t]he fibrous septae in subcutaneous fat layers can be contracted to tighten the soft tissue." *Id.* at 14:16–17.

In context, we understand Knowlton's description of focused ultrasound to be directed to subcutaneous tissue rather than the dermis. In particular, this portion of Knowlton discloses a method of tightening subcutaneous tissue, e.g., to achieve liposculpture, rather than a treatment of wrinkles in the skin. *See id.* at 14:21.[7]

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[6] The other cited portions of Knowlton describe the composition of the skin (*id.* at 1:9–14), and a method of contracting collagen with a reverse thermal gradient and the production of scar collagen in the dermis (*id.* at 5:20–26, 11:25–27).

[7] Petitioner argued at oral argument that the embodiment of Knowlton Figure 4 includes the dermis layer because Dr. Palmeri agreed that collagen tissue 14, in another embodiment (i.e., the embodiment of Figure 1), includes the dermis. Tr. 9:6–10:20, 16:6–10. This argument was not

Further, we understand the use of the term "subcutaneous" to mean below the skin, i.e., below the dermis.[8] The Knowlton reference uses the term "subcutaneous" in contradistinction to the dermis, and to refer to areas below the dermis. *See* Ex. 1005, 12:7–9; Fig. 2; *see also* Ex. 1015, 909; Ex. 2003, 174:3–9, 174:12–24; PO Resp. 21–22, 46; Tr. 29:17–30:25 (discussing Ex. 1005, 14:23–15:8).

The next issue is whether the embodiment of Knowlton's Figure 1 itself can be understood to use focused ultrasound, or whether Knowlton otherwise discloses or suggests the use of focused ultrasound in the dermis. In particular, Petitioner argues that Knowlton describes applying energy to heat and denature collagen in the dermis layer, and asserts that ultrasound is one of the energy sources that can be used to heat the dermis. Pet. 34 (citing Ex. 1005, 11:3–7, 11:25–27). Petitioner argues that the Knowlton reference "broadly discloses" the use of ultrasound. Reply 4; Pet. 34 (citing Ex. 1005,

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developed in the Petition. Nevertheless, the Petition contains arguments regarding collagen in grouping the embodiments, and we will therefore address this aspect of Petitioner's argument. Pet. 34; Reply 7. Patent Owner argues that the ultrasound in the embodiment of Knowlton Figure 4 passes through epidermis layer 12 and through other skin layers before being focused on the collagen tissue of the fibrous septae of the subcutaneous layer. PO Resp. 23, 28 (citing Ex. 1005, 16:16–26; Ex. 2003, 74:22–75:12, 146:9–21, 159:15–25, 174:12–24). We agree with Patent Owner. Although there may be collagen in both the dermis layer and the subcutaneous layer, the embodiment of Figure 4 is discussing the collagen of the subcutaneous layer rather than the collagen of the dermis. Ex. 1005, 14:16–15:8, 16:16–26.

[8] Petitioner argued at oral argument that its expert testified that "subcutaneous" can mean below the surface of the skin. Tr. 60:18–20. However, we find that the evidence of record indicates that the subcutaneous layer is the layer below the dermis. *See, e.g.*, Ex. 1015, 909.

11:3–7, 15:1–8). Petitioner asserts that Knowlton discloses contouring subcutaneous layers, and that this is the same mechanism used to denature dermal collagen. Reply 6 (citing Ex. 1005, 1:9–22, 5:20–26, 12:7–9, 14:23–15:8, 16:22–23, Fig. 2). Petitioner also argues that Patent Owner seeks to improperly limit the disclosure of Knowlton to exemplary embodiments. Reply 7–8 (citing, e.g., *Ultradent Prods. v. Life-Like Cosmetics*, 127 F.3d 1065, 1068 (Fed. Cir. 1997)).

Patent Owner argues that Petitioner's expert agreed that Figure 1 does not identify an element as a convergent lens. *See* PO Resp. 17–18, 20 (citing Ex. 2003, 79:12–16, 79:25–80:8, 128:15–22, 69:14–24). As above, Patent Owner argues that Knowlton discloses two distinct methods with different purposes and different targets. Patent Owner contends that the conventional wisdom was that focusing was needed for deeper applications but that unfocused energy would be better for the dermis because there would be uniform heating and less risk of a focal burn. PO Resp. 14–26 (citing Ex. 2002 ¶ 61).[9]

We find that Knowlton only discloses the use of focusing element 62 for treatment of the subcutaneous layer. Ex. 1005, 14:16–15:8; Ex. 2002 ¶ 57; Ex. 2003, 174:12–24. Although Knowlton discloses the use of ultrasound to heat the dermis in the embodiment of Figure 1, it is unclear at

[9] Patent Owner argues that Knowlton fails to disclose focused ultrasound in the dermis and also teaches away therefrom. PO Resp. 24–26. Petitioner argues that Knowlton does not teach avoiding the dermis. Reply 9–10 (citing, e.g., *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). Although we credit the expert testimony of Dr. Palmeri that there may be a focal burn from focused ultrasound, Ex. 2002 ¶ 61, *inter alia*, based on the Technomed PCT's teachings, discussed *infra*, we do not understand this teaching to come from Knowlton itself.

best whether this ultrasound is focused or unfocused. We credit the testimony of Dr. Palmeri that unfocused ultrasound may be used for heating, that focused ultrasound has different applications than unfocused ultrasound, and that there may be reasons to use one application as opposed to another. Ex. 2002 ¶ 61. As such, Petitioner has not shown that Knowlton necessarily discloses focused ultrasound in the embodiment of Figure 1, as opposed to unfocused ultrasound. *See Southwire Co. v. Cerro Wire LLC*, 870 F.3d 1306, 1311 ("While '[w]e have recognized that inherency may supply a missing claim limitation in an obviousness analysis,' *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1194–95 (Fed. Cir. 2014) (collecting cases), we have emphasized that 'the limitation at issue *necessarily* must be present' in order to be inherently disclosed by the reference, *id.* (emphasis added)."). *See also Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A.*, 865 F.3d 1348, 1354–55 (Fed. Cir. 2017).

Petitioner asserts that a person of ordinary skill would have had a choice between two types of ultrasound, focused or unfocused. Reply 5 (citing Ex. 1024:15–20).[10] We recognize that a choice among a limited set of options might be obvious where the behavior of the system is predictable.

[10] Petitioner appears to argue that Knowlton actually discloses focused ultrasound in the dermis, but because this is a ground based on obviousness, we consider as part of this discussion whether it would have been obvious to a person of ordinary skill to combine the embodiments of Knowlton with each other. *See* Reply 5, 8 (citing *Musculoskeletal Transplant Found. v. MiMedx Grp.*, Inc., IPR2015-00664, 2016 WL 8944642, at *15 (Aug. 16, 2016) ("[A] reference disclosure is not limited only to its preferred embodiments, but is available for all that it discloses and suggests to one of ordinary skill in the art."); *see also* Pet. 34. For the reasons set forth herein, we conclude that Petitioner has not established that it would have been obvious to a person of ordinary skill to combine the embodiments.

See KSR, 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."). However, Petitioner has not demonstrated that focused ultrasound behaves predictably in the same manner as unfocused ultrasound.

To the contrary, we agree with Patent Owner that focused ultrasound has the potential for destructive effects, i.e., from heating and cavitation. *See* Ex. 1009, 1:30–2:3 ("In the case of a moderate temperature and a long application period, a heat diffusion phenomenon occurs around the focal point, . . . which in turn may lead to the destruction of healthy areas . . . . In the case of elevated temperature and a short application period, the acoustic intensity at the focal point exceeds the aforementioned cavitation threshold, resulting in cavitation effects having a substantial destructive power. . . . This leads to poorly controlled tissue destruction . . . ."); PO Resp. 6, 43, 52, 55, 58; *see also* Ex. 2002 ¶¶ 91, 107–108. In view of these effects at the focal point, we are not persuaded by Petitioner's argument that focused ultrasound and unfocused ultrasound are interchangeable, or that it would have been obvious to use focused ultrasound with the embodiment of Knowlton's Figure 1.

B. Treatment of varicosities and superficial varicose veins in the Technomed patent publication

In the alternative, Petitioner asserts that the Technomed patent publication discloses "focusing ultrasound in a dermis layer." Pet. 34–36, 39 (citing Ex. 1007, 5:6–10). Petitioner asserts that the Technomed patent publication is discussing the dermis when it discusses "treatment of varicosities and superficial varicose veins." *See id.* at 34–35; *id.* at 39 (claim

chart) (citing Ex. 1007, 2:17–21; 5:1–10; Figs. 3, 4; Ex. 1003 ¶¶ 29, 54, 62). Petitioner asserts that the dermis would have received focused ultrasound in the embodiment of the Technomed patent publication because, according to Petitioner, "varicosities and superficial varicose veins" would have been understood to be located in the dermis. *See id.* at 34–35 (citing Ex. 1003 ¶¶ 29, 54; Ex. 1018, 36, 39). Petitioner argues that the Technomed patent publication thereby discloses heating the dermis by applying focused ultrasound. *Id.* at 36 (citing Ex. 1007, 5:6–10; Ex. 1003 ¶ 54).

Patent Owner disagrees, and asserts that "varicose veins" refer to dilated subcutaneous veins, i.e., larger than 4 mm. PO Resp. 32–33 (citing Ex. 2002 ¶ 74; Ex. 2012, 488; Ex. 2008, 639; Ex. 2003, 272:6–12). According to Patent Owner, there are also medium-sized veins below the dermis referred to as reticular veins. *Id.* at 33 (citing Ex. 2002 ¶ 75; Ex. 2012, 488; Ex. 2003, 268:20–269:7). Patent Owner asserts that the tiny vessels in the dermis "were not even called 'veins,'" but were called "venules." *Id.* (citing Ex. 2012, 488; Ex. 1018). Patent Owner asserts that the Technomed patent publication makes no mention of telangiectasia, venules, or the dermis, and a person of ordinary skill would interpret the Technomed patent publication's disclosure of varicose veins to refer to the subcutaneous region. *Id.* at 43–44 (citing Ex. 2002 ¶ 93; Ex. 2003, 316:9–317:9). Patent Owner argues that a person of ordinary skill in the art would have recognized the veins illustrated in the Technomed patent publication to be saphenous veins and their great tributaries, which are located in the subcutaneous layer. *Id.* at 37, 46 (citing Ex. 1007, Figs. 1, 3, 4, 5, 6, 8, 9; Ex. 2002 ¶ 83; Ex. 1018, 36–38; Ex. 2005, 1596; Ex. 2003, 274:25–275:11). Petitioner argues that the figures from the Technomed patent publication are

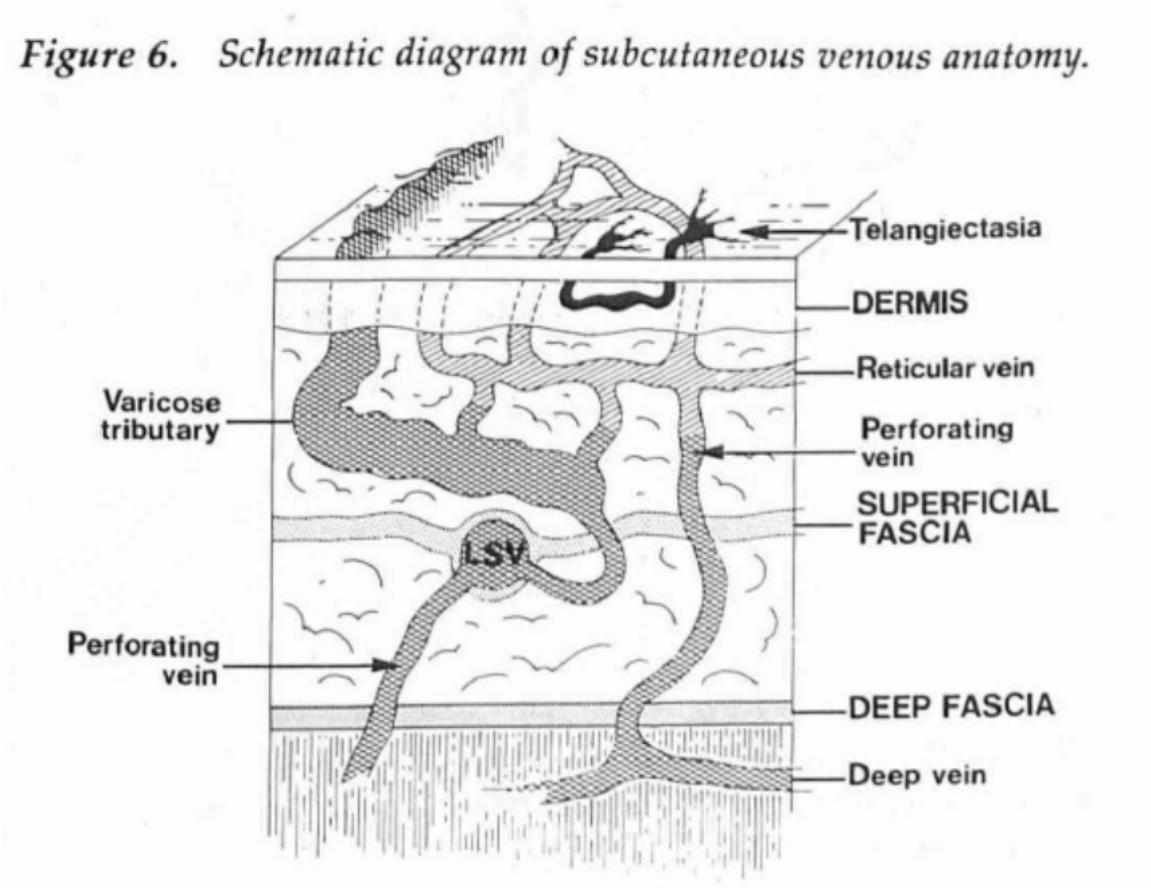
not drawn to scale and are not intended to depict the precise location of the veins. Reply 14 (citing *Hockerson-Halberstadt, Inc. v. Avia Group, Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000)).

We address the treatment of (1) superficial varicose veins and (2) varicosities in the Technomed patent publication as follows.

1. Treatment of superficial varicose veins in the Technomed patent publication

Petitioner argues that treating superficial varicose veins as described in the Technomed patent is essentially treating tissue in the dermis. Pet. 6, 31 (citing Ex. 1003 ¶ 29). Petitioner argues that one skilled in the art would understand that various blood vessels and capillaries are located within the dermis. Pet. 24, 30, 31, 33–35, 37–39 (citing Ex. 1003 ¶ 29; Ex. 1015, 909–910; Ex. 1018, 39); Reply 15 (citing Ex. 2003, 84:2–18, 287:7–18, 289:8–17). Petitioner asserts that a person skilled in the art would also appreciate that varicose veins are located immediately beneath the skin and may be located within the dermis or directly beneath and in contact with the dermis. *Id.* at 24 (citing Ex. 1003 ¶ 29; Ex. 1018, 36).

Petitioner relies, *inter alia*, on the following anatomical diagram of subcutaneous venous anatomy:



Schematic diagram of subcutaneous venous anatomy from Anatomy of the Superficial Venous System, Dermatol. Surg. 39 (1995) (Ex. 1018, *reproduced in* Pet. 25).

Patent Owner asserts that, in this three-dimensional drawing, the dashed lines for varicose and reticular veins indicate that they run below the dermis, and not on the surface of the skin. PO Resp. 47 (citing Ex. 2002 ¶ 96).

Dr. Schafer avers that "varicose veins are tissues located immediately beneath the skin, and may be located directly beneath and in contact with the dermis or may be located within the dermis." Ex. 1003 ¶ 29 (quoting Ex.

1018, 36 ("The etiology of varicose veins may be multifactorial, but there is only one final common manifestation: that is the dilated venous conduit, with incompetent valves. The smallest valve-containing venules, in which incompetence may occur, are situated in the lower dermis. According to the size and position of the intradermal and subcutaneous varicose veins they are categorized as telangiectases (blue to red), venulectases, reticular veins, and nonsaphenous and saphenous varicose veins.")).[11]

According to Patent Owner and Patent Owner's Declarant, the term "superficial varicose veins" has two possible meanings. Patent Owner argues that the word "superficial" in "superficial varicose vein" means superficial to the deep muscle fascia, but that the term can be also used to refer in particular to the subcutaneous region, i.e., below the dermis. *See* PO Resp. 35. According to Dr. Palmeri, "superficial varicose veins" is an umbrella term that can refer either to (a) all dilated veins (including smaller venules) or (b) can more particularly refer to larger subcutaneous veins:

> 73. At the time of the invention, one of ordinary skill would have understood that "varicose veins" had two different meanings depending on the context. In some contexts, "varicose vein" was used as an umbrella term to include any vein with a malfunctioning (incompetent) valve, including a small venule in the skin. However, even in this general sense, varicose veins typically referred to large, subcutaneous veins (e.g., the saphenous veins of the leg). Ex. 2023 at 1702–03 (varicose veins: "swollen, distended, and knotted veins, <u>usually in the subcutaneous tissues of the leg</u>. They result from a stagnated or sluggish flow of the blood, in combination with defective valves and weakened walls of the veins." (emphasis added)); Ex. 2014

[11] We understand Exhibit 1018 to be including "varicose veins" and "venules" as part of the same discussion, and that it is unclear from Exhibit 1018 whether the terms are being used interchangeably or differently.

> at 1575–76 (same); Ex. 2022 at 1694 (varicose vein: "A tortuous, dilated vein with incompetent valves. . . . . The saphenous veins of the legs are most often affected." (emphasis added)); Ex. 2013 (Mosby's 1990) 1225 (same).
>
> 74. In other contexts, the term "varicose veins" was used to refer *only* to large subcutaneous veins. This meaning was well-known and accepted at the time of the invention. For example, in 1996, an international committee of experts in chronic venous diseases published a "Consensus Statement" documenting accepted definitions in the field. Ex. 2012 (1996 Consensus Statement). "Varicose veins" were defined as "palpable, dilated subcutaneous veins usually larger than 4 mm." *Id.* at 488; Ex. 2008 (Consensus Reporting Standards) 639 (similar definition).

Ex. 2002 ¶¶ 73–74; *see also* Ex. 2012, 488. We find Dr. Palmeri's testimony to be credible because, *inter alia*, rather than simply arguing for one narrow meaning, he acknowledges that there is more than one possible meaning for the term "superficial varicose veins." *See id.* We further find Dr. Palmeri's testimony that superficial varicose veins refers to subcutaneous veins in the context of the Technomed patent publication to be supported by record evidence. *See* Ex. 2002 (Palmeri Decl.) ¶ 71. As set forth herein, we determine that Petitioner has not proven that the term "superficial varicose veins" in the Technomed patent publication refers to venous structures in the dermis.

Dr. Palmeri's testimony is supported, *inter alia*, by a definition that defines varicose veins as being subcutaneous veins. Ex. 2012 ("Consensus Statement"), 488 ("Varicose veins are palpable, dilated subcutaneous veins usually larger than 4 mm"). This definition classifies veins in

contradistinction to smaller venules, which are referred to as telangiectases when dilated. *Id.*[12]

Moreover, Petitioner's own Declarant, Dr. Schafer, acknowledged on cross-examination that there are two possible meanings for "superficial vein": (a) a "colloquial[]" meaning that refers to structures in the dermis and (b) an "anatomical" meaning that refers to venous structures "further beneath." Ex. 2003, 33:5–34:23. At bottom, Petitioner asks us to apply what Dr. Schafer refers to as a "colloquial[]" understanding to the Technomed patent publication. *See id.* We decline to do so for the reasons that follow.

First, to the extent that Petitioner is relying on its definition of a person of ordinary skill in the art as an engineer rather than a physician in asking for a "colloquial" understanding of the Technomed patent publication, we determine, as above, that a person of ordinary skill in the art would be an engineer with sufficient biomedical understanding to safely apply focused ultrasound into human subjects. Further, we would expect an engineer to use precise language when required. As such, the fact that an

[12] Petitioner suggests that Dr. Palmeri's testimony in this regard does not reflect that of a person of ordinary skill because Dr. Palmeri did not recall previously consulting the Consensus Statement of Exhibit 2012 and invoked attorney client privilege in refusing to answer how he learned of some of the other references. Reply 12 n.1 (citing Ex. 1024, 200:3–8, 19:15–20, 21:8–22:20). Petitioner further asserts that Dr. Palmeri was a sophomore in college at the time of filing of the '559 patent in 1997, with no experience in ultrasound. Reply 19 n.2 (citing Ex. 1024, 7:15–8:1, 9:7–22). Although we consider this cross-examination testimony in weighing the credibility of Dr. Palmeri, we find that Dr. Palmeri's testimony is consistent with other evidence of record, including the testimony of Dr. Schafer. *See, e.g.*, Ex. 2003, 33:5–34:23.

engineer rather than a physician uses a term does not necessarily mean that the engineer would intend a "colloquial" meaning for a term.

Further, we are not persuaded by Petitioner's other arguments that a person of ordinary skill would have understood the Technomed patent publication to use focused ultrasound in the dermis. Petitioner argues that the Technomed patent publication cites, as background, articles that use "varicose vein" in the broader sense. Reply 13 (citing Ex. 1007, 1:5–25; Ex. 1022, 221, 222, 227, 229; Ex. 1023, 130–131); Tr. 64:9–65:21. Patent Owner responds that these articles are not incorporated by reference. Tr. 53:1–56:23. We agree that these articles are not incorporated by reference into the Technomed patent publication. Ex. 1007, 1:5–25.

Patent Owner argues that, in any event, the referenced articles are in the context of laser treatment rather than ultrasound. Tr. 53:1–56:23.[13] Although the Technomed patent publication cites background prior art of both ultrasound and laser treatments, Petitioner only relies on the background laser treatment articles for evidence that the term "varicose vein" has a broader meaning. *See* Reply 13 (citing Ex. 1022, 221, 222, 227, 229; Ex. 1023, 130–131). As such, we agree with Patent Owner that the reference in the Technomed patent publication to laser treatment articles does not establish that "varicose veins," as used in the Technomed patent publication, refers to the dermis, nor that a person of ordinary skill would have understood from the Technomed patent publication that ultrasound could be directed into the dermis.

[13] We consider this argument made at oral argument because it was Patent Owner's first opportunity to respond to arguments made in Petitioner's Reply.

Patent Owner asserts that, at the time of the invention, focused ultrasound lacked the precision to target these venules due to their small size and branching network. PO Resp. 38 (citing Ex. 2002 ¶ 84; Ex. 2003, 84:20–85:2, 87:10–88:8, 89:20–92:12). Patent Owner asserts that a person of ordinary skill in the art at the time of the invention would have used more precise methods such as laser treatment or the injection of chemicals to collapse and harden venules (sclerotherapy). *Id.* at 38–39 (citing Ex. 2002 ¶¶ 85–86; Ex. 2015, 66; Ex. 2016, 470, 472, 474). Patent Owner argues that the method of the Technomed patent publication would have been understood to target large, subcutaneous veins but that it would not have made sense to use with dermal telangiectasia that have a diameter (1 mm or less), which is smaller than the focal region used in the Technomed patent publication. *See id.* at 39–41 (citing Ex. 1007, 10:7–11, 11:14–19, 11:23–29, Figs. 3–6, 8; Ex. 2002 ¶ 87; Ex. 2003, 227:2–4, 232:1–6, 219:4–220:3, 220:5–13; Ex. 2016, 472), 50 (citing Ex. 1003 ¶ 54; Ex. 2002 ¶¶ 100–101). Patent Owner argues that it would have been unsafe to target venules in the dermis, which do not dissipate heat as well as the larger subcutaneous veins. *See id.* at 41 (citing Ex. 2002 ¶ 88).

We are mindful of the destructive capacity of focused ultrasound treatment, caused by both heating and explosive cavitation effects. *See* Ex. 1009, 1:30–2:3.[14] In the face of this destructive potential of focused

[14] Patent Owner argues that the Technomed patent publication teaches away from focusing ultrasound into the dermis because it teaches avoiding target tissue. *See* PO Resp. 30 (citing Ex. 2002 ¶ 69). Although we do not understand the Technomed patent publication itself to describe harm to the dermis, we understand the Technomed PCT to warn of the destructive capacity of focused ultrasound as described herein.

ultrasound, and absent a clear statement in the Technomed patent publication as to the particular type of venous structures being targeted by focused ultrasound, Petitioner has not demonstrated that a person of ordinary skill in the art would have understood the Technomed patent publication to disclose that it is safe to apply focused ultrasound to the dermis. Petitioner argues that Patent Owner is inaccurate in arguing that blood vessels within the dermis "could not be treated." *See* Reply 15. The premise of this argument appears to be incorrectly shifting the burden of persuasion to Patent Owner, and also appears to be based on an incorrect standard—the issue is not whether a person of ordinary skill in the art could have treated the dermis, but rather whether it would have had a reason to treat the dermis and whether the prior art was sufficiently enabling so as to confer a reasonable expectation of success on a person of ordinary skill in the art.

Petitioner also, in its Reply, relies on prior art treatment of the cornea for the proposition that focused ultrasound can be safely applied to the dermis. *See* Reply 16 (citing Ex. 1013 (Klopotek '334), 4:31–35, 5:35–57, Fig. 3).[15] Nevertheless, at oral argument, counsel for Petitioner acknowledged that Petitioner was not relying on Klopotek '334's treatment of the cornea for satisfying the "dermal layer" limitation, recited in claim 1.

[15] Ex. 1013, US 5,230,334, iss. July 27, 1993 to Klopotek ("Klopotek '334"), was cited in the Petition at pages 19–20 as part of a general background discussion that focused ultrasound had been used to treat tissue, but Petitioner argues for the first time in the Reply Brief that Klopotek '334 is evidence that focal ultrasound can be used at shallow depths. *See* Reply 23. Klopotek '334 was not relied on as part of any of the asserted or instituted grounds of unpatentability. As such, we consider the Klopotek '334 reference only as part of Petitioner's rebuttal arguments regarding safety.

Tr. 21:24–22:12. Rather, Petitioner stated that it was merely relying on the corneal treatment prior art in support of its arguments regarding safety. *See id.* Also at oral argument (which was the first time Patent Owner had the opportunity to respond to this argument), Patent Owner distinguished this prior art as having a different wavelength and treatment area of focused ultrasound. Tr. 56:3–57:3.

We find that Petitioner has not adequately established that Klopotek '334's treatment of the cornea demonstrates a reasonable expectation of success for a person of ordinary skill in the art to treat venous structures (or wrinkles) in the dermis with focused ultrasound, in part because Petitioner has not established that the wavelengths and focal areas in Klopotek '334 would have been comparable to those used in Knowlton or the Technomed patent publication. *See* Reply 16. Nor is this a situation with a limited number of options. Petitioner states that it was known in the art to use focal lengths of 1 mm or less for ultrasound (citing Ex. 2003, 85:3–25), but Petitioner does not rely on the Technomed patent publication or Knowlton for this teaching. Reply 16.

Petitioner points to the Technomed patent publication for treating (dermal) spider veins. *Id.* (citing Ex. 1007, 1:7–15; Exs. 1022, 1023). However, the cited portion of the Technomed patent publication refers to other articles on laser treatment (Ex. 1022, 1023) rather than on ultrasound. As such, Petitioner does not point to a teaching in the Technomed patent publication of using focused ultrasound to treat spider veins in the dermis.

Instead, we credit the testimony of Dr. Palmeri who stated that the Technomed PCT taught that when destructive energy was used, it was critical to keep the focal region of an ultrasound beam away from the tissue

to be preserved and that it was particularly important to preserve the skin. Ex. 2002 ¶¶ 89–90. Dr. Palmeri testified that a person of ordinary skill in the art "would have found it unsafe . . . to treat spider veins in the dermis, knowing that the dermis itself would certainly be destroyed (i.e., irreversibly damaged)." *Id.* ¶ 88. Rather, a person of ordinary skill would have used focused ultrasound to treat large, subcutaneous veins. *Id.* ¶ 86.[16]

Petitioner has at most shown two possible valid definitions of "varicose veins," one being a colloquial, umbrella term for all dilated venous structures and the other referring to those anatomically defined as larger veins. However, Petitioner bears the burden of persuasion of proving unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e). We find that Petitioner has not proven that it is more likely than not that the Technomed patent publication uses the "colloquial" definition which includes superficial varicose veins.[17] Weighing the evidence as a whole, we find that Petitioner has not established by a preponderance of the evidence

[16] Petitioner argues that a person of ordinary skill, applying Patent Owner's logic, would have understood that focused ultrasound would have been superior for treating wrinkles because they are small in size. Reply 22. However, Petitioner does not provide evidentiary support for this proposition.

[17] Petitioner also appears to argue that even if the Technomed patent discloses directing focused ultrasound into the subcutaneous tissue, that the treatment zone would have included adjacent tissue in the dermis, e.g., that the focused ultrasound would have caused heating of the dermis. *See* Reply 18 (citing Ex. 1024, 89:14–19, 91:9–93:15, 183:6–18; Ex. 1007, 4:17–18, 5:3–4, 5:20–23; Ex. 2003, 223:2–15). However, Patent Owner does not dispute that heat could diffuse from the subcutaneous tissue to adjacent tissue. Petitioner has not proven that the focal region of the ultrasound in the Technomed patent publication would have encompassed more than the subcutaneous layer.

that a person of ordinary skill in the art would have understood the Technomed patent publication to have applied focused ultrasound to the dermis.

2. Treatment of varicosities in the Technomed patent publication

The Technomed patent publication also discloses treatment of "varicosities." Ex. 1007, 1:1–2. Petitioner does not appear to distinguish "varicosities" from "superficial varicose veins," in relying on the teachings of the Technomed patent publication. *See* Pet. 39; *see also id.* at 7, 54 (mentioning varicosities). Patent Owner asserts that "varicosities" is a synonym for "varicose veins." PO Resp. 31 (citing Ex. 2002 ¶ 70; Ex. 2023, 1703; Ex. 2014, 1576; Ex. 2025, 2063; Ex. 2026, 1250; Ex. 2003, 296:11–297:24; Pet. 27). According to Patent Owner's Declarant, "varicosities" is an umbrella term that can refer to any blood vessel or can more particularly refer to varicose veins:

> At the time of the invention, "varicosities" would have had two meanings to one of ordinary skill. It could refer to swollen vessels generally (e.g., arteries or lymph nodes). Or, more commonly, it was a synonym for varicose veins. Ex. 2022 at 1694 (varicosity: "1. An abnormal condition, usually of a vein, characterized by swelling and tortuosity. 2. A vein in this condition."); Ex. 2023 at 1703 (varicosity: "A varix, or varicose vein."); Ex. 2014 (Miller-Keane 1992) 1576 (same); Ex. 2025 at 2063 (varix: "1. A tortuous dilatation of a vein. SEE: Varicose vein"). In the context of Technomed, which was concerned with varicose veins (and not arteries or lymph nodes), "varicosities" was used as a synonym for varicose veins. The Petition recognizes this in the context of its related reference, Technomed PCT. Pet. 27 ("varicosities (i.e. varicose veins)").

Ex. 2002 ¶ 70. In view of this testimony (Ex. 2002 ¶ 70; Ex. 2023, 1703), and because Petitioner does not separately argue the disclosure of

"varicosities" from "superficial varicose veins," we do not understand the Technomed patent publication's description of varicosities to remedy the deficiency in Petitioner's reliance on "superficial varicose veins." In other words, Petitioner has not established that the Technomed patent publication discloses focusing ultrasound in the dermis as opposed to focusing ultrasound in the subcutaneous layer below the dermis.

C. Whether the "focusing" limitation is taught by, or obvious in view of, a combination of references

Petitioner argues for applying the power levels of the Technomed patent publication to the treatment method of Knowlton. Pet. 30 ("One skilled in the art would have been motivated to look at the Technomed patent, which identifies ultrasound power levels that are safe and clinically effective for treating tissue beneath the skin surface.") (citing Ex. 1003 ¶¶ 51, 53, 56). In response, Patent Owner argues that Petitioner's proposed reasoning for the combination of references is conclusory. PO Resp. 56–59 (citing Ex. 2002 ¶¶ 113–114, 116–119; *In re Nuvasive, Inc.*, 842 F.3d 1376, 1384 (Fed. Cir. 2016)). Patent Owner also argues that neither Knowlton nor the Technomed patent publication disclose "focusing ultrasound in a dermal layer," and that Petitioner fails to argue the "focusing" limitation based on a combination of Knowlton and the Technomed patent publication. PO Resp. 13; *see also* Tr. 25:6–20 (arguing lack of expert testimony).

We agree with Patent Owner inasmuch as the Petition does not explain how one would have combined the references to arrive at targeting focused ultrasound in the dermal layer. Petitioner has not demonstrated that the dermal embodiment of Knowlton makes use of focused ultrasound. Therefore, although a person of ordinary skill might have been motivated to

apply the teachings of the Technomed patent publication to the embodiments in Knowlton relating to focused ultrasound, *in subcutaneous structures*, Petitioner has not established that a person of ordinary skill in the art would have applied the teachings of the Technomed patent publication to the treatment of the embodiments in Knowlton relating to the dermis, i.e., because those embodiments may relate to unfocused ultrasound.

Petitioner asserts that a person of ordinary skill in the art "would have appreciated the need to select only the necessary and applicable energy intensities to achieve the desired denaturing of collagen, and thus would have combined Knowlton and Technomed in a safe and efficacious manner." Reply 20 (citing Ex. 1003 ¶¶ 53, 56). Petitioner argues that it was known to use focused ultrasound for non-destructive applications such as diagnostic medical imaging. *Id.* at 24 (citing Ex. 1024, 98:8–18). Petitioner further argues that Knowlton teaches safe temperature ranges for heating the dermis and also teaches the cooling of the skin. *Id.* at 20 (citing Ex. 1005, 115:16–2). Petitioner appears to be suggesting that a person of ordinary skill might have been able to safely apply focused ultrasound by monitoring the temperature of the target area. However, Petitioner's Declarant does not supply evidence that a person of ordinary skill would have monitored the temperature to achieve a reasonable expectation of success in directing focused ultrasound. *See* Ex. 1003 ¶ 56. At most, Petitioner has suggested a roadmap for experimentation, without proving a reasonable expectation of therapeutic success.

Patent Owner argues that, in any event, one would not have combined the focused ultrasound of Knowlton (or of the Technomed patent publication) with treatment of a dermal layer because of the potential for

destructive effects. PO Resp. 50–59. We agree. Putting aside issues of motivation, Petitioner has not established that a person of ordinary skill would not have had a reasonable expectation of success in applying focused ultrasound *to the dermal layer* given the capacity for destructive effects. *See* Ex. 1009, 1:30–2:3.[18]

D. Summary

We find that Petitioner has failed to prove by a preponderance of the evidence that the combination of Knowlton and the Technomed patent publication discloses the limitation "focusing ultrasound in a dermis layer of the region of skin," as recited in independent claim 1, and we determine that Petitioner has failed to prove that the combination renders the limitation obvious. Accordingly, we determine that Petitioner has failed to prove by a preponderance of the evidence that the combination of Knowlton and the Technomed patent publication renders obvious independent claim 1.

b. Claims 2–4, 6, 7, and 12–16

We determine that Petitioner has failed to prove by a preponderance of the evidence that the combination of Knowlton and the Technomed patent publication renders obvious claims 2–4, 6, 7, and 12–16 for the same reasons discussed in connection with claim 1, from which they depend.

[18] Because we find that Petitioner has not demonstrated that claim 1 of the '559 patent is obvious based on the combination of Knowlton and the Technomed patent publication, i.e., based on its case-in-chief, we do not reach Patent Owner's arguments regarding objective indicia of nonobviousness. *See* PO Resp. 61–64.

E. Obviousness Over Knowlton, the Technomed patent publication, and the Technomed PCT (Ex. 1009)

Petitioner sets forth in the Petition its allegations with respect to claims 8, 9, 11, 17, and 18. Pet. 50–61. Patent Owner disagrees. PO Resp. 60–61.

1. Overview of the Technomed PCT

The Technomed PCT relates to an apparatus performing therapy using ultrasonic waves that produce thermal and cavitation effects. Ex. 1009, 1:1–5. The Technomed PCT explains that ultrasonic acoustic waves of high intensity (above a threshold) will exhibit a mixture of thermal-effect waves and cavitation-effect waves, with predominantly cavitation, whereas ultrasonic waves of low intensity (below a threshold) will exhibit only thermal effect waves. *Id.* at 11:19–24, Fig. 2. The Technomed PCT further explains that cavitation effects can have a substantial destructive power (*id.* at 2:1–6), but that a prolonged application of heat even at a moderate temperature can lead to destruction of healthy areas with conduction and diffusion of heat to other areas (*id.* at 1:30–34). Upon the application of heat and an increase in temperature, the threshold for cavitation diminishes. *Id.* at 15:1–13, Fig. 4. The Technomed PCT describes an optional step of cooling the tissue areas at the interface with the therapy device with a cooling fluid. *See id.* at 17:1–5.

2. Analysis

Petitioner does not rely on the Technomed PCT to remedy the deficiency in the combination of Knowlton and the Technomed patent publication, i.e., Petitioner does not argue that the Technomed PCT discloses sending focused ultrasound into the dermis. Petitioner argues that the

Technomed PCT discloses benefits of combining hyperthermia with cavitation in order to limit heat diffusion caused by focused ultrasound. Pet. 53 (citing Ex. 1009, 8:13–15). However, we do not find that this portion of the Technomed PCT, alone or in combination with the other asserted prior art, discloses applying focused ultrasound to the dermis or that Petitioner has otherwise demonstrated a reasonable expectation of success in applying focused ultrasound to the dermis with the addition of this reference.[19] Accordingly, we determine that Petitioner has failed to prove by a preponderance of the evidence that the combination of Knowlton, the Technomed patent publication, and the Technomed PCT renders obvious claims 8, 9, 11, 17, and 18 for the same reasons explained for the asserted ground of obviousness of independent claim 1 over Knowlton and the Technomed patent publication.

III. CONCLUSION

We conclude that Petitioner has not established by a preponderance of the evidence that claims 1–4, 6, 7, and 12–16 of the '559 patent are unpatentable as obvious over Knowlton and the Technomed patent

[19] The Technomed PCT suggests an approach that attempts to cabin the destructive effects of focused ultrasound to the focal point but does not necessarily eliminate the destructive effects of ultrasound, e.g., from thermal effects. *See id.* at 2:7–12. As such, we do read the Technomed PCT as creating a reasonable expectation of success of focusing ultrasound in the dermis. Petitioner does not rely on any expert testimony to the contrary. Rather, Petitioner relies on Technomed for the teaching of cavitation effects, which may limit heat diffusion but are nonetheless destructive. *See* Pet. 53 (quoting Ex. 1009, 8:13–15 ("The combination of cavitation and thermal treatment has the effect of reinforcing the destructive potential of the treatment, hence limiting the duration of treatment pulses and thus avoiding heat diffusion in the tissue.")); *see also id.* at 10, 51–54.

publication, nor that claims 8, 9, 11, 17, and 18 are unpatentable as obvious over Knowlton, the Technomed patent publication, and the Technomed PCT.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–4, 6–9, and 11–18 have *not* been shown to be unpatentable on the grounds as asserted and instituted in this proceeding.

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