Trials@uspto.gov
Tel: 571-272-7822

Paper 11
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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*.

DECISION
Decision on Institution of *Inter Partes* Review
37 C.F.R. § 42.108

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.

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108. For the reasons set forth below, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–4, 6–9, and 11–18 of the '559 patent are unpatentable.

Accordingly, we institute an *inter partes* review for claims 1–4, 6–9, and 11–18.

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:

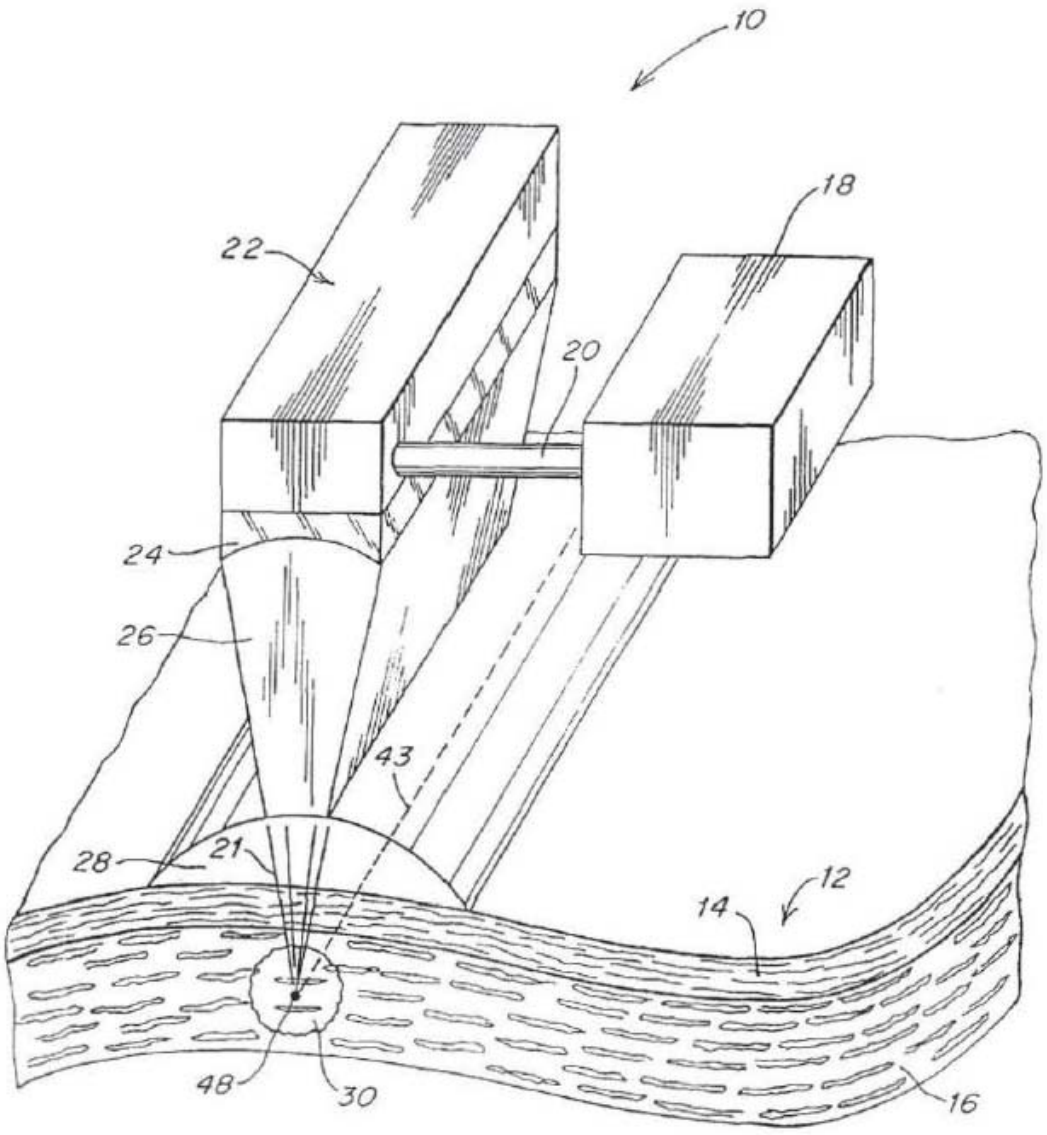

Fig. 1

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

C. Illustrative Claim

The Petition challenges claims 1–18 of the '559 patent. 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. The Alleged Grounds of Unpatentability

In the Petition, Petitioner sets forth its contentions that claims 1–18 are unpatentable on the following grounds (Pet. 29–61):

References	Basis	Claims challenged
Knowlton[1] and the Technomed patent publication[2]	§ 103	1–7 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 35 U.S.C. § 102(b). Therefore, for clarity, we refer to it as "the Technomed patent publication."

References	Basis	Claims challenged
Knowlton, the Technomed patent publication, and Technomed PCT[3]	§ 103	8–11, 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 In re Cuozzo Speed Techs., LLC*, 136 S. Ct. 2131, 2142–46 (2016). Under that standard, and absent any special definitions, 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. Upon review of the Petition, and on this record, we do not provide an express construction of any terms for purposes of this Decision on Institution. *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).

[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").

B. 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 1–7 and 12–16. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 1–4, 6, 7, and 12–16.

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.

[4] Knowlton includes ultrasound in a list of "electromagnetic energy sources." Ex. 1005 at 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 inasmuch as Knowlton discloses ultrasound notwithstanding the disclosure of other modalities.

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, beginning with denaturation of the triple helix of the collagen molecule, followed forty-eight hours later by the proliferation of fibroblasts at the injured site which produce scar collagen. *Id.* at 1:19–20, 2:8–11, 11:25–27. Knowlton describes a "reverse thermal gradient from the skin layer to the underlying collagen tissue," e.g., to heat the dermis "above 65 degrees" while avoiding blistering on 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, 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 1–7 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 1–7 and 12–16. Pet. 29–49. We determine, on the

current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 1–4, 6, 7, and 12–16.

i. Claim 1

Petitioner maps Knowlton and the Technomed patent publication to the limitations of claim 1. Pet. 33–41. In particular, Petitioner relies on Knowlton's disclosure of denaturing proteins, tightening skin, and reducing wrinkles for the preamble and 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." Pet. 37–38, 40–41 (citing Ex. 1005, 3:16–18, 5:13–19).

Petitioner relies primarily on Knowlton's disclosure of heating the dermis to 40°C to 80°C, and of using an ultrasound energy source, for the limitations "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 47º C. to about 75º C." Pet. 38–39 (citing Ex. 1005, 11:3–7, 11:25–27, claim 49). At the same time, Petitioner relies on the Technomed patent publication, in combination therewith, for the disclosure of ultrasonic intensity in the focal region of between 100 W/cm^2 and 2 kW/cm^2 for a sufficient period of time to accomplish the thermal destruction of the endothelium of the veins. Pet. 39 (citing Ex. 1007, 5:6–10). Petitioner relies on both references for the limitation "identifying a region of skin to be treated." Pet. 38 (citing Ex. 1005, 14:8–11; Ex. 1007, 3:18–20).

Petitioner relies on expert testimony for the understanding that a person of ordinary skill would have combined the teachings of Knowlton and the Technomed patent publication. 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). As to the disclosure in the Technomed patent publication of the ultrasonic treatment of varicose veins, Dr. Schafer avers that a person having skill in the art would understand 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. Dr. Schafer further avers that the Technomed patent publication discloses safe and therapeutically effective power levels that can be used in the treatment of varicose structures, which may be located within the skin. *Id.* ¶ 31.

Based on the supporting declaration of Dr. Schafer, and on our independent review of the evidence, we determine that Petitioner has established a sufficient showing, at this stage of the proceeding, that Knowlton and the Technomed patent publication disclose the recited steps of claim 1. Further, on this record, we credit the testimony of Dr. Schafer that a person of ordinary skill would have looked to the Technomed patent publication for safe power levels to implement ultrasound therapy of the dermis. At this stage of the proceeding, we therefore determine that Petitioner has established a reasonable likelihood of prevailing on its assertion that Knowlton and the Technomed patent publication render obvious claim 1.

ii. Claims 2, 3, 12, and 14

Petitioner relies, *inter alia*, on the above-identified disclosures in Knowlton and the Technomed patent publications for the further recitations of claims 2 and 3, i.e., "wherein a step of stimulating or irritating the dermis

layer comprises elevating the temperature of the dermis layer" (claim 2) and "wherein the step of depositing energy in the dermis layer further comprises applying the focused ultrasound beam for a time sufficient to cause proteins in the dermis layer to denature" (claim 3). Pet. 42.

Petitioner relies, *inter alia*, on the same disclosures in Knowlton and the Technomed patent publication for the further recitations of claims 12 and 14, i.e., "wherein a step of depositing energy further comprises irritating the dermis layer without adversely damaging the epidermis layer" (claim 12) and "wherein the region of human skin includes a wrinkle and the method further comprises the step of scanning the focused ultrasound beam over an area occupied by the wrinkle" (claim 14). *See* Pet. 46–48.

For similar reasons as for independent claim 1, we determine, on the basis of the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertions that Knowlton and the Technomed patent publication render obvious claims 2, 3, 12, and 14.

iii. Claims 4 and 5

Petitioner relies on the disclosure in Knowlton that the method for skin tightening can be applied numerous times for the limitation "wherein a step of applying a focused ultrasound beam comprises repeatedly applying the focused ultrasound beam over a period of days or months," as recited in claim 4. Dr. Schafer avers that a person having ordinary skill in the art would have understood that repeated applications of treatment could be provided over a period of days or months. Ex. 1003 ¶ 67. Based on the current record, we determine there is a reasonable likelihood that a person of ordinary skill would understand the numerous applications in Knowlton to disclose treatment over multiple days. *See* Ex. 1003 ¶ 67. Accordingly, we

determine that Petitioner has established a reasonable likelihood of prevailing on its assertions that Knowlton and the Technomed patent publication render obvious claim 4.

Claim 5 recites "wherein the ultrasound beam is repeatedly applied until the wrinkles are visibly reduced." As above, Petitioner has not offered a construction for "until the wrinkles are visibly reduced," and we determine that Petitioner has not persuasively explained how the prior art meets this limitation. For example, as Petitioner notes (Pet. 44), Knowlton discloses how "[f]ollowing the deposition of nascent scar collagen in the dermis, contraction of collagen with a reverse thermal gradient *corrects* wrinkling of the skin without resorting to resurfacing techniques that require the application of a standard thermal gradient burn to the skin." Ex. 1005, 5:23–26 (emphasis added). Nonetheless, Petitioner has not explained sufficiently how the correction of wrinkling teaches or suggests that the "ultrasound beam is repeatedly applied until the wrinkles are *visibly reduced*" as required by claim 5. Further, Dr. Schafer's testimony largely mirrors Petitioner's arguments in the Petition and does not further explain persuasively how Knowlton discloses this claimed feature. Accordingly, we exercise our discretion and determine not to institute an *inter partes* review with respect to dependent claim 5. *See* 35 U.S.C. § 314(a).

iv. Claims 6 and 7

Petitioner relies on the disclosures in the Technomed patent publication of ultrasonic intensity of 100 W/cm^2 and about 2 kW/cm^2 for the limitation "wherein a step of depositing energy further comprises using a power level in the range of approximately 500 W/cm^2 to 1500 W/cm^2 at the focal point of the ultrasound beam," as recited in claim 6. *See* Pet. 45.

Where, as here, the prior art range overlaps the claimed range, the claimed range is generally considered obvious over the prior art range unless there is a criticality to the claimed range or unless the behavior of the system does not remain the same over a range of values. *See ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012); *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006). The Specification of the '559 patent does not distinguish the prior art ultrasound intensity in any way. Therefore, on the basis of the current record, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertions that Knowlton and the Technomed patent publication render obvious claim 6.

Claim 7 recites "wherein the step of depositing energy in the dermis layer further comprises focusing the ultrasound beam at a depth below the epidermis in a range between approximately 5 microns and 5 millimeters." Knowlton discloses application of ultrasound to the dermis, as discussed above, without disclosing the depth corresponding thereto. However, Dr. Schafer avers that a person having skill in the art would understand that the dermis layer is located below the epidermis within a range between approximately 5 microns and 5 millimeters of depth. *See* Ex. 1003 ¶ 70. Based on the current record, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertions that Knowlton and the Technomed patent publication render obvious claim 7.

v. Claim 13

Claim 13 recites a further step "of cooling the region of human skin at least one of before, during, or after depositing the ultrasound energy." Petitioner relies on the disclosure in Knowlton of a reverse temperature

gradient (Ex. 1005, 15:29–16:2) and on the disclosure in the Technomed patent publication that: " . . . it can be provided that the coupling liquid can be made to circulate in the means 242 at a predetermined adjustable temperature, so as to possibly produce a cooling of the surface of the patient's skin" (Ex. 1007, 13:6–8). Pet. 47. *See* Ex. 1003 ¶ 72 (claim chart). Based on the current record, we determine that Petitioner has demonstrated a reasonable likelihood that the Technomed patent publication discloses cooling the surface, i.e., when the temperature of the coupling liquid is adjusted to a cooler temperature. Accordingly, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertions that Knowlton and the Technomed patent publication render obvious claim 13.

vi. Claims 15 and 16

Claims 15 and 16 relate to treatment of larger areas, and respectively recite "wherein the step of scanning further comprises scanning the focused ultrasound beam over an area of the skin that is larger than the wrinkle" (claim 15) and "wherein the step of scanning further comprises scanning the focused ultrasound beam over an area of the skin that is approximately ten times larger than an area of the wrinkle" (claim 16).

For these limitations, Petitioner relies on the disclosure in Knowlton of treatment of "thighs, knees, arms, back and hips," which Petitioner argues involve applying the ultrasound beam over an area larger than the size of a single wrinkle and scanning the ultrasound beam over an area of skin that is approximately ten times larger than an area of the wrinkle. Pet. 48–49 (citing Ex. 1003 ¶¶ 74–75; Ex. 1005, 14:8–13). Based on the current record, we determine that Petitioner has established a reasonable likelihood of

prevailing on its assertions that Knowlton and the Technomed patent publication render obvious claims 15 and 16.

C. 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 8–11, 17, and 18. Pet. 50–61. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 8, 9, 11, 17, and 18.

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 11:21–24, 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 15:9–13, Fig. 4. The Technomed PCT describes a method of applying thermal-effect waves during a first time period (e.g., 100 milliseconds to 10 seconds) followed by predominantly cavitation-effect waves during a second time period (e.g., 0.5 to 50 microseconds). *Id.* at 15:9–36, Figs. 5, 7. The cavitation-effect waves include negative amplitude components. *Id.* at 4:4–

5, 11:10–12, 11:27–29, Fig. 6. 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

In its Petition, Petitioner alleges how each limitation of claims 8–11, 17, and 18 would be understood to be disclosed by Knowlton, the Technomed patent publication, and the Technomed PCT, and its assertions as to why it would have been obvious to a person of ordinary skill in the art to combine the references to arrive at the inventions of claims 8–11, 17, and 18. Pet. 50–61. We determine, on the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 8, 9, 11, 17, and 18.

i. Claim 8

Petitioner maps Knowlton, the Technomed patent publication, and the Technomed PCT to the limitations of claim 8, which depends from claim 1. Pet. 33–41. In particular, Petitioner relies on the disclosure in the Technomed PCT of using ultrasound to produce a cavitation effect for the limitation "wherein a step of depositing energy in the dermis layer further comprises inducing cavitation in the dermis layer." As to the reasons for the asserted combination, Petitioner contends that one skilled in the art would have been motivated to combine the disclosure of cavitation in Technomed PCT with the disclosure of hyperthermia in Knowlton and Technomed patent publication in order to limit the duration of heat treatment to avoid the effects of heat diffusion that may spread beyond the area being treated. *See* Pet. 53; Ex. 1003 ¶ 36.

On this record, we credit the testimony of Dr. Schafer that a person of ordinary skill in the art reading the Technomed PCT would seek the benefit of combining thermal treatment with cavitation in order to avoid the deleterious effects of prolonged heat therapy. *See* Ex. 1003 ¶ 36; Ex. 1009, 1:30–34, 2:1–6, 15:9–36, Figs. 5, 7. This testimony is consistent with the Technomed PCT, which further describes the use of a cooling fluid, *inter alia*, to limit cavitation effects. Ex. 1009, 20:29–36. As such, we determine, on the basis of the current record, that Petitioner has established a reasonable likelihood of prevailing on its assertion that the combination of Knowlton, the Technomed patent publication, and the Technomed PCT render obvious claim 8.

ii. Claims 9 and 11

Claim 9 depends from claim 8 and further recites "wherein a step of depositing energy further comprises repeatedly applying the focused ultrasound beam in over a period of days or months." For similar reasons as for claims 4 and 8, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claim 9. *See* Pet. 56–57.

Claim 11 depends from claim 8 and further recites "wherein the step of depositing energy further comprises focusing the ultrasound beam at a depth below the epidermis in a range between approximately 5 microns and 5 millimeters." For similar reasons as for claims 7 and 8, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claim 11. *See* Pet. 57–58.

iii. Claim 10

Claim 10 depends from claim 9 and further recites "wherein the ultrasound beam is repeatedly applied until the wrinkles are visibly

reduced." For similar reasons as for claim 5, we exercise our discretion not to institute an *inter partes* review with respect to claim 10. *See* 35 U.S.C. § 314(a).

iv. Claims 17 and 18

Claims 17 and 18 relate to the mechanical disruption of tissue. Claim 17 depends from claim 1 and further recites "wherein a step of depositing energy in the dermis layer further comprises depositing sufficient energy in the dermis layer to mechanically disrupt tissue to cause a dermal inflammation." Claim 18 depends from claim 17 and further recites "wherein the step of depositing energy further comprises generating a shock wave to mechanically disrupt the tissue in the dermis layer."

For each of claims 17 and 18, Petitioner relies on the disclosure in the Technomed PCT of cavitation linked to the formation of microscopic gas bubbles that explode when they reach a critical diameter leading to the destruction of neighboring tissue. Pet. 58–61 (citing Ex. 1009, 1:19–21). Dr. Schafer avers that a person of ordinary skill in the art would understand this description to constitute a mechanical disruption that causes inflammation, as recited in claim 17, and a deposit of energy with shock waves, as recited in claim 18. Ex. 1003 ¶¶ 96–97. On this record, we credit the testimony of Dr. Schafer and determine that Petitioner has established a reasonable likelihood of prevailing on its assertion as to claims 17 and 18.

III. CONCLUSION

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–4, 6–9, and 11–18 of the '559 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on the following grounds:

Claims 1–4, 6, 7, and 12–16 as obvious over Knowlton and the Technomed patent publication;

Claims 8, 9, 11, 17, and 18 as obvious over Knowlton, the Technomed patent publication, and the Technomed PCT;

FURTHER ORDERED that no other proposed grounds of unpatentability are authorized; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

PETITIONER:

Michelle E. Armond
John B. Sganga, Jr.
Matthew S. Bellinger
KNOBBE, MARTENS, OLSON & BEAR, LLP
2mea@knobbe.com
2jbs@knobbe.com
2msb@knobbe.com

PATENT OWNER:

Sean Luner
DOVEL AND LUNER, LLP
sean@dovel.com

Timothy M. Salmon
tsalmon@empireipllc.com