

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SIENNA BIOPHARMACEUTICALS, INC.,
Petitioner,

v.

WILLIAM MARSH RICE UNIVERSITY,
Patent Owner.

Case IPR2017-00045
Patent 6,530,944 B2

Before GEORGIANNA W. BRADEN, ZHENYU YANG, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

BRADEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION

35 U.S.C. § 318 and 37 C.F.R. § 42.73

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6, and 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 shown by a preponderance of the evidence that claims 1, 6–8, and 12 (“the challenged claims”) of U.S. Patent No. 6,530,944 B2 (Ex. 1001, “the ’944 patent”) are unpatentable.

A. Procedural History

Sienna Biopharmaceuticals, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of the challenged claims of the ’944 patent. William Marsh Rice University (“Patent Owner”) timely filed a Preliminary Response (Paper 6, “Prelim. Resp.”).

Pursuant to 35 U.S.C. § 314(a), we instituted an *inter partes* review of (1) claims 1 and 7 as unpatentable under 35 U.S.C. § 102(b)¹ in view of Tankovich I²; (2) claims 1, 6, and 7 as unpatentable under 35 U.S.C. § 102(b) in view of Tankovich II³; (3) claims 1, 6–8, and 12 as unpatentable under 35 U.S.C. § 102(e) in view of Esenaliev⁴; (4) claims 6, 8, and 12 as

¹ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 100 et seq. effective on March 16, 2013. The ’944 patent issued from an application filed before March 16, 2013; therefore, we apply the pre-AIA versions of the statutory bases for unpatentability.

² U.S. Patent No. 5,226,907, filed Oct. 29, 1991, issued July 13, 1993 (Ex. 1002, “Tankovich I”).

³ U.S. Patent No. 5,817,089, filed June 12, 1995, issued Oct. 6, 1998 (Ex. 1003, “Tankovich II”).

⁴ U.S. Patent No. 6,165,440, filed July 9, 1998, issued Dec. 26, 2000 (Ex. 1005, “Esenaliev”).

unpatentable under 35 U.S.C. § 103(a) in view of Tankovich I and Esenaliev; and (5) claims 8 and 12 as unpatentable under 35 U.S.C. § 103(a) in view of Tankovich II and Esenaliev. See Paper 7 (“Dec. to Inst.”), 36.

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 23, “PO Resp.”), to which Petitioner filed a Reply (Paper 28, “Reply”). Patent Owner also filed Objections to Evidence (Papers 10, 29, 44) and a Motion to Exclude Evidence (Paper 37). Petitioner opposed the Motion to Exclude (Paper 43) and Patent Owner submitted a Reply in support of its Motion to Exclude (Paper 45). In addition, Patent Owner filed a list of alleged improper reply arguments (Paper 31) to which Petitioner filed a Response (Paper 32).

Petitioner also filed Objections to Evidence (Paper 26) and a Motion to Exclude Evidence (Paper 39). Patent Owner opposed the Motion to Exclude (Paper 41) and Petitioner submitted a Reply in support of its Motion to Exclude (Paper 46).

An oral argument was held on December 18, 2017, together with co-pending Case IPR2017-00046.⁵ A transcript of the oral argument is included in the record. Paper 51 (“Tr.”).

B. Related Proceedings

Petitioner informed us that at the time the Petition was filed, it was unaware of any related matters that would affect or be affected by this proceeding. Pet. 3; see also Paper 4, 2 (Patent Owner’s Mandatory Notice).

⁵ The parties each filed objections to demonstrative exhibits. Papers 48, 49. In this Final Written Decision, we rely directly on the arguments presented properly in the parties’ briefs and the evidence of record. The demonstrative exhibits were not considered; therefore, the objections are moot.

Subsequently, Patent Owner filed a Request for *Ex Parte* Reexamination of the '944 patent, which was granted by the USPTO and given Control No. 90/013,924. See Paper 7, 2 (Patent Owner's Updated Mandatory Notice).

Petitioner filed a Motion to Stay *Ex Parte* Reexamination (Paper 12), which was opposed by Patent Owner (Paper 16), and to which Petitioner filed a reply (Paper 17). We stayed the *Ex Parte* Reexamination pending the outcome of this Final Written Decision. Paper 22.

C. The '944 Patent

The application that led to the '944 patent was filed on February 8, 2001, and is titled "Optically-Active Nanoparticles for Use in Therapeutic and Diagnostic Methods." Ex. 1001, Title. It is directed to methods for localized delivery of heat and the localized imaging of biological materials. *Id.* at Abstract. According to the '944 patent, "[t]he method involves localized induction of hyperthermia in a cell or tissue by delivering nanoparticles to said cell or tissue and exposing the nanoparticles to an excitation source under conditions wherein they emit heat." *Id.* In order to accomplish such localized hyperthermia, "particles are administered to cells and/or tissue, which upon their exposure to light, effect the *in vitro* or *in vivo*, local heating of their immediate environment." *Id.* at 4:57–59.

The '944 patent teaches "the nanoparticles . . . [are] excited using radiation such as near infrared light (approximately 800 to 1300 nm)," and that "[u]pon excitation, the nanoshells emit heat." *Id.* at 8:17–22. In one example, highlighting the role of the nanoparticles in heating the local tissue upon exposure, the '944 patent describes how "[e]xposure to the laser in the absence of nanoshells did not induce visible tissue damage," but "tissues . .

injected with nanoshells before exposure . . . sustained extensive tissue damage.” *Id.* at 31:65–32:1.

D. Illustrative Claim

As noted above, an *inter partes* review was instituted as to claims 1, 6–8, and 12, with claim 1 being the only independent claim. Claim 1 is illustrative of the challenged claims, and is reproduced below:

1. A method for inducing localized hyperthermia in a cell or tissue comprising the steps of delivering nanoparticles to said cell or tissue and exposing said nanoparticles to infrared radiation under conditions wherein said nanoparticles emit heat upon exposure to said infrared radiation.

Ex. 1001, 33:53–57.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their 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, 2144–46 (2016) (“We conclude that the regulation represents a reasonable exercise of the rulemaking authority that Congress delegated to the Patent Office.”). 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. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). An inventor, however, may provide a meaning for a term that is different from its ordinary meaning by defining the term in the specification with “reasonable clarity, deliberateness, and precision.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Limitations, however, are not to be read from the specification into the claims. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993). In addition, the Board may not “construe claims during [an *inter partes* review] so broadly that its constructions are *unreasonable* under general claim construction principles.” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017).

The parties dispute the proper construction of the terms “nanoparticles,” “infrared radiation,” and “inducing localized hyperthermia.”

1. Nanoparticles

The challenged claims of the '944 patent recite the term “nanoparticles.” Independent claim 1 specifically recites, “delivering nanoparticles to said cell or tissue,” “exposing said nanoparticles to infrared radiation,” and “wherein said nanoparticles emit heat upon exposure.” Ex. 1001, 33:53–57. The limitation also is recited in challenged dependent claim 7, “said nanoparticles absorb said radiation,” and claim 8, “coupling molecules to the nanoparticles.” *Id.* at 34:4–8.

Petitioner contends that the broadest reasonable interpretation of the claim term “nanoparticles” is “particles of any size, shape or morphology having a diameter of from 1 to 1000 nanometers” because (1) that is its plain and ordinary meaning and (2) this is consistent with the definition explicitly provided in the '944 patent. Pet. 10–11 (citing Ex. 1001, 6:65–67 (defining term as a “particle having a diameter of from 1 to 1000 nanometers, having any size, shape or morphology”); Ex. 1009, 824 (Webster’s dictionary definition of nanoparticle, copyright 2012, defining term as “a microscopic particle whose size is measured in nanometers”); Ex. 1006 ¶ 44).

Patent Owner contests Petitioner’s proposed construction as overly broad and encompassing non-plasmonic nanoparticles. PO Resp. 14–18. According to Patent Owner, the term “nanoparticles” is limited to only “plasmonic nanoparticles.” *Id.* at 18. Patent Owner cites to the claims and to the written description to support its position. *Id.* at 14–18.

First, Patent Owner contends that Petitioner’s proposed construction is too broad and ignores the ’944 patent specification. PO Resp. 14. Patent Owner argues that although “the ’944 patent includes a general definition of ‘nanoparticle’ . . . the specification of the ’944 patent expressly requires additional limitations to the general meaning of ‘nanoparticles’ not included in the general definition.” *Id.* (citing Ex. 2008 ¶¶ 62–64). According to Patent Owner, “there are a number of statements in the specification that makes it clear that not all ‘nanoparticles’ are intended to be the subject of the invention. For example, the statement in the Background of the Invention that says that ‘. . . the nanoparticles of this invention are more amenable to a directed shift in their plasmon resonance . . . than these solid metal nanoparticles.’” *Id.* at 15 (citing Ex. 1001, 2:49–51 (Patent Owner’s emphasis omitted); Ex. 2018).

Patent Owner further argues that the ’944 patent specification discusses prior art patents to Gordon and then distinguishes the nanoparticles disclosed in the Gordon patents. *Id.* at 17. Specifically, Patent Owner relies on the following passage from the ’944 patent specification:

U.S. Pat. Nos. 4,106,488 and 4,303,636 to Gordon describe particles of nanometer scale dimensions. However, the excitation source is different from that which is used herein and outside the scope of the present invention. As such, it is believed

that the underlying physical excitation mechanisms of these earlier works differs from that of the present invention.

Id. at 17 (citing Ex. 1001, 2:61–67). Patent Owner asserts that the Gordon patents describe light absorbing, non-plasmonic nanoparticles. *Id.* at 18 (citing Ex. 2012, 4:38–41; Ex. 2013; Ex. 2008 ¶¶ 47, 69). Patent Owner, therefore, argues that the complete disclosure of the '944 patent specification differentiates between those nanoparticles with plasmonic properties and those nanoparticles without such unique plasmonic properties, and therefore, Petitioner's construction, which encompasses non-plasmonic nanoparticles, is too broad. PO Resp. 18.

Second, Patent Owner contends that dependent claim 4 supports its position that the claimed “nanoparticles” are plasmonic. *Id.* at 16–17. Claim 4 depends from claim 1 and recites “nanoparticles are comprised of silica doped with rare earth emitters.” Ex. 1001, 33:63–64. Patent Owner argues that a person of ordinary skill in the art would have understood claim 4 to be directed to “a doped silica sphere with a metal shell,” because: (1) the '944 patent states that “the rare earth nanoemitters can be nanoparticles lacking a shell layer, or alternatively they may take the form of nanoshells having a core material and one or more shell layers” (Ex. 2008 ¶ 73; Ex. 1001, 11:41–44); and (2) the '944 patent incorporates by reference U.S. Provisional Patent Application No. 60/222,437, which states “[a] further variation includes surrounding a doped silica sphere with a metal shell” (Ex. 1001, 1:7–10; Ex. 2008 ¶ 73; Ex. 2009, 2). *Id.* at 17. In view of the '944 patent specification including the documents incorporated by reference, Patent Owner asserts a person of ordinary skill in the art would have understood claim 4 to be directed to “a doped silica sphere with a metal

shell,” which the ’944 patent describes as plasmonic. *Id.* (citing Ex. 2008 ¶¶ 49, 74; Ex. 1001, 10:42–45).

Lastly, Patent Owner contends Petitioner’s proposed construction ignores the prosecution history of the ’944 patent. *Id.* at 15–16. Patent Owner specifically argues that, during prosecution, the applicants of the ’944 patent distinguished the subject matter of claim 1 from the methods claimed in the Kirpotin and Carroll patents. *Id.* (citing Ex. 2008 ¶ 70; Ex. 1008, 132–133, 145–148; Ex. 2010; Ex. 2011). According to Patent Owner, both of these references describe nanometer scale sized light-absorbing particles. *Id.* at 16 (citing Ex. 2008 ¶ 70; Ex. 1008, 132–133). Patent Owner, therefore, argues that “Petitioner, in reaching its BRI of ‘nanoparticles,’ clearly did not consider the ’944 Patent’s Prosecution History finding that the light-absorbing nanoparticles of the Kirpotin and Carroll patents are not the nanoparticles of the present invention.” *Id.* (citing Ex. 2008 ¶ 70).

We agree with Patent Owner that lexicographic definitions in a specification may be express, but they need not be. PO Resp. 14; *compare In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (“Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history *when those sources expressly disclaim* the broader definition.”) (emphasis added), *with Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001) (“[A] claim term may be clearly redefined without an explicit statement of redefinition. . . . In other words, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents.”) (citations and internal

quotation marks omitted), and *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.”). Yet, here the ’944 patent expressly discloses a definition for the term “nanoparticle.” Ex. 1001, 6:65–67. And Patent Owner’s citations to certain preferred embodiments do not support a narrow construction that is at odds with the expressed definition. See PO Resp. 14–15 (citing Ex. 1001, 2:49–51), 17 (citing Ex. 1001, 2:61–67).

Patent Owner’s citations to the background section of the ’944 patent discuss alleged attributes of prior art nanoparticles, but these statements are not clear and unequivocal evidence that the claimed invention excludes a particular embodiment, e.g., non-plasmonic particles, or acts as a narrowing lexicographic definition. For example, the specification states that a “specific embodiment of these nanoparticles act as absorbers of radiation” (Ex. 1001, 2:16–17), and that certain metal colloids have a plasmonic response in “narrow wavelength ranges and cannot readily be shifted” (*id.* at 2:39–43). Under Patent Owner’s construction of nanoparticles, such colloid still would be encompassed. Additionally, we do not agree that the ’944 patent specification discussion of the prior art patents to Gordon distinguishes the nanoparticles disclosed in the Gordon patents based on plasmonic properties. See Ex. 1001, 59–65. Instead, the ’944 patent specification distinguishes the Gordon patents based on excitation source, because the ’944 patent uses infrared radiation (Ex. 1001, 2:61–67), while the Gordon patents use high frequency alternating electro-magnetic energy, (see Ex 2012, Abst; Ex. 2013, Abst.).

Moreover, Patent Owner’s arguments appear to be an attempt to import limitations from specific embodiments into the claims. *See* PO Resp. 14–17. The challenged claims, however, are broader than the cited embodiments as indicated by both the express definition of “nanoparticles” and by the claim language itself. Therefore, in keeping with the guidance from our reviewing courts, we decline to read limitations from embodiments into the claims. *See Ericsson, Inc. v. D-Link Systems, Inc.*, 773 F.3d 1201, 1218 (Fed. Cir. 2014) (stating that although patent claims must be read in light of the specification, it is important that a court avoids importing limitations from the specification into the claims); *3M Innovative Properties Co. v. Tredegar Corp.*, 725 F.3d 1315, 1321 (Fed. Cir. 2014) (“While we construe the claims in light of the specification, limitations discussed in the specification may not be read into the claims.”); *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) (holding that limitations are not to be read from the specification into the claims).

Second, we do not agree with Patent Owner’s position that a person of ordinary skill in the art would understand dependent claim 4 to be directed to “a doped silica sphere with a metal shell,” which the ’944 patent describes as plasmonic. *See* PO Resp. 17 (citing Ex. 2008 ¶¶ 49, 74; Ex. 1001, 10:42–45). Dependent claim 4 explicitly recites nanoparticles that are doped with rare earth emitters. It is silent regarding the use of a metal shell. The ’944 patent discloses that “the rare earth nanoemitters can be nanoparticles lacking a shell layer, or alternatively they may take the form of nanoshells having a core material and one or more shell layers.” *See* Ex. 1001, 11:41–44. Given this explicit disclosure in the specification that the rare earth nanoemitters can be nanoparticles lacking a shell layer, we decline to read

such a requirement into the claim where the claim is silent about the presence of a shell. Additionally, we credit the testimony of Petitioner's declarant, Kenneth S. Suslick, Ph.D. ("Dr. Suslick") that "silica doped with rare earth emitters" is an insulating material, and thus, non-plasmonic. See Ex. 2007, 230:18–23, 232:3–22. Patent Owner's declarant, Prashant K. Jain, Ph.D. ("Dr. Jain") also testified that silica is an insulator, and as such, would be non-plasmonic. See Ex. 1017, 97:3–20. The disclosure of an insulator that is doped with rare earth emitters that can be a nanoparticle lacking a shell counsels against a construction of "nanoparticles" that includes a requirement for a plasmonic property.

Lastly, we do not agree with Patent Owner that the prosecution history of the '944 patent necessitates a construction that the claimed "nanoparticles" be plasmonic. The meaning of the claim language is informed, as needed, by the prosecution history. *Pass & Seymour, Inc. v. Int'l Trade Com'n*, 617 F.3d 1319, 1327 (Fed. Cir. 2010). In the present case, even when the prosecution history is considered, it does not support Patent Owner's position. See PO Resp. 16 (citing Ex. 1008, 132–133, 145–148; Ex. 2010; Ex. 2011).

In the cited passages from the prosecution history of the '944 patent, applicants specifically traverse the Examiner's rejection over Kirpotin (Ex. 1008, 132) arguing that the reference "is limited to ferromagnetic particles, specifically γ -ferric oxide and a polymer. Additionally, Kirpotin only teaches the use of radio frequency (RF) excitation." *Id.* at 145. The applicant further argues "[t]he teachings of Kirpotin '730 are limited to the use of magnetic iron oxide particles excited by RF radiation. The Kirpotin reference nowhere provides an enabling disclosure or teaching to one of

ordinary skill in the art for nanoparticles or methods of making nanoparticles which absorb electromagnetic radiation at other regions of the electromagnetic spectrum.” *Id.* The applicant then argues against the Examiner’s application of Carroll (*id.* at 133), stating “[t]he enabling teachings of Carroll with respect to hyperthermia and imaging are limited to the use of iron or copper colloids and in the case of excitation using electromagnetic radiation, to spectral regions absorbed by iron or copper colloids” (*id.* at 146) and “[a]s shown by these references, the spectral region in which iron and copper colloids exhibit significant absorbance is not within the infrared region” (*id.* at 147–148). Thus, we understand the prosecution history to demonstrate that the patent applicant distinguished the claims based on the type and frequency of the radiation applied to the nanoparticles and not on any plasmonic properties of the nanoparticles. Accordingly, the prosecution history does not support Patent Owner’s position.

Having reviewed the entirety of the ’944 patent specification and its prosecution history, we find that the ’944 patent provides an explicit definition of the term “nanoparticle” as a “particle having a diameter of from 1 to 1000 nanometers, having any size, shape or morphology.” Ex. 1001, 6:65–67. The language of the claims, the embodiments in the specification, and the prosecution history generally appear to apply this definition. *See e.g.*, Ex. 1001, 10:16–29, 24:26–29, 26:14–15; Ex. 1008, 145–246. We, thus, see no reason to read limitations into the claims from certain embodiments or from the characterization of prior art in the specification. *See In re Van Geuns*, 988 F.2d at 1184. Therefore, based on our analysis of

the entire record, we construe “nanoparticle” as a “particle having a diameter of from 1 to 1000 nanometers, having any size, shape or morphology.”

2. “*infrared radiation*”

The challenged claims of the ’944 patent recite the phrase “infrared radiation.” Specifically, independent claim 1 recites, “exposing said nanoparticles to infrared radiation . . . wherein said nanoparticles emit heat upon exposure to said infrared radiation.” Ex. 1001, 33:55–57. The limitation also is recited by dependent claim 6, “the infrared radiation is of wavelengths from 800 nm to 1300 nm or from 1600 nm to 1850 nm.” *Id.* at 34:1–3.

Petitioner contends that the broadest reasonable interpretation of the claim term “infrared radiation” is “electromagnetic radiation whose wavelength lies in the range from 700 nanometers to 1 millimeter.” Pet. 12. According to Petitioner, the plain and ordinary meaning of “infrared radiation” is reflected in their proposed construction and is corroborated by the standard dictionary definition of “infrared radiation”: “situated outside the visible spectrum at its red end – used of radiation having a wavelength between about 700 nanometers and 1 millimeter.” *Id.* (citing Ex. 1009, 642; Ex. 1006 ¶ 46).

Patent Owner’s construction “is not dissimilar to that proposed by Petitioner,” but narrows the spectrum range to between 750 nanometers to 1 million nanometers (1 millimeter) based on a definition from a technical dictionary. PO Resp. 19 (citing Ex. 2008 ¶ 77; Ex. 2063).

Crediting Patent Owner’s technical dictionary over Petitioner’s general dictionary, we construe “infrared radiation” as: “situated outside the visible spectrum at its red end – radiation having a wavelength between

about 750 nanometers and 1 millimeter.”

3. “*inducing localized hypothermia*”

Patent Owner contends the preamble phrase “inducing localized hypothermia” should be construed and given patentable weight because (1) “[i]t is essential to understand limitations in the body of the claims,” and (2) [it] is grammatically essential to the claims with another term in the body of the claims deriving “antecedent basis” from the preamble, i.e., “heat.” PO Resp. 19. Patent Owner asserts that “‘inducing localized hyperthermia in a cell or tissue’ means causing hyperthermia that is localized to a targeted cell or tissue with minimal, if any, heat dissemination outside the targeted area.” PO Resp. 20 (citing Ex. 1001, Abst., 1:15–22, 2:19–20, 4:48–50, 6:54–59, 7:59–61, 8:25–29, 22:8–29, 25:33–35, 25:48–50, claim 47). According to Patent Owner, “[t]he methods that are challenged in the ’944 Patent are a significant improvement, as a medical procedure, over the prior art’s more expansive ‘cell death’ procedures of the crowded art cited by the Petitioner.” *Id.* at 21. Therefore, Patent Owner argues that a person of ordinary skill in the art would have understood the phrase “inducing localized, targeted hyperthermia in such cell or tissue therapy,” as used in the Summary of the Invention, to describe the essence of the invention. *Id.* at 22 (citing Ex. 2008 ¶ 46). Moreover, Patent Owner asserts that Petitioner seeks to ignore the preamble calling for “localized” “hyperthermia,” so that it can simply look for disclosures of “heat” in the prior art. *Id.* Patent Owner argues, however, that hyperthermia and heat are different – hyperthermia requires an extreme temperature elevation, not simply “heat.” *Id.*

Petitioner contends the body of claim 1 is structurally complete and therefore, the preamble should not be given patentable weight as it merely

states a purpose or intended use for the claimed invention. Reply 13–14. Petitioner specifically argues that claim 1 recites the steps of delivering nanoparticles to the tissue and exposing the nanoparticles to infrared radiation, wherein the nanoparticles emit heat. Tr. 7:16–18. Petitioner notes that the process steps are able to stand alone, and the preamble clause does not add an additional method step or limitation. *Id.* at 7:19–22. Petitioner then argues that Patent Owner’s declarant agrees that the clause for inducing localized hyperthermia merely states an objective of the invention or of the intended use. Tr. 7:24–26.

Moreover, according to Petitioner, the clause for induced localized hyperthermia does not serve as an antecedent basis in the body of the claim. Although Patent Owner argues the term “heat” in challenged claim 1 “deriv[es] antecedent basis’ from the preamble,” (presumably from the term “hyperthermia”) (PO Resp. 19), Petitioner notes that the claim term “heat” is introduced without definite antecedent earlier in the claim. Reply 14 (citing Ex. 1001, 33:57). Additionally, Petitioner argues that hyperthermia (as an effect of heat) does not introduce the term “heat,” rather it represents a desired outcome or objective of that heat introduced later in the body of the claim. *Id.*

Petitioner then contests Patent Owner’s attempt “to animate the preamble of claim 1, and make the meaning of ‘localized’ an issue.” *Id.* Petitioner notes that the ’944 patent provides an express definition for “localized” as “substantially limited to the desired areas with only minimal, if any, dissimulation outside of the area.” *Id.* at 14–15 (citing Ex. 1001, 7:59–61).

Petitioner further contests Patent Owner’s proposed construction of “hyperthermia” as overly narrow, because it “require[s] ‘cell death’ and heating to ‘an extremely high temperature.’” *Id.* at 16–17 (citing PO Resp. 3; Ex. 2008 ¶¶ 41, 42, 61). According to Petitioner, “[t]he plain and ordinary meaning of hyperthermia is an exceptionally high fever, especially when induced artificially for therapeutic purposes. Though Rice’s construction does not require it, Rice argues that hyperthermia means extremely high temperatures.” Tr. 8:19–23. Petitioner argues that Patent Owner’s declarant, Dr. Jain, defined hyperthermia in one of his prior publications “as moderate heating of the tissue in the range of 106 to 117 degrees Fahrenheit.” Reply 17 (citing Ex. 1015, 1); Tr. 8:23–25. Petitioner then argues that Patent Owner’s other declarant, Ivan J. Dmochowski, Ph.D. (“Dr. Dmochowski”) agrees that a temperature of 106 to 117 degrees Fahrenheit represents a particularly high fever, which would meet the plain and ordinary meaning of localized hyperthermia. *Id.* (citing Ex. 1018, 65:22–66:2). Therefore, Petitioner contends that the broadest reasonable construction of hyperthermia means “raising the temperature of the cell or tissue to only above 106 degrees Fahrenheit.” Tr. 9:4–6.

“Whether to treat a preamble term as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.” *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (internal quotation marks omitted). “Absent clear reliance on the preamble in the prosecution history, or in situations where it is necessary to provide antecedent basis for the body of the claim, the preamble ‘generally is not limiting.’” *Symantec Corp. v. Computer Assoc. Int’l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008). Preamble language that

merely states the purpose or intended use of an invention generally is not treated as limiting the scope of a claim. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). When the limitations in the body of the claim rely upon or derive essential structure from the preamble, however, then the preamble acts as a necessary component of the claimed invention and is limiting. *See Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003). Moreover, if the preamble recites a specific characteristic for a component of an invention recited in the body of the claim, then the preamble must be given patentable weight. *See, e.g., Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995) (noting that a claim drafter may choose to use both the preamble and the body of the claim to define the subject matter of the claimed invention).

In the present case, the recitation “for inducing localized hyperthermia” in the preamble in claim 1 states an intended use for the recited method. Specifically, the body of the claim recites complete limitations that dictate that the method deliver nanoparticles to a cell or tissue and expose those nanoparticles to infrared radiation so the nanoparticles emit heat. Ex. 1001, 33:53–57. Therefore, there is no reliance upon the preamble to define the subject matter of the claimed invention (i.e., a method of delivering nanoparticles to a cell or tissue and exposing the nanoparticles to infrared radiation), because it is expressed explicitly in the body of the claims.

Second, the phrase “for inducing localized hyperthermia” does not provide antecedent basis for a limitation in the body of the claim and is not

necessary to give meaning to the recited method steps. We agree with Patent Owner's statement that "hyperthermia" and "heat" are different. PO Resp. 22. Therefore, we do not find that "hyperthermia" provides an antecedent basis for "heat" as recited in the body of the claim.⁶

Accordingly, we find the recitation "for inducing localized hyperthermia" in the preamble to claim 1 in the '944 patent to be a non-limiting statement of the purpose of the claimed method.

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 102 if a prior art reference discloses every limitation of the claimed invention, either explicitly or inherently. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995). If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure. *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999). To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present," or inherent, in the single anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). "Inherency, however, may not be established by *probabilities* or *possibilities*. The mere fact that a certain thing may

⁶ Although "a cell or tissue" as recited in the preamble of independent claim 1 of the '944 patent serves as the antecedent basis for "said cell or tissue" recited in the body of each claim, we are not required to construe as a claim limitation the entirety of a preamble even if a portion of it is construed as a limitation. *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323 (Fed. Cir. 2015); *see, e.g., Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 868 (Fed. Cir. 1985), *overruled in part on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) (en banc in part).

result from a given set of circumstances is not sufficient.” *Id.* at 1269 (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (emphasis added)). Inherent anticipation, however, does not require recognition in the prior art. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (“*Continental Can* does not stand for the proposition that an inherent feature of a prior art reference must be perceived as such by a person of ordinary skill in the art before the critical date”).

A claim is unpatentable under 35 U.S.C. § 103(a) if “the differences between the subject matter sought to be patented 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, i.e., secondary considerations. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

“A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors, and it is error to reach a conclusion of obviousness until all those factors are considered.” *Apple v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) (citations omitted). “This requirement is in recognition of the fact that each of the *Graham* factors helps inform the ultimate obviousness determination.” *Id.*

“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 burden of proof in *inter partes* review). Furthermore, 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).

Thus, to prevail in an *inter partes* review, Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable. At this final stage, we determine whether a preponderance of the evidence of record shows that the challenged claims would have been obvious over the proposed combinations of prior art.

We analyze the instituted grounds of unpatentability in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, we consider the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. “The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991). The person of ordinary

skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). The level of ordinary skill in the art may be reflected by the prior art of record. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the technology, and educational level of active workers in the field. *GPAC*, 57 F.3d at 1579. In a given case, one or more factors may predominate. *Id.* Generally, it is easier to establish obviousness under a higher level of ordinary skill in the art. *Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) (“A less sophisticated level of skill generally favors a determination of nonobviousness . . . while a higher level of skill favors the reverse.”).

Petitioner’s Declarant, Dr. Suslick, opines that a person of ordinary skill in the art relevant to the ’944 patent would have had “either (i) a Bachelor’s degree in chemical engineering, physics, chemistry, materials science, or a similar field, and two or three years of work experience in materials technology, chemical or biomedical research or related fields, or (ii) a Master’s degree in chemical engineering, physics, chemistry, materials science, or a similar field and one or two years of work experience in materials technology, chemical or biomedical research or related fields.” Ex. 1006 ¶ 20.

Patent Owner disputes Dr. Suslick’s testimony, relying on the testimony of its declarant, Dr. Jain. PO Resp. 8 (citing Ex. 2008). Dr. Jain testifies that a person of ordinary skill in the art relevant to the ’944 patent at the time of the invention “would have at least three years of post-graduate

education in medicine, biomedical sciences, or related fields with experience in nanochemistry or optics; or, at least three years of post-graduate education in chemistry, chemical engineering, materials science, optics, or a similar field with experience in nanochemistry and medicine, biomedical sciences, or a related field.” Ex. 2008 ¶ 27.

Based on our review of the ’944 patent, the types of problems and solutions described in the ’944 patent and cited prior art, and the testimony of Dr. Suslick and Dr. Jain, we find that a person of ordinary skill in the art at the time of the claimed invention would have had at least three years of post-graduate education in material sciences, chemistry, chemical engineering, optics, physics, or biomedical sciences with at least one year of work experience in nanotechnology, nanochemistry, materials technology, chemical or biomedical research or related fields.

D. Alleged Anticipation of Claims 1 and 7 in view of Tankovich I

Petitioner contends claims 1 and 7 of the ’944 patent are unpatentable under 35 U.S.C. § 102(b) in view of Tankovich I. Pet. 13–20. Patent Owner disputes Petitioner’s contentions. PO Resp. 26–29. For reasons that follow, we determine Petitioner established by a preponderance of the evidence that the challenged claims of the ’944 patent are unpatentable under 35 U.S.C. § 102(b) as anticipated by Tankovich I.

1. Overview of Tankovich I

Tankovich I is a U.S. patent titled “Hair Removal Device and Method.” Ex. 1002, Title. Tankovich I is directed to the permanent removal and of unwanted human hair. *Id.* at [57]. One embodiment disclosed in Tankovich I is shown in Figures 2A, 2B, and 2C, reproduced below.

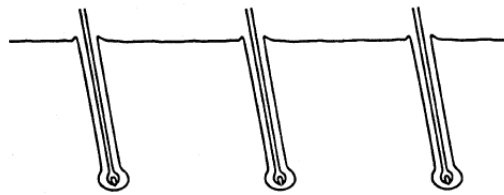


FIG. 2A

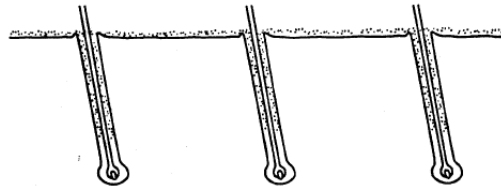


FIG. 2B

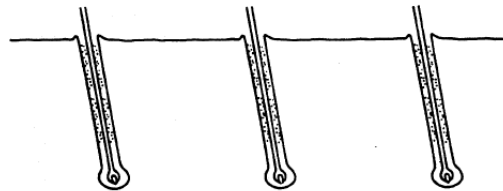


FIG. 2C

Figure 2A, above, shows a cross section of skin and three hairs. *Id.* at 1:44–46. In Figure 2B, a laser absorbing carbon suspension is rubbed on the skin so that the suspension infiltrates the hair ducts of the hair. *Id.* at 2:4–8. According to the teachings of Tankovich I, the particle size of the powder in the suspension is about 10–20 nm. *Id.* at 1:68–2:1. In Figure 2C, the surface of the skin is wiped clean so that only the hair pores are contaminated with the suspension. *Id.* at 2:8–11.

Tankovich I indicates its invention produces death of the follicles by heating and by photochemical reaction. According to Tankovich I, the heating and photochemical reaction are created using a laser device, such as a CO₂ pulse laser that has spikes in the range of 10.6 microns. *Id.* at [57], 2:14–16. Tankovich I discloses that light in this range will pass through the surface of the skin of a person with fair skin and is absorbed by the carbon suspension as shown in Figure 3, reproduced below. *Id.* at 2:16–18.

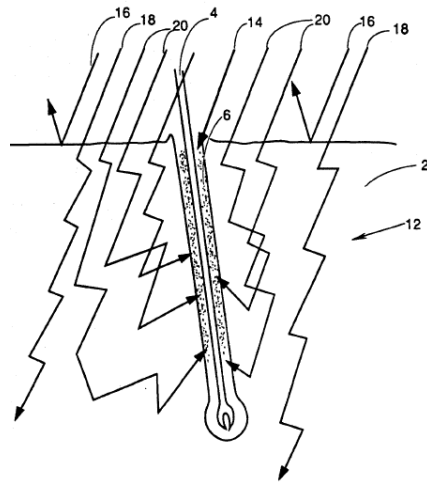


Figure 3 illustrates using laser pulse illumination to heat the suspension, which in turn heats the hair follicles and the blood vessels feeding the follicles to temperatures high enough to kill the hair follicles and the tissue feeding the follicles but to minimize the heat to the rest of the skin tissue. *Id.* at 2:51–57.

2. *Analysis of Cited Art as Applied to Independent Claim 1 and Dependent Claim 7*

a. *Preamble to Claim 1*

We have determined that the recitation of “for inducing localized hyperthermia” in the preamble to claim 1 in the ’944 patent to be a non-limiting statement of the purpose of the claimed method. *See supra* Section II.A.3.

b. *“delivering nanoparticles to said cell or tissue”*

Petitioner contends Tankovich I discloses “delivering nanoparticles to said cell or tissue,” as recited by claims 1 and 7. According to Petitioner, Tankovich I describes preparing a suspension of carbon nanoparticles in oil and rubbing the mixture into a clean section of skin to infiltrate hair ducts containing the follicles to be heated. Pet. 15 (citing Ex. 1002, 1:67–2:8)

Petitioner argues that Tankovich I's disclosed particle size range, from 10–20 nanometers, is within the size range of “nanoparticles” of 1 to 1000 nanometers, as described in the '944 patent. *Id.* at 15–16 (citing Ex. 1006 ¶ 50).

Patent Owner, however, disputes Petitioner's contentions that the carbon powder particles anticipate the nanoparticles recited in the challenged claims. PO Resp. 27. Patent Owner specifically argues that Tankovich I does not disclose carbon powder nanoparticles that are plasmonic and one of ordinary skill in the relevant art would not have considered Tankovich I's carbon powder to be plasmonic. *Id.* at 27–28. Patent Owner further argues that the heating disclosed in Tankovich I is not localized and is not hyperthermic. *Id.* at 28 (citing Ex. 2007, 118:19–123:8, 124:10–126:3; Ex. 2008 ¶ 86). According to Patent Owner, Petitioner and its expert, Dr. Suslick, did not consider the documented failure of the process disclosed in Tankovich I. *Id.* Patent Owner specifically notes the Anderson⁷ patent discloses that Tankovich I uses an explosive photomechanical mechanism to damage hair follicles. *Id.* (citing Ex. 1004, 7:37–43). According to Patent Owner, the use of an explosive mechanism is a failing that the '944 patent addressed, because “the ‘localized hyperthermia’ claimed in the '944 patent can target on a cellular and molecular level, with minimal collateral damage.” *Id.* at 29 (citing Ex. 2008 ¶¶ 41, 42, 52–54, 62).

We agree with Petitioner's contentions for multiple reasons. First, the '944 patent defines “delivering” nanoparticles to a location “as effecting the

⁷ U.S. Patent No. 6,183,773 B1; filed Jan. 4, 1999, issued Feb. 6, 2001 (Ex. 1004, “Anderson”).

placement of the nanoparticles attached to, next to, or sufficiently close to the location such that any heat generated by the nanoparticles is transferred to the location and any imaging of the local environment by the nanoparticles includes imaging of the desired location.” Ex. 1001, 6:54–59. Tankovich I discloses rubbing a carbon particle suspension (with particles in the size range of 10–20 nm) on skin so that the suspension infiltrates the hair ducts of the hair that is to be removed. Ex. 1002, 1:67–2:8. Based on the definition of “delivering” nanoparticles provided in the ’944 patent, we find that Tankovich I “delivers” nanoparticles to the hair follicle.

Second, based on our construction of “nanoparticles” and the failure of the challenged claims to recite “plasmonic” nanoparticles, we do not agree with Patent Owner’s position that the carbon powder particles of Tankovich I must be plasmonic in order to anticipate the claim. *See supra* Section II.A.1. The disclosure of 10–20 nm particles satisfies the claim limitation.

Third, based on our determination that the preamble phrase “for inducing localized hyperthermia” is not limiting, we do not agree with Patent Owner’s position that Tankovich I fails to meet the “purpose” of claim 1. Moreover, even if we had determined this preamble phrase to be limiting, we do not agree with Patent Owner’s interpretation that “localized” means anything other than the explicit definition disclosed in the ’944 patent. *See* PO Resp. 20–21. Specifically, as defined by the ’944 patent, “localized” means “substantially limited to a desired area with only minimal, if any, dissemination outside such area.” Ex. 1001, 7:59–61. According to the specification and to the explicit language of the claim, the desired area would include “a cell or tissue” with a tissue being a cell or cells. *Id.* at

20:62–63. Based on this definition of “localized,” we find that Tankovich I discloses this element, because Tankovich I discloses heating “to about above 70°–80°C . . . enough to kill the follicles and/or the vessels feeding the follicles . . . [while] minimal heat is transferred to the skin tissue except that tissue immediately surrounding the follicle.” *See* Ex. 1002, 2:60–67. The follicles and vessels meet the claim limitation for “tissue” because it is a collection of specialized epithelial cells that make hair. Thus, we find Tankovich I’s method targets the specific tissue of the follicles and is limited substantially to that tissue with minimal heat transferred to other skin tissue.

Additionally, we agree with Patent Owner that hyperthermia is different from heat. Specifically, we credit the definition from Patent Owner’s declarant, Dr. Jain, that “[h]yperthermia is commonly defined as heating tissue to a temperature in the range 41–47°C for tens of minutes.” *See* Ex. 1015, 1. The claims, however, specifically recite “said nanoparticles emit heat” and do not require that the nanoparticles emit heat of a specific temperature or for a specific duration.

Lastly, we are unmoved by Patent Owner’s argument that Tankovich I’s use of an explosive photomechanical mechanism to damage hair follicles is a failing addressed by the ’944 patent, which distinguishes challenged claim 1. *See* PO Resp. 28. Specifically, there is nothing in the recited steps of claim 1 that prohibit or exclude the use of an explosive photomechanical mechanism in addition to delivering heat emitting nanoparticles. *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) (“The transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.”). Additionally, we find insufficient support in the specification for a negative claim limitation

regarding use of an explosive photomechanical mechanism. *See Santarus, Inc. v Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012) (“Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation.”).

Accordingly, based on the entirety of the record, we determine Tankovich I discloses “delivering nanoparticles to said cell or tissue,” as recited by claim 1.

- c. *“exposing said nanoparticles to infrared radiation under conditions wherein said nanoparticles emit heat upon exposure to said infrared radiation”*

Petitioner contends Tankovich I discloses “exposing said nanoparticles to infrared radiation under conditions wherein said nanoparticles emit heat upon exposure to said infrared radiation,” as recited by claim 1. Pet. 16. Tankovich I describes use of a “laser device . . . which has spikes in the range of 10.6 microns,” that is “readily absorbed in carbon.” *Id.* (citing Ex. 1002, 2:14–18). Petitioner relies on the declaration of Dr. Suslick, who testifies that “[e]lectromagnetic radiation of wavelength of 10.6 microns is infrared radiation in the wavelength range of 700 nanometers to 1 millimeter.” *Id.* (citing Ex. 1006 ¶ 51). According to Petitioner, Tankovich I discloses that the parameters of the radiation “have been chosen to preferentially heat the suspension [of carbon nanoparticles] which in turn heats the hair follicles and the blood vessels feeding the follicles to temperatures high enough to kill the hair follicles[.]” *Id.* (citing Ex. 1002, 2:51–64).

Patent Owner does not dispute Petitioner's contentions. Nonetheless, the burden remains on Petitioner to demonstrate unpatentability. *See Dynamic Drinkware*, 800 F.3d at 1378.

Claim 1 of the '944 patent recites "infrared radiation" and claim 7 (depending directly from claim 1) recites "said radiation." We have construed "infrared radiation" to mean "situated outside the visible spectrum at its red end – radiation having a wavelength between about 750 nanometers and 1 millimeter." *See supra* Section II.A.2. We, thus, find Tankovich I's disclosure of a CO₂ pulse laser having spikes in the range of 10.6 microns (e.g., 10,600 nanometers) meets the required "infrared radiation" limitation recited in claims 1 and 7 as we have so construed it.

Additionally, we find that Tankovich I's disclosure that the parameters of the radiation "have been chosen to preferentially heat the suspension [of carbon nanoparticles] *which in turn heats* the hair follicles and the blood vessels feeding the follicles to temperatures high enough to kill the hair follicles" (*see* Ex. 1002, 2:51–64 (emphasis added)) indicates that the nanoparticles emit heat upon exposure to the infrared radiation.

d. Claim 7

Claim 7 further recites that the "nanoparticles absorb said radiation." Ex. 1001, 34:4–5. Petitioner contends that Tankovich I discloses that "[l]ight in this range . . . is readily absorbed by the carbon." Pet. 19–20 (quoting Ex. 1002, 2:16–18) (citing Ex. 1002, 1:67–2:1; Ex. 1006 ¶ 53). Patent Owner does not dispute Petitioner's contention. PO Resp. 26–29.

We are persuaded by Petitioner's contention. Specifically, Tankovich I explains that the infrared radiation emitted by the pulse laser "is absorbed by the carbon" nanoparticles. Ex. 1002, 2:16–18.

e. Summary

Accordingly, having analyzed the entirety of the record and evidence, we determine Petitioner has established by a preponderance of the evidence that claims 1 and 7 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Tankovich I.

E. Alleged Anticipation of Claims 1, 6, and 7 in view of Tankovich II

Petitioner contends claims 1, 6, and 7 of the '944 patent are unpatentable under 35 U.S.C. § 102(b) in view of Tankovich II. Pet. 20–25. Patent Owner disputes Petitioner's contentions. PO Resp. 29–31. For reasons that follow, we determine Petitioner established by a preponderance of the evidence that the challenged claims of the '944 patent are unpatentable under 35 U.S.C. § 102(b) as anticipated by Tankovich II.

1. Overview of Tankovich II

Tankovich II is a U.S. patent titled "Skin Treatment Process Using Laser." Ex. 1003, Title. Tankovich II is directed to (1) the removal of superficial epidermal skin cells in human skin (2) the reduction or removal of unwanted hair and (3) the mitigation of skin conditions such as acne and seborrhea. *Id.* at [57]. One embodiment disclosed in Tankovich II is shown in Figures 3A–3F, reproduced below.

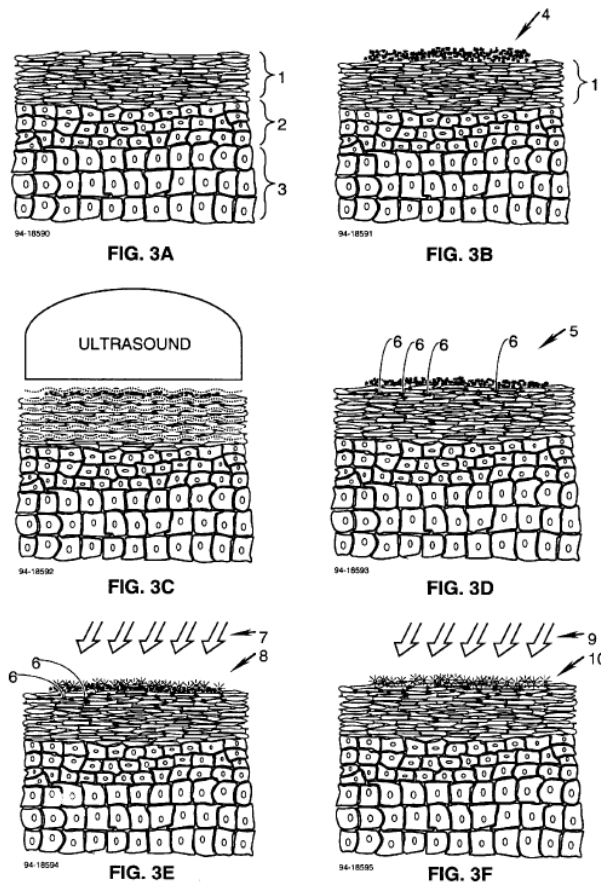


Figure 3A, above, shows a typical cross section of a section of the outer portion (the top three strata) of human epidermis. *Id.* at 3:31–33. Tankovich II discloses topically applying a layer of carbon solution of 1 micron graphite powder to the skin surface. *Id.* at 3:47–50, Fig. 3B. Then, according to the teachings of Tankovich II, some of the carbon particles are forced down below the surface of the stratum corneum using an ultrasound unit. *Id.* at Fig. 3C, 3:51–53.

The result of the ultrasound treatment is shown in Figure 3D above, where two layers of graphite particles are left on the surface and a portion of particles 6 are distributed below the surface. *Id.* at 3:61–67. Tankovich II discloses that the next step is to irradiate the skin surface with Nd:YAG laser

pulses of about 3 J/cm^2 at a wavelength of $1.06 \text{ }\mu\text{m}$. *Id.* at 4:3–4. According to Tankovich II, pulse frequency is about 5 Hz but it scans the beam so that each location is subjected to pulses at a frequency of about 1 Hz. *Id.* at 4:5–7. Tankovich II indicates that graphite is very absorptive of laser energy at the $1.06 \text{ }\mu\text{m}$ wavelength, and that the latent heat of vaporization is about 105 J/cm^2 for cold solid graphite. *Id.* at 4:7–9.

Tankovich II then discloses that as a result of first pulse 7, the first layer of graphite particles is exploded, and the second layer and the skin surface is effectively shielded from first pulse 7 by the first layer. *Id.* at 4:22–25, Fig. 3E. According to the teachings of Tankovich II, some of the carbon particles above the skin have been pushed into the skin as a result of the shockwaves resulting from the explosion of the particle in the first layer. *Id.* at 4:25–28. Tankovich II lastly discloses that second pulse 9, coming one second later, vaporizes the second layer. *Id.* at 4:28–30, Fig. 3F.

2. *Analysis of Cited Art as Applied to Independent Claims 1, 6, and 7*

a. *Preamble to Claim 1*

We have determined that the recitation of “for inducing localized hyperthermia” in the preamble to claim 1 in the ’944 patent to be a non-limiting statement of the purpose of the claimed method. *See supra* Section II.A.3.

b. *“delivering nanoparticles to said cell or tissue”*

Petitioner contends Tankovich II discloses “delivering nanoparticles to said cell or tissue,” as recited by claim 1. Pet. 22. According to Petitioner, Tankovich II discloses a process where, “[t]he first step . . . is to topically apply a layer of carbon solution to the skin surface . . . comprised

of 1 micron graphite powder in baby oil.” *Id.* (citing Ex. 1003, 3:47–50; Ex. 1006 ¶ 57). Petitioner, therefore, concludes that the particles have a diameter in the range of 1 to 1000 nm and qualify as nanoparticles. *Id.*

Patent Owner, however, disputes Petitioner’s contentions that the carbon powder particles of Tankovich II anticipate the nanoparticles recited in the challenged claims. PO Resp. 30–31. Patent Owner specifically argues that Tankovich II’s carbon powder nanoparticles are not plasmonic and one of ordinary skill in the relevant art would not have considered Tankovich II’s nanoparticles to be plasmonic. *Id.* at 31. According to Patent Owner, “a mere disclosure of light-absorbing nanoparticles does not anticipate the plasmonic nanoparticles claimed in the ’944 Patent.” *Id.* (citing Ex. 2008 ¶ 69, 92, 93; Ex. 1008, 132–133, 145–146, 162).

Patent Owner further argues that the heating disclosed in Tankovich II is not localized or hyperthermic. *Id.* at 30 (citing Ex. 2007, 118:19–123:8, 124:10–126:3; Ex. 2008 ¶¶ 41, 42, 62, 94, 95). Patent Owner argues that Tankovich II suffers from the same flaws as Tankovich I, because it uses an explosive photomechanical mechanism to damage hair follicles. *Id.* (citing Ex. 1004, 7:37–43). According to Patent Owner, the use of an explosive mechanism is a failing that the ’944 patent addressed, because “the ‘localized hyperthermia’ claimed in the ’944 patent can target on a cellular and molecular level, with minimal collateral damage.” *Id.* (citing Ex. 2008 ¶¶ 55). Patent Owner asserts that the “localized hyperthermia” claimed in the ’944 Patent, targets on a molecular level, with minimal collateral damage. *Id.* (citing Ex. 2008 ¶¶ 41, 42, 62, 94, 95).

We agree with Petitioner’s contentions for multiple reasons. First, the ’944 patent defines “delivering” nanoparticles to a location “as effecting the

placement of the nanoparticles attached to, next to, or sufficiently close to the location such that any heat generated by the nanoparticles is transferred to the location and any imaging of the local environment by the nanoparticles includes imaging of the desired location.” Ex. 1001, 6:54–59. Tankovich II discloses topically applying a carbon solution (of micron graphite power) to skin. Ex. 1003, 3:47–50. Based on the definition of “delivering” nanoparticles provided in the ’944 patent, we find that Tankovich II “delivers” nanoparticles to target epithelial cells.

Second, based on our construction of “nanoparticles” and the failure of the challenged claims to recite “plasmonic” nanoparticles, we do not agree with Patent Owner’s position that the carbon powder particles of Tankovich II must be plasmonic in order to anticipate the claim. *See supra* Section II.A.1. The disclosure of one micron particles, e.g., 1000 nanometers, satisfies the claim limitation.

Third, based on our determination that the preamble is not limiting, we do not agree with Patent Owner’s position that Tankovich II fails to meet the “purpose” of claim 1. Moreover, as discussed previously, even if we had determined the preamble to be limiting, we do not agree with Patent Owner’s interpretation that “localized” means anything other than the explicit definition disclosed in the ’944 patent. *See* PO Resp. 20–21. Specifically, as defined by the ’944 patent, “localized” means “substantially limited to a desired area with only minimal, if any, dissemination outside such area.” Ex. 1001, 7:59–61. According to the specification and to the explicit language of the claim, the desired area would include “a cell or tissue” with a tissue being a cell or cells. *Id.* at 20:62–63. Based on this construction of “localized,” we find that Tankovich II discloses this element,

because Tankovich II discloses “destruction of epithelium tissue making up the surface of the inside wall of the sebaceous glands which tissue produces the sebum.” *See* Ex. 1003, 3:47–50, 5:64–67, 6:29–32. The epithelium tissue of the surface of the inside wall of the sebaceous glands meet the claim limitation for “tissue.” Thus, we find Tankovich II’s method targets the specific epithelium tissue of the sebaceous glands and is limited substantially to that tissue with minimal heat transferred to other skin tissue.

Additionally, as previously discussed, we agree with Patent Owner that hyperthermia is different from heat. Specifically, we credit the definition from Patent Owner’s declarant, Dr. Jain, that “[h]yperthermia is commonly defined as heating tissue to a temperature in the range 41–47°C for tens of minutes.” *See* Ex. 1015, 1. The claims, however, specifically recite “said nanoparticles emit heat” and do not require that the nanoparticles emit heat of a specific temperature or for a specific duration.

Lastly, we are unmoved by Patent Owner’s argument that Tankovich II uses an explosive photomechanical mechanism to damage epithelium tissue is a failing addressed by ’944 patent, which distinguishes challenged claim 1. *See* PO Resp. 30. Specifically, given the explicit steps recited in claim 1, there is nothing in the claims that prohibits or excludes the use of an explosive photomechanical mechanism in addition to the heat emitting nanoparticles. Additionally, we find insufficient support in the specification for a negative claim limitation regarding use of an explosive photomechanical mechanism. *See Santarus*, 694 F.3d at 1351 (“Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation.”)

Accordingly, based on the entirety of the record and evidence, we determine Tankovich II discloses “delivering nanoparticles to said cell or tissue,” as recited by claim 1.

c. *“exposing said nanoparticles to infrared radiation under conditions wherein said nanoparticles emit heat upon exposure to said infrared radiation”*

Petitioner contends Tankovich II discloses “exposing said nanoparticles to infrared radiation under conditions wherein said nanoparticles emit heat upon exposure to said infrared radiation,” as recited by claim 1. Pet. 22. Tankovich II describes “irradiat[ing] the skin surface with Nd:YAG laser pulses of about 3 J/cm² at a wavelength of 1.06 μm,” noting that the “[g]raphite [nanoparticles are] very absorptive of laser energy at the 1.06 μm wavelength,” *Id.* 22–23 (citing Ex. 1003, 4:3–8). Petitioner relies on the declaration of Dr. Suslick, who testifies that “[e]lectromagnetic radiation of wavelength of 1.06 [microns] is infrared radiation in the wavelength range of 700 nanometers to 1 millimeter.” *Id.* at 23 (citing Ex. 1006 ¶ 58). According to Petitioner, Tankovich II further describes how “[t]he damage to the tissue appears to be the combined result of both the heating effect of the hot carbon particles and oil and possibly some mechanical damage due to the kinetic energy of the particles and fragments.” *Id.* (citing Ex. 1003, 5:64–67).

Patent Owner does not dispute Petitioner’s contentions. Nonetheless, the burden remains on Petitioner to demonstrate unpatentability. See *Dynamic Drinkware*, 800 F.3d at 1378.

Claim 1 of the ’944 patent recites “infrared radiation” and claim 7 (depending directly from claim 1) recites “said radiation.” Claim 6, which

depends directly from claim 1 recites “wherein the infrared radiation is of wavelengths from 800 nm to 1300 nm or from 1600 nm to 1850 nm.”

We have construed “infrared radiation” to mean “situated outside the visible spectrum at its red end – radiation having a wavelength between about 750 nanometers and 1 millimeter.” *See supra* Section II.A.2. We, thus, find Tankovich II discloses irradiating skin with light having a wavelength of 1.06 μm (Ex. 1003, 4:3–4), which corresponds to 1060nm, and which is within the wavelength range of infrared radiation specified in dependent claim 6 the ’944 patent (Ex. 1001, 34:1–3). Moreover, Tankovich II discloses that this radiation causes the nanoparticles to emit heat. Ex. 1003, 5:64–67 (“The damage to the tissue appears to be the combined result of both the heating effect of the hot carbon particles and oil and possibly some mechanical damage . . .”). Additionally, we are persuaded that Tankovich II discloses the use of graphite nanoparticles that are “very absorptive of laser energy at 1.06 μm wavelength” (Ex. 1003, 4:6–8), which meets the limitation of “said nanoparticles absorb said radiation” as recited in dependent claim 7 of the ’944 patent (Ex. 1001, 34:4–5). Therefore, we are satisfied that Tankovich II’s disclosure meets the required limitations recited in claims 1, 6, and 7.

d. Summary

Accordingly, having analyzed the entirety of the record and evidence, we determine Petitioner has established by a preponderance of the evidence that claims 1, 6, and 7 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Tankovich II.

F. Alleged Anticipation of Claims 1, 6–8, and 12 in view of Esenaliev

Petitioner contends claims 1, 6–8, and 12 of the '944 patent are unpatentable under 35 U.S.C. § 102(e) in view of Esenaliev. Pet. 32–41. Patent Owner disputes Petitioner's contentions. PO Resp. 31–33. For reasons that follow, we determine Petitioner established by a preponderance of the evidence that the challenged claims of the '944 patent are unpatentable under 35 U.S.C. § 102(e) as anticipated by Esenaliev.

1. Overview of Esenaliev

Esenaliev is a U.S. patent titled "Radiation and Nanoparticles for Enhancement of Drug Delivery in Solid Tumors." Ex. 1005, Title. Esenaliev is directed to using electromagnetic pulses or ultrasonic radiation to help nano- and microparticles perforate tumor blood vessels or cancer cell membranes to enhance delivery of therapeutic agents from blood into cancer cells. *Id.* at [57]. Esenaliev discloses that nanoparticles can be attached to antibodies directed against antigens in tumor vasculature and selectively delivered to tumor blood vessel walls. *Id.* at 1:63–66. According to the teachings of Esenaliev, cavitation induced by ultrasonic waves or local heating of the particles by pulsed electromagnetic radiation results in perforation of tumor blood vessels, microconvection in the interstitium, and perforation of cancer cell membrane. *Id.* at 1:66–2:3. This method provides enhanced delivery of macro-molecular therapeutic agents from the blood into cancer cells with minimal thermal and mechanical damage to normal tissues. *Id.* at 2:3–6.

Esenaliev indicates that the nanoparticles or microparticles can be metal particles, carbon particles, graphite particles, polymer particles loaded with an absorbing dye, liquid particles loaded with an absorbing dye, or

porous particles having gas-filled pores. *Id.* at 2:24–27. The nanoparticle has a diameter from about 0.1 nm to about 7000 nm. *Id.* at 2:28–29. Esenaliev then discloses that once the nanoparticles are delivered to the cancer cells, the cells can be irradiated using optical pulsed radiation generated from a laser or non-laser source. *Id.* at 2:30–31. Esenaliev specifically discloses that the optical radiation is in the spectral range from 0.2 μm to 2 μm and delivered through the skin surface or via optical fibers inserted in a needle or endoscopes to the tumor. *Id.* at 2:31–34. One embodiment disclosed in Esenaliev is shown in Figure 1b, reproduced below.

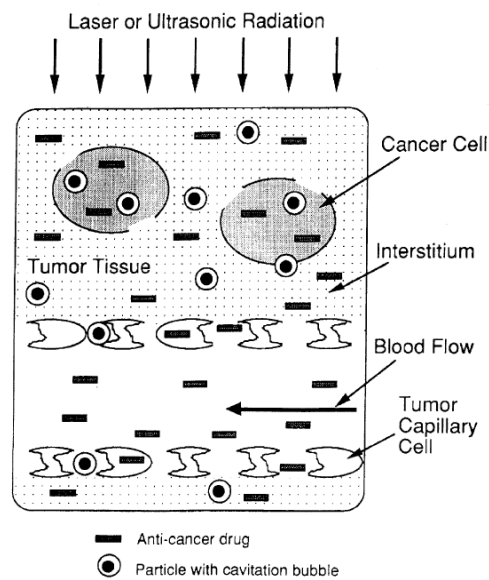
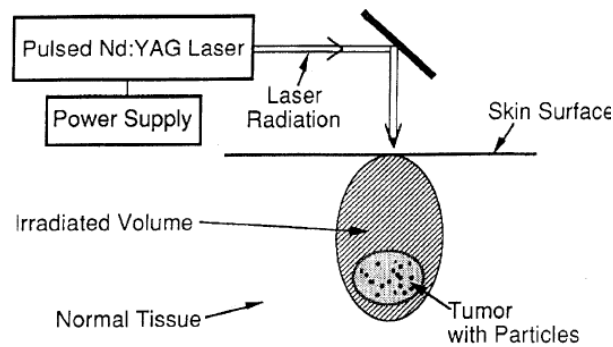


Figure 1b, above, shows the interaction of microparticles with pulsed laser. *Id.* at 6:58–59. Another embodiment disclosed in Esenaliev is shown in Figure 2A, reproduced below.



According to the teachings of Esenaliev, using a nanosecond Nd:YAG laser with radiation in the wave length of 1064 nm induced local heating of strongly absorbing nanoparticles. *Id.* at 7:4–7.

2. *Analysis of Cited Art as Applied to Independent Claim 1, and dependent claims 6–8, 12*

a. *Preamble to Claim 1*

We have determined that the recitation of “for inducing localized hyperthermia” in the preamble to claim 1 in the ’944 patent to be a non-limiting statement of the purpose of the claimed method. *See supra* Section II.A.3.

b. *“delivering nanoparticles to said cell or tissue”*

Petitioner contends Esenaliev discloses “delivering nanoparticles to said cell or tissue,” as recited by claim 1. Pet. 34. Petitioner specifically argues that Esenaliev discloses “nanoparticles or microparticles [that] can be metal particles, carbon particles, graphite particles,” or others that have “a diameter from about 0.1 nm to about 7000 nm.” *Id.* (citing Ex. 1005, 2:24–29). According to Petitioner, the size corresponds to the ’944 patent’s definition of nanoparticles having a diameter of from 1 to 1000 nanometers. *Id.* (citing Ex. 1001, 6:65–67). Petitioner then notes that Esenaliev goes on to describe the nanoparticles being “selectively delivered to tumor blood

vessel walls.” *Id.* (citing Ex. 1005, 1:65–66; Ex. 1006 ¶ 73). Petitioner, therefore, concludes that Esenaliev meets the claimed limitation. *Id.*

Patent Owner disputes Petitioner’s contentions that Esenaliev meets the claimed limitation, because: (1) the only specific particles Esenaliev discusses are 1 micron activated carbon particles in Example 5 and 1 to 2 micron activated carbon and graphite particles in Example 6 (Ex. 1005, 7:62–9:6); (2) Esenaliev does not disclose that its particles are plasmonic (Ex. 2008 ¶ 38); and (3) Esenaliev does not teach or suggest localized hyperthermia, rather it uses a very distinct method of cavitation which involves emulsification produced by disruption of liquid gas two phase system (Ex. 2008 ¶ 103; Ex. 1005, 1:65–2:3). PO Resp. 32–33.

We do not agree with Patent Owner’s position for several reasons. First, based on our construction of “nanoparticles” and the failure of the challenged claims to recite “plasmonic” nanoparticles, we do not agree with Patent Owner’s position that the particles of Esenaliev must be plasmonic in order to anticipate the claim. *See supra* section II.A.1. Yet, even if we had accepted Patent Owner’s construction of “nanoparticles” as requiring plasmonic properties, Esenaliev discloses the use of “gold, silver, [or] platinum” particles and, Patent Owner’s expert indicates gold and silver “configured in the nano range. . . exhibit plasmonic behavior”. *See* Ex. 1017, 96:12–15.

Second, we find that Esenaliev meets the claimed “nanoparticles” limitation, because the particles contemplated to be nanoparticles by Esenaliev (particles having a diameter from about 0.1 nm to about 7000 nm) overlap with those contemplated to be nanoparticles by the ’944 patent (a particle having a diameter of from 1 to 1000 nanometers). *See* Ex. 1001,

6:65–66; Ex. 1005, 4:8–14. Esenaliev discloses that these particles are delivered to cells or tissue, as that term is defined by the '944 patent. Ex. 1001, 6:54–59. Specifically, Esenaliev discloses that the nanoparticles can be attached to antibodies directed against antigens in tumor vasculature and selectively delivered to tumor blood vessel walls. Ex. 1005, 1:63–66.

Third, based on our determination that the preamble is not limiting, we do not agree with Patent Owner's position that the Esenaliev fails to meet the "purpose" of claim 1 with regard to "localized hyperthermia." Moreover, as discussed previously, even if we had determined the preamble to be limiting, we do not agree with Patent Owner's interpretation that "localized" means anything other than the explicit definition disclosed in the '944 patent. See PO Resp. 20–21. Specifically, as defined by the '944 patent, "localized" means "substantially limited to a desired area with only minimal, if any, dissemination outside such area." Ex. 1001, 7:59–61. According to the specification and to the explicit language of the claim, the desired area would include "a cell or tissue" with a tissue being a cell or cells. *Id.* at 20:62–63. Based on this construction of "localized," we find that Esenaliev discloses this element, because Esenaliev discloses nanoparticles being "selectively delivered to tumor blood vessel walls." See Ex. 1005, 1:65–66. The tumor blood vessel walls meet the claim limitation for "tissue." Thus, we find Esenaliev's method targets tumor blood vessel walls and is limited substantially to that tissue with minimal heat transferred to other tissue.

Additionally, as previously discussed, we agree with Patent Owner that hyperthermia is different from heat. Specifically, we credit the definition from Patent Owner's declarant, Dr. Jain, that "[h]yperthermia is

commonly defined as heating tissue to a temperature in the range 41–47°C for tens of minutes.” See Ex. 1015, 1. The claims, however, specifically recite “said nanoparticles emit heat” and do not require that the nanoparticles emit heat of a specific temperature or for a specific duration.

Lastly, we are unmoved by Patent Owner’s argument that Esenaliev’s use of cavitation involving emulsification produced by disruption of a liquid gas two phase system (Ex. 2008 ¶ 103; Ex. 1005, 1:65–2:3) is distinguished or prohibited by challenged claim 1. See PO Resp. 32–33. Specifically, there is nothing in the recited steps of claim 1 that prohibits or excludes the use of a cavitation mechanism in addition to delivering heat emitting nanoparticles. Additionally, we find insufficient support in the specification for a negative claim limitation regarding use of an explosive photomechanical mechanism. See *Santarus*, 694 F.3d at 1351 (“Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation.”).

Accordingly, based on the entirety of the record, we determine Esenaliev discloses this limitation recited in claim 1.

c. *“exposing said nanoparticles to infrared radiation under conditions wherein said nanoparticles emit heat upon exposure to said infrared radiation”*

Petitioner contends Esenaliev discloses “exposing said nanoparticles to infrared radiation under conditions wherein said nanoparticles emit heat upon exposure to said infrared radiation,” as recited by claim 1. Pet. 34. According to Petitioner, Esenaliev describes “local heating of the particles by pulsed electromagnetic radiation,” in particular stating that its system “utilizes nanosecond Nd:YAG laser radiation with the wavelength of 1064

nm to induce local heating of strongly absorbing particles,” which Petitioner argues falls within the wavelength range of 700 nanometers to 1 millimeter for infrared radiation. *Id.* at 34–35 (citing Ex. 1005, 1:66–67, 7:4–7; Ex. 1006 ¶ 74). Petitioner further notes that Esenaliev discloses “the advantages of using [o]ptical radiation in the near infra-red and visible spectral ranges due to low attenuation in tissues.” *Id.* at 35 (citing Ex. 1005, 9:39–42; Ex. 1006 ¶ 74).

Patent Owner does not dispute Petitioner’s contentions. Nonetheless, the burden remains on Petitioner to demonstrate unpatentability. *See Dynamic Drinkware*, 800 F.3d at 1378.

Claim 1 of the ’944 patent recites “infrared radiation” and claim 7 (depending directly from claim 1) recites “said radiation.” Claim 6, which depends directly from claim 1 recites “wherein the infrared radiation is of wavelengths from 800 nm to 1300 nm or from 1600 nm to 1850 nm.”

We have construed “infrared radiation” to mean “situated outside the visible spectrum at its red end – radiation having a wavelength between about 750 nanometers and 1 millimeter.” *See supra* Section II.A.2. We, thus, find Esenaliev meets the claimed limitation, for at least two reasons. First, Esenaliev discloses that using a nanosecond Nd:YAG laser with radiation in the wavelength of 1064 nm induced local heating of strongly absorbing nanoparticles. *See* Ex. 1005, 7:4–7. The use of 1064 nm wavelength falls with the wavelength range specified in dependent claim 6, while Esenaliev’s use of strongly absorbing nanoparticles falls squarely within the scope of dependent claim 7. Therefore, we are satisfied that Esenaliev’s disclosure meets this limitation recited in claims 1, 6, and 7.

d. Analysis of Cited Art as Applied to Dependent Claims 8 and 12

Dependent claim 8 recites “further comprising the step of coupling molecules to the nanoparticles wherein said molecules specifically bind to the cell or tissue,” while dependent claim 12 recites “wherein said cell is a cancer cell.” We find that Esenaliev meets the claimed limitations in dependent claims 8 and 12, because it specifically teaches that “[t]he [nano]particles can be attached to antibodies directed against antigens in tumor vasculature and selectively delivered to tumor blood vessel walls.” See Ex. 1005, 1:63–66.

e. Summary

Accordingly, for the foregoing reasons, we determine based on the entirety of the record before us, Petitioner has established by a preponderance of the evidence that challenged claims 1, 6–8, and 12 of the ’944 patent are unpatentable under 35 U.S.C. § 102(e) as anticipated by Esenaliev.

G. Alleged Obviousness of Claims 6, 8, and 12 in view of Tankovich I and Esenaliev

Petitioner contends dependent claims 6, 8, and 12 of the ’944 patent are unpatentable under 35 U.S.C. § 103 in view of Tankovich I and Esenaliev. Pet. 41–46. Patent Owner disputes Petitioner’s contentions. PO Resp. 34–35. For reasons that follow, we determine Petitioner established by a preponderance of the evidence that the challenged claims of the ’944 patent are unpatentable under 35 U.S.C. § 103(a) as obvious in view of Tankovich I and Esenaliev.

1. Overview of Tankovich I

See supra Section II.D.1.

2. Overview of Esenaliev

See supra Section II.F.1.

3. Analysis of Cited Art as Applied to Challenged Dependent Claims 6, 8, and 12

Dependent claim 6 recites “the infrared radiation is of wavelengths from 800 nm to 1300 nm or from 1600 nm to 1850 nm” (Ex. 1001, 34:1–3), while claim 8 recites “coupling molecules to the nanoparticles wherein said molecules specifically bind to the cell or tissue” (*id.* at 34:6–8), and claim 12 recites “said cell is a cancer cell” (*id.* at 34:14–15).

Petitioner contends the limitations of claims 6, 8, and 12 of the ’944 patent would have been obvious to a person of ordinary skill in the art in view of the combined teachings of Tankovich I and Esenaliev. Pet. 41–43. Petitioner further contends that a person of ordinary skill in the art, would have had reasons to use aspects of Esenaliev’s system for targeted delivery of nanoparticles to tissues and for treating cancer within Tankovich I’s system for hair removal using locally heated nanoparticles. *Id.* at 43. Petitioner notes that both Tankovich I and Esenaliev discuss the delivery of nanoparticles specifically to the skin. *Id.* (citing Ex. 1002, 1:67–2:8; Ex. 1005, 2:16–19). In particular, Petitioner argues that Tankovich I describes the destruction of undesirable skin tissue (i.e., hair and follicle) using localized heating via irradiated nanoparticles, while Esenaliev similarly describes destroying skin cancers using the same localized heating by irradiating nanoparticles applied to the skin. *Id.* (citing Ex. 1002, 1:67–2:8; Ex. 1005, 2:16–19).

According to Petitioner, “[t]he slight modifications to one reference proposed by Petitioner based on the highly-similar teachings of the other reference are well within the level of skill of a [person of ordinary skill in the art] (that level being even higher under Rice’s proposal).” Reply 24 (citing Pet. 43–46; Ex. 1006 ¶ 86). Petitioner contends “[b]oth Petitioner’s and Rice’s experts agree there exist reasons for combining Tankovich I and Esenaliev.” *Id.* at 24–25 (citing Ex. 1006 ¶¶ 86–89; Ex. 2008 ¶ 109). Petitioner further argues that “each reference describes the goal of targeting hyperthermia to kill particular tissues, and thus it would have been obvious for a PHOSITA to adopt the targeting methodologies of Esenaliev (*e.g.*, coupling the nanoparticles to tissue-targeting molecules) to further the desired result expressed in Tankovich I, as well as to extend the class of treatable tissues to include cancer cells.” *Id.* at 25 (citing Ex. 1006 ¶¶ 88–89). Petitioner, therefore, concludes that it would have been obvious to a person of ordinary skill in the art to extend Tankovich I’s destruction of hair follicles to include Esenaliev’s destruction of skin cancers. Pet. 43 (citing Ex. 1006 ¶ 86).

Patent Owner contests Petitioner’s position. PO Resp. 34–35. Specifically, Patent Owner argues Petitioner fails to provide a reason to combine Tankovich I and Esenaliev, fails to specify which elements would be combined from each references, and fails to demonstrate a likelihood of success in combining the teachings of the references. *Id.* at 34. According to Patent Owner, the only reason for combining them is that they both explode carbonaceous material. *Id.* (citing Ex. 2008 ¶ 109). Patent Owner further argues that because neither Tankovich I nor Esenaliev disclose (i) the use of a plasmonic nanoparticles – nanoparticles on which plasmon

resonance is induced – or (ii) localized hyperthermia resulting from the use of plasmonic nanoparticles having a metal surface, there is no combination of these references that results in any of the claims of the '944 patent. *Id.* at 35 (citing Ex. 2008 ¶ 110).

a. Recited Claim Limitations

For reasons detailed above in Sections II.D.2.b. and II.F.2.b, we do not agree with Patent Owner that the claims require “plasmonic nanoparticles” or “localized hyperthermia” as argued by Patent Owner.

Additionally, we find that Esenaliev’s explicit disclosure of treating cancer cells by coupling molecules to nanoparticles in order to target the nanoparticles to the cancer cells reads on the limitations recited in claims 8 and 12. *See* Ex. 1005, 1:62–66. Esenaliev also discloses the use of infrared radiation that falls within the ranges recited in claim 6. *See* Ex. 1005, 2:30–32, 7:4–7.

b. Alleged Rationale to Combine Asserted Art

Despite Patent Owner’s arguments, we agree with Petitioner’s position, as supported by the testimony of Dr. Suslick. Specifically, both references are directed to the use of nanoparticles capable of absorbing electromagnetic radiation, which are introduced to human tissue, and exposed to such radiation in order to induce a localized heating effect. Ex. 1002, 1:67–2:8, 2:14–18, 2:51–64, Fig. 3; Ex. 1005, 1:63–2:3, 2:24–32, 7:4–7, 9:39–47, Fig. 1b. And, as Patent Owner’s declarant notes, both Tankovich I and Esenaliev disclose therapeutic systems having a high degree of similarity in structure, purpose, and operation. *See* Ex. 2008 ¶ 109 (“[B]oth [references] explode carbonaceous material.”). Therefore, given Tankovich I’s explicit disclosure of wanting “to minimize the heat to the rest

of the skin tissue” (Ex. 1002, 2:56–57), we agree that a person of ordinary skill in the art would have had reason to use the types of molecules (e.g., antibodies, directed against antigens in the targeted tissues) described in Esenaliev (Ex. 1005, 1:63–66) to accomplish Tankovich I’s goal of targeted delivery. Moreover, we credit the testimony of Dr. Suslick that it would have been obvious to a person of ordinary skill in the art to extend Tankovich I’s destruction of hair follicles to include Esenaliev’s destruction of skin cancers. Ex. 1006 ¶ 86. We, thus, find Petitioner has articulated sufficient reasoning with rational underpinning to combine Tankovich I and Esenaliev.

Accordingly, for the foregoing reasons, we determine based on the entirety of the record before us, Petitioner has established by a preponderance of the evidence that the challenged claims 6, 8, and 12 of the ’944 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over the teachings of Tankovich I and Esenaliev.

H. Alleged Obviousness of Claims 8 and 12 in view of Tankovich II and Esenaliev

Petitioner contends dependent claims 8 and 12 of the ’944 patent are unpatentable under 35 U.S.C. § 103 in view of Tankovich II and Esenaliev. Pet. 46–49. Patent Owner disputes Petitioner’s contentions. PO Resp. 35–36. For reasons that follow, we determine Petitioner established by a preponderance of the evidence that the challenged claims of the ’944 patent are unpatentable under 35 U.S.C. § 103(a) as obvious in view of Tankovich II and Esenaliev.

1. Overview of Tankovich II

See supra Section II.E.1.

2. *Overview of Esenaliev*

See supra Section II.F.1.

3. *Analysis of Cited Art as Applied to Challenged Dependent Claims 8 and 12*

Dependent claim 8 recites “coupling molecules to the nanoparticles wherein said molecules specifically bind to the cell or tissue” (Ex. 1001, 34:6–8), and claim 12 recites “said cell is a cancer cell” (*id.* at 34:14–15).

Petitioner contends the limitations of claims 8 and 12 of the ’944 patent are disclosed or suggested by the combined teachings of Tankovich II and Esenaliev. Pet. 46–47. Petitioner further contends that a person of ordinary skill in the art, would have had reasons to use aspects of Esenaliev’s system for targeted delivery of nanoparticles to tissues and for treating cancer within Tankovich II’s system for skin treatments using locally heated nanoparticles. *Id.* at 47. According to Petitioner, both Tankovich II and Esenaliev discuss the delivery of radiation-absorbing nanoparticles specifically to the skin. *Id.* (citing Ex. 1003, 3:47–50; Ex. 1005, 2:16–19). In particular, Petitioner argues that Tankovich II describes treating and mitigating skin disorders, such as acne and seborrhea, by localized heating using irradiated nanoparticles, while Esenaliev similarly describes destroying skin cancers using the same localized heating by irradiating nanoparticles applied to the skin. *Id.* at 47–48 (citing Ex. 1003, 2:54–58; Ex. 1005, 2:16–19). Thus, Petitioner concludes that it would have been obvious to a person of ordinary skill in the art to extend Tankovich II’s treatment of skin disorders to include Esenaliev’s treatment of skin cancers. *Id.* (citing Ex. 1006 ¶ 94).

Patent Owner contests Petitioner’s position. PO Resp. 35–36. Specifically, Patent Owner argues Petitioner fails to provide a reason to combine Tankovich II and Esenaliev, fails to specify which elements would be combined from each references, and fails to demonstrate a likelihood of success in combining the teachings of the references. *Id.* at 35. According to Patent Owner, the only reason for combining them is that they both explode carbonaceous material. *Id.* at 36 (citing Ex. 2008 ¶ 112). Patent Owner further argues that because neither Tankovich II nor Esenaliev disclose (i) the use of a plasmonic nanoparticles – nanoparticles on which plasmon resonance is induced – or (ii) localized hyperthermia resulting from the use of plasmonic nanoparticles having a metal surface, there is no combination of these references that results in any of the claims of the ’944 patent. *Id.* at 35 (citing Ex. 2008 ¶ 113).

a. Recited Claim Limitations

For reasons detailed above in Sections II.D.2.b. and II.F.2.b, we do not agree with Patent Owner that the claims require “plasmonic nanoparticles” or “localized hyperthermia” as argued by Patent Owner.

Additionally, we find that claims 8 and 12 read on Esenaliev’s explicit disclosure of treating cancer cells by coupling molecules to nanoparticles in order to target the nanoparticles to the cancer cells. *See* Ex. 1005, 1:62–66.

b. Alleged Rationale to Combine Asserted Art

Despite Patent Owner’s arguments, we agree with Petitioner’s position, as supported by the testimony of Dr. Suslick. Specifically, both references discuss skin treatments via delivery of radiation absorbing nanoparticles specifically to the skin. *See* Ex. 1003, 3:47–50; Ex. 1005, 2:16–19. In particular, Tankovich II describes treating and mitigating skin

disorders, such as acne and seborrhea, by localized heating using irradiated nanoparticles, and Esenaliev describes treating skin cancers also by localized heating with irradiated nanoparticles. *See* Ex. 1003, 2:54–58; Ex. 1005, 2:16–19. And, as Patent Owner’s declarant notes, both Tankovich II and Esenaliev disclose therapeutic systems having a high degree of similarity in structure, purpose and operation. *See* Ex. 2008 ¶ 112 (“[B]oth [references] explode carbonaceous material.”). Therefore, given Tankovich II’s apparent goal of selective delivery of nanoparticles to targeted tissues, and awareness of the possible dangers of improperly targeted laser treatments, we agree that a person of ordinary skill in the art would have had reason to use the types of molecules (e.g., antibodies, directed against antigens in the targeted tissues) described in Esenaliev (*see* Ex. 1005, 1:63–66) to accomplish Tankovich II’s goal of targeted delivery. Moreover, we credit the testimony of Dr. Suslick that it would have been obvious to a person of ordinary skill in the art to use Esenaliev’s selective targeting methodologies to achieve Tankovich II’s desired targeted delivery, and to extend the range of Tankovich II’s treatment options by applying those same treatment methodologies to cancer cells as taught in Esenaliev. *See* Ex. 1006 ¶¶ 94–96. We, thus, find Petitioner has articulated sufficient reasoning with rational underpinning to combine Tankovich II and Esenaliev.

Accordingly, for the foregoing reasons, we determine based on the entirety of the record before us, Petitioner has established by a preponderance of the evidence that the challenged claims 8 and 12 of the ’944 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over the teachings of Tankovich II and Esenaliev.

III. MOTIONS TO EXCLUDE EVIDENCE

A. *Patent Owner's Motion to Exclude Evidence*

Patent Owner filed Objections to Evidence (Papers 10, 29, 44) and a Motion to Exclude Evidence (Paper 37, "PO Mot."). Petitioner opposed the Motion to Exclude (Paper 43, "Pet Opp.") and Patent Owner submitted a Reply in support of its Motion to Exclude (Paper 45, "PO Reply").

Patent Owner specifically moves to exclude the testimony of Petitioner's declarant, Dr. Suslick, as submitted in Dr. Suslick's Declaration (Ex. 1006) and Dr. Suslick's Supplemental Declaration (Ex. 1009). According to Patent Owner, Dr. Suslick's declarations fail to comply with PTAB rules because (1) the original declaration (Ex. 1006) is not an affidavit as it was not made under oath (PO Mot. 2–3), (2) Dr. Suslick's supplemental declaration (Ex. 1019) is untimely and unauthorized (*id.* at 4), (3) Dr. Suslick's opinions are unsupported because he did not review the prosecution history of the '944 patent (*id.* at 3–4); and (4) Dr. Suslick did not apply the correct legal standards, thus, his testimony is unreliable (*id.* at 5). During oral arguments, Patent Owner further argued that Dr. Suslick's testimony in Exhibit 1019 is inconsistent with the testimony in Exhibit 1006, and the submission of Exhibit 1019 prejudiced Patent Owner. Tr. 30:2–31:12, 42:11–43:5.

Patent Owner also moves to exclude Exhibit 1003 under Federal Rules of Evidence 401, 402 (relevance), 403 (probative value outweighed by prejudice, confusing of issues, wasting time), 602, 802/805, 901, as well as 37 C.F.R. § 42.61(c). PO Mot. 6. Patent Owner contends that neither Petitioner nor Dr. Suslick have personal knowledge of the observations

recited in this exhibit, regarding the heating effect of carbon particles, and that there is no objective scientific data reflected in the exhibit. *Id.* Patent Owner further moves to exclude Exhibits 1011, 1012, 1013, 1016, 1018, and 1020 under various provision of the Federal Rules of Evidence. *Id.* at 6–9.

Petitioner opposes Patent Owner’s Motion. Pet. Opp. Specifically, Petitioner argues that Patent Owner’s objection to Exhibit 1006 was untimely and is rendered moot by Exhibit 1019 (Dr. Suslick’s Supplemental Declaration). Petitioner lists citations within Dr. Suslick’s original declaration (Ex. 1006), which demonstrate support for each of Dr. Suslick’s opinions and which show the application of the correct legal standards. See Pet. Opp. 4–5, 7–8. Petitioner contests Patent Owner’s characterizations that Exhibit 1006 is “at odds with” Exhibit 1019 and that Exhibit 1019 “introduces a belated and new opinion centered on the prosecution history.” *Id.* at 5. Rather, according to Petitioner, Dr. Suslick explicitly states that he “would not change and ha[s] not changed any of the opinions expressed in” his first declaration. *Id.* (citing Ex. 1019 ¶ 2). Petitioner then argues that “[t]he basis of [Patent Owner]’s assertion that Ex. 1019 is ‘belated’ or that it should be excluded as ‘new opinion’ is unclear, and [Patent Owner] cites no legal authority to support its position.” *Id.*

Regarding Exhibit 1003 (Tankovich II), Petitioner contends Tankovich II’s statement is not offered to prove the truth of what is asserted, but rather as evidence to prove what the specification describes, namely the heating of oil and of nanoparticles by applied radiation. *Id.* at 1 (citing 37 C.F.R. § 42.61(c) (“A specification . . . is admissible as evidence only to prove what the specification . . . describes.”)). Petitioner argues that “[t]he challenged statement in Tankovich II is, itself, *direct* evidence of what it

describes (*i.e.*, disclosure of the claimed invention) and is admissible under 37 C.F.R. § 42.61(c).” *Id.* at 1–2 (citing *Noven Pharms., Inc. v. Novartis AG*, IPR2014-00550, Paper 69 at 41 (PTAB Sept. 28, 2015) (denying exclusion under 37 C.F.R. § 42.61(c) because statement only offered to prove what the specification describes); 77 Fed. Reg. 48612, 48624 (Aug. 14, 2012) (explaining that 37 C.F.R. § 42.61(c) addresses the “problem in which a party mistakenly relies on a specification to prove a fact other than what the specification says”)). Additionally, Petitioner argues that U.S. patents are self-authenticating and subject to hearsay exceptions. *Id.* at 2 (citing Fed. R. Evid. 803(8), 803(14)–(15), 902(5)).

Petitioner opposes Patent Owner’s arguments regarding Exhibits 1011, 1012, 1013, 1016, 1018, and 1020 and presents arguments in support of its position. *Id.* at 9–15.

Because our Decision does not rely on the challenged Exhibits 1011, 1012, 1013, 1016, 1018, and 1020, we *dismiss* Patent Owner’s motion as moot as to these exhibits.

The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested, namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence. *See* 37 C.F.R. §§ 42.20(c), 42.62(a). We do not find Patent Owner has met its burden to demonstrate that Exhibit 1003 is inadmissible. Contrary to Patent Owner’s assertions, we do not find that Petitioner or Dr. Suslick rely on statements in Tankovich I to prove a fact other than what the Tankovich I specification describes. *See* 37 C.F.R. § 42.61(c) (specification of a patent is admissible as evidence only to prove what the specification describes). Thus, for Exhibit 1003, we *deny* Patent Owner’s motion.

Regarding Exhibits 1006 and 1019, Patent Owner again bears the burden of proof. As an initial matter, we find Patent Owner's objection to Exhibit 1006, which objection was filed on April 24, 2017 (Paper 10), to be filed timely from the issuance of the Decision to Institute on April 10, 2017 (Paper 8). See 37 C.F.R. 42.64(b)(1) ("Any objection to evidence submitted during a preliminary proceeding must be filed within ten business days of the institution of the trial."). Despite the timely objection, we do not find Patent Owner has met its burden to demonstrate that either of Exhibit 1006 or Exhibit 1019 is inadmissible. Although Exhibit 1006 does not include the required statement of oath, Exhibit 1019 does include such an oath and explicitly states "[h]aving reviewed the prosecution history of the '944 patent, I would not change any of the opinions expressed in my October 7, 2016 declaration." Considering that none of the opinions were changed, we do not agree with Patent Owner that the opinions thereby expressed in Exhibit 1019 to be new, changed, or prejudicial to Patent Owner. Moreover, having analyzed Exhibit 1006, we find Dr. Suslick's testimony to be supported by citations to the record and in accord with the correct legal standards. Thus, for Exhibits 1006 and 1019, we *deny* Patent Owner's motion.

Accordingly, we *deny* Patent Owner's motion to exclude Exhibits 1003, 1006, and 1019, and we *dismiss* as moot Patent Owner's motion to exclude Exhibits 1011, 1012, 1013, 1016, 1018, and 1020.

B. Petitioner's Motion to Exclude Evidence

Petitioner filed Objections to Evidence (Paper 26) and a Motion to Exclude (Paper 39, "Pet. Mot.") Exhibits 2008, 2014–2015, 2020–2056 and

2060–2062. Patent Owner opposed the Motion to Exclude (Paper 41, “PO Opp.”) and Petitioner submitted a Reply in support of its Motion to Exclude (Paper 46).

Petitioner specifically argues that “[t]he opinions of Rice’s expert, Dr. Jain, as set forth in Exhibit 2008, are founded on incorrect and incomplete legal standards, and thus must be excluded as irrelevant and prejudicial under Fed. R. Evid. 401–403.” Pet. Mot. 1. Petitioner further notes multiple deficiencies in Exhibit 2008 that it argues warrant exclusion. *Id.* at 3–4. Petitioner also moves to exclude Exhibits 2014–2015, 2020–2056 and 2060–2062 under various provision of the Federal Rules of Evidence. *Id.* at 4–8.

Patent Owner opposes Petitioner’s arguments regarding Exhibits 2008, 2014–2015, 2020–2056 and 2060–2062 and presents arguments in support of its position. PO Opp. 1–8.

Because our Decision does not rely on Exhibits 2014–2015, 2020–2056, or 2060–2062, we *dismiss* Petitioner’s motion as moot as to those challenged exhibits.

Regarding Exhibit 2008, the party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested, namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence. *See* 37 C.F.R. §§ 42.20(c), 42.62(a). We do not find Petitioner has met its burden to demonstrate this exhibit is inadmissible. Rather, Petitioner’s arguments go to the weight to be accorded to the evidence. The Board is capable of determining and assigning the appropriate weight to the evidence. Additionally, even without excluding this evidence, we have

determined that Petitioner has established, based on a preponderance of the evidence, the unpatentability of claims 1, 6–8, and 12 of the '944 patent.

Accordingly, we *deny* Petitioner's motion to exclude Exhibit 2008, and we *dismiss* as moot Petitioner's motion to exclude Exhibits 2014–2015, 2020–2056 and 2060–2062.

IV. CHALLENGE TO PETITIONER'S REPLY ARGUMENTS

Patent Owner filed a list of alleged improper reply arguments (Paper 31) to which Petitioner filed a Reply (Paper 32). Patent Owner lists several portions of Petitioner's Reply and evidence allegedly beyond the scope of what can be considered appropriate for a reply. *See* Paper 31 (citing Reply).

We have considered Patent Owner's listing, but disagree that the cited portions of Petitioner's Reply and reply evidence are beyond the scope of what is appropriate for a reply. Replies are a vehicle for responding to arguments raised in a corresponding Patent Owner Response. Petitioner's arguments and evidence are not beyond the proper scope of a reply because we find that they fairly respond to Patent Owner's arguments raised in Patent Owner's Response. *See Idemitsu Kosan Co., LTD. v. SFC Co. LTD*, 870 F.3d 1376, 1381 (Fed. Cir. 2017) ("This back-and-forth shows that what [Patent Owner] characterizes as an argument raised 'too late' is simply the by-product of one party necessarily getting the last word. If anything, [Patent Owner] is the party that first raised this issue, by arguing—at least implicitly—that [a reference] teaches away from non-energy-gap combinations. [Petitioner] simply countered, as it was entitled to do.").

V. CONCLUSION

For the foregoing reasons, we conclude Petitioner has shown by a preponderance of the evidence that: (1) claims 1 and 7 of the '944 patent are unpatentable under 35 U.S.C. § 102(b) in view of Tankovich I; (2) claims 1, 6, and 7 of the '944 patent are unpatentable under 35 U.S.C. § 102(b) in view of Tankovich II; (3) claims 1, 6–8, and 12 of the '944 patent are unpatentable under 35 U.S.C. § 102(e) in view of Esenaliev; (4) claims 6, 8, and 12 of the '944 patent are unpatentable under 35 U.S.C. § 103(a) in view of Tankovich I and Esenaliev; and (5) claims 8 and 12 of the '944 patent are unpatentable under 35 U.S.C. § 103(a) in view of Tankovich II and Esenaliev.

VI. ORDER

For the reasons given, it is

ORDERED that, by a preponderance of the evidence, claims 1, 6–8, and 12 of the '944 patent are unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude Exhibits 1011, 1012, 1013, 1016, 1018, and 1020 is *dismissed as moot*;

FURTHER ORDERED that Patent Owner's Motion to Exclude Exhibits 1003, 1006, and 1019 is *denied*;

FURTHER ORDERED that Petitioner's Motion to Exclude Exhibits 2014–2015, 2020–2056 and 2060–2062 is *dismissed as moot*;

FURTHER ORDERED that Petitioner's Motion to Exclude Exhibit 2008 is *denied*; and

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

IPR2017-00045
Patent 6,530,944 B2

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