

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEOXANE S.A.,

Petitioner,

v.

ALLERGAN, PLC ET AL.,

Patent Owner.

Case IPR2017-02002

Patent 8,450,475 B2

Before LORA M. GREEN, GRACE KARAFFA OBERMANN, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

OBERMANN, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

Petitioner filed a Petition seeking *inter partes* review of claims 1–9 and 18–37 of U.S. Patent No. 8,450,475 B2. Ex. 1001 (“the ’475 patent”). Paper 1 (“Pet.”). Patent Owner filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). With Board preauthorization, Petitioner filed a Reply (Paper 11) and Patent Owner filed a Sur-Reply (Paper 13) limited to “two narrow evidentiary issues identified by Petitioner in Exhibit 3001.” Paper 10; *see* Ex. 3001 (identifying those two issues, pertaining to the printed publication status of an asserted prior art reference applied in a related proceeding¹ and the translation declaration of a different reference that is applied in the Petition). We denied Petitioner’s request to file a third brief directed to the printed publication status of one or more asserted references. *See* Ex. 3002 (copy of email correspondence).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). An *inter partes* review may be instituted only upon a showing that “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Taking account of the information presented, we determine that the Petition fails to make out that threshold showing for review. Accordingly, we deny the Petition and decline to institute a trial.

I. BACKGROUND

A. *Related Proceedings*

Neither party identifies any pending district court or administrative review proceedings involving the ’475 patent. Pet. 1; Paper 8, 2. Both parties identify the following prior district court action, which was dismissed with prejudice on

¹ Concurrently herewith, we issue a decision denying institution of trial in Case IPR2017-01906, which involves the same parties and a related patent.

June 12, 2015: *Allergan USA, Inc., et al. v. Medicis Aesthetics, Inc., et al.*, 8:13-cv-01436-AG-JPR (C.D. Cal.) (filed December 6, 2013). Pet. 1; Paper 5, 2. The parties also identify a prior administrative proceeding (Case IPR2014–01417), which was terminated by joint motion on June 19, 2015. Pet. 1; Paper 8, 2. In addition, Patent Owner identifies several pending or abandoned continuation applications that claim priority through the '475 patent. Paper 8, 3.

B. The '475 Patent (Ex. 1001)

The '475 patent is titled “Hyaluronic Acid-Based Gel Including Lidocaine.” Ex. 1001, [54]. The '475 patent specification discloses a composition, and a method for preparing a composition, comprising hyaluronic acid (“HA”), which is “also known as hyaluronan,” and “is a naturally occurring water soluble polysaccharide, specifically a glycosaminoglycan, which is a major component of the extra-cellular matrix and [] is widely distributed in animal tissues.” *Id.* at 1:66–2:2. In addition to HA, the composition may include “a therapeutically effective amount of at least one anesthetic agent,” such as “lidocaine.” *Id.* at 2:36–42.

By way of background, the '475 patent explains that, “as a person ages, the face beings to show effects of gravity, sun-exposure, and years of facial muscle movement” such that the skin’s youthful appearance may “begin to break down,” which often results “in laugh lines, smile lines, ‘crow’s feet’ and facial creases.” *Id.* at 1:23–27. “Collagen based soft tissue fillers were developed over 20 years ago” but resulted in “allergic reactions” and, further, degraded “rapidly upon injection.” *Id.* at 1:42–52. By December of 2003, HA-based fillers had been developed as an alternative to collagen and approved by the FDA. *Id.* at 1:60–65.

According to the specification, “HA has excellent biocompatibility and does not cause allergic reactions when implanted into a patient.” *Id.* at 2:2–4. The specification further discloses, however, that known HA-based filler compositions

were viscous when stable, making injection through fine gauge needles difficult, whereas “HA-based fillers that are relatively easily injected through fine gauge needles often have relatively inferior stability properties in vivo.” *Id.* at 2:9–14. As a result, methods of preparing HA-based filler compositions were developed in the art, which resulted in compositions that included both “free HA” as well as “[c]rosslinked HA,” which “is formed by reacting free HA with a crosslinking agent.” *Id.* at 2:15–19.

The ’475 patent acknowledges that, at the time of the invention, it was known in the art to add lidocaine to HA-based fillers. *Id.* at 2:20–22. According to the specification, however, the addition of “lidocaine during the manufacturing process” resulted in a composition “prone to partial or almost complete degradation prior to injection.” *Id.* at 2:22–25. That disadvantageous degradation occurred, in particular, when the HA-based composition comprising lidocaine was subjected to “high temperature sterilization steps” or was “placed in storage for any significant length of time.” *Id.* at 2:25–27.

The ’475 patent is directed to a “stable” HA-composition that includes lidocaine and a method of preparing that “stable” composition. *Id.* at 4:41–48, 5:39–46 (defining stability in terms of specific properties or characteristics of the composition that are present after autoclave sterilization). According to the specification, the stable compositions of the invention “maintain their integrity in terms of rheology, viscosity, appearance and other characteristics even when stored for a lengthy period of time, for example,” “at least about 6 months, about 9 months, about 12 months, of 36 months or greater”—“even after being subjected to sterilization procedures” such as “autoclaving.” *Id.* at 6:46–54. The specification of the ’475 patent emphasizes that the lidocaine-containing, HA-based composition of the invention has “an enhanced stability, relative to conventional HA-based

compositions” that include “lidocaine, when subjected to high temperatures and pressure sterilization techniques” or “when stored at ambient temperature for an extended period of time.” *Id.* at 5:28–38.

In one embodiment, the HA component is “crosslinked with a crosslinking agent” such as 1,4-butanediol diglycidyl ether (“BDDE”). *Id.* at 2:50–54; *see id.* at 16:42–43 (claim 1). “A method is provided for preparing a HA-based composition including an effective amount of lidocaine” that results in “a precursor composition comprising a cohesive crosslinked HA-based gel, adding a solution containing lidocaine,” “and homogenizing the mixture to obtain a cohesive, at least partially crosslinked, HA-based composition” that includes “lidocaine” and “is stable to autoclaving.” *Id.* at 6:23–31. In one embodiment, the “cohesive, crosslinked HA-based gel” so formed may include “no greater than about 1% to about 10% of free HA material by volume (w/v%).” *Id.* at 6:31–24.

The ’475 patent explains: “Without wishing to be bound by any particular theory of operability, it is believed that the high cohesivity of the precursor composition” “of the invention acts to substantially or entirely prevent or impede any breakdown or degradation of the crosslinked HA in the composition with the addition of lidocaine.” *Id.* at 6:36–41. Further, the specification informs “that such degradation may primarily occur because many, perhaps most crosslinked HA based gels are conventionally manufactured in a manner that produces gels which are not sufficiently cohesive to prevent such degradation when lidocaine is added.” *Id.* at 6:42–46.

According to the specification, “[i]t has now been discovered that the addition of lidocaine to sufficiently cohesive crosslinked HA-based compositions does not cause substantial or significant degradation of the compositions, and the compositions maintain their integrity in terms of,” for example, “rheology,

viscosity, [and] appearance” “even when stored for a length period of time,” such as “at least 6 months to a year or more, and even after being subjected to sterilization” by “autoclaving.” *Id.* at 6:46–54. A “cohesive, crosslinked HA-based precursor composition” containing lidocaine may be prepared as a “gel” by “homogenizing the mixture” and, in one embodiment, may include “no greater than about 1% to about 10% of free HA by volume.” *Id.* at 6:59–7:3.

C. Illustrative Claims

Claim 1 illustrates the subject matter of the invention and is reproduced below:

1. A stable, sterile soft tissue filler comprising:

a hyaluronic acid (HA) component comprising HA crosslinked with 1,4- butanediol diglycidyl ether (BDDE), and uncrosslinked HA, wherein the HA component comprises greater than about 10% uncrosslinked HA by volume; and

lidocaine combined with said crosslinked HA component..

Ex. 1001, 16:40–46 (indentation added).

To the extent necessary to our decision, in our analysis below, we discuss certain limitations of other challenged claims.

D. The Evidence Relied Upon

The Petition asserts the following references as prior art in the stated grounds of unpatentability (Pet. 9):

(1) Hunter, U.S. Pat. Pub. No. 2006/0040894, published Feb. 23, 2006, Ex. 1004 (“Hunter”);

(2) Lupo, Ex. Abstract of Poster, published Feb. 2–6, 2007, Ex. 1015 (“Lupo”);

(3) Toth, Abstract of Poster, published Feb. 2007, Ex. 1019 (“Toth”);

(4) Kinney, Aesthetic Surgery Journal, 26:741–746 (2006), Ex. 1016 (“Kinney”);

(5) Levy, Abstract of Poster, published April 10–12, 2008, Ex. 1007 (“Levy”);

(6) Reinmuller I, W.O. 2005/067944, published Jul. 28, 2005, Ex. 1002 (“Reinmuller I”);

(7) Reinmuller II, U.S. Pat. No. 5,731,298, issued March 24, 1998, Ex. 1023 (“Reinmuller II”);

(8) Debacker, Ex. 1009 (“Debacker”);

(9) Sadozai, Ex. 1025 (“Sadozai”);

(10) Expert Anti-Aging, Ex. 1014 (“Expert Anti-Aging”); and

(11) Lebreton, Ex. 1027 (“Lebreton”).

The Petition is supported by the Declaration of Glenn D. Prestwich, Ph.D. Ex. 1041.

E. The Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 9):

Reference(s)	Statutory Ground(s)	Claim(s)
Hunter	§ 102(b)	1–7, 9
Lupo, Toth, Kinney	§ 103(a)	1–9, 27–30
Levy	§ 102(a)	1–4, 5, 8, 9, 27–29
Lupo, Toth, Kinney, Reinmuller I	§ 103(a)	18, 31–37
Debacker, Sadozai	§ 103(a)	1–4, 8, 9, 34–36
Debacker, Sadozai, Reinmuller II	§ 103(a)	5–7, 18, 27–33, 37

Reference(s)	Statutory Ground(s)	Claim(s)
Expert Anti-Aging, Sadozai, Lebreton	§ 103(a)	19–26

II. DISCUSSION

We organize our discussion into three parts. First, we address the level of ordinary skill in the art. Second, we discuss claim construction. Third, we resolve whether the information presented demonstrates a reasonable likelihood that Petitioner would prevail at trial in showing that at least one challenged claim of the '475 patent is unpatentable. We conclude, for reasons that follow, that Petitioner fails to make out the threshold showing for trial institution and, accordingly, we deny the Petition and decline to institute an *inter partes* review.

A. *The Level of Ordinary Skill in the Art*

Petitioner argues that a person of ordinary skill in the art at the time of the invention would have had a B.S. or M.S. in biochemistry, polymer chemistry, medicinal chemistry, pharmaceutical chemistry, or a related field with “several years” of practical experience. Alternatively, according to Petitioner, the ordinary artisan would have had less practical experience but a Ph.D. in one of those fields, or an M.D. in dermatology, plastic surgery, or a specialty related to the clinical use of dermal fillers. Pet. 10 (citing Ex. 1041 ¶¶ 12–13). Patent Owner does not contest that argument in the Preliminary Response. For purposes of this decision, we accept Petitioner’s definition, which, on this record, is consistent with the level of skill reflected in the asserted prior art references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself may reveal the level of ordinary skill in the art).

B. Claim Construction

The Board interprets claims in an unexpired patent using the “broadest reasonable construction in light of the specification of the patent.” 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, claim terms are given their ordinary and customary meaning in view of the specification, as understood by a person 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). We resolve disputed claim terms only to the extent necessary to our decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 475, 803 (Fed. Cir. 1999))).

We determine that “stable” is the only claim term that requires express construction for purposes of this decision. See Ex. 1001, 21:22 (appearance of the word “stable” in claim 29). Patent Owner “does not concede that Petitioner’s proposed constructions are the broadest reasonable constructions,” but does not propose alternative constructions, arguing instead that the threshold for review is unmet under Petitioner’s constructions. Prelim. Resp. 3–4.

As an initial matter, a question arises whether the term “stable” is limiting in claim 1, given that it appears only in the preamble of the claim. Ex. 1001, 16:40. Several facts persuade us that the preamble term “stable” is limiting in claim 1. First, neither party argues that the word “stable” in the preamble does not limit the composition specified in claim 1. On the contrary, Petitioner, who carries the burden of setting forth in the Petition “[h]ow the claim is to be construed” (37 C.F.R. § 42.104(b)(3)), suggests that the word “stable” is limiting, by advancing an

express construction that should be assigned to that term. Pet. 10–11 (citing Ex. 1041 ¶¶ 90–98).

Second, a term in a patent preamble is limiting when it “breathes life and meaning into the patent claims.” *In re Wertheim*, 541 F.2d 257, 269 (CCPA 1976). “Whether to treat a preamble as a limitation is a determination ‘resolved only on review of the entire’ patent disclosure ‘to gain an understanding of what the inventors actually invented and intended to encompass by the claim.’” *Catalina Mktg. Int’l. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989)).

Our review of the ’475 patent persuades us that the inventors “actually invented and intended to encompass by” claim 1 a stable composition as defined in the specification. *Catalina Mktg. Int’l.*, 289 F.2d at 808. The inventors disclosed and claimed a “stable” composition containing both HA and lidocaine that overcame the “relative inferior stability properties” of prior art compositions. Ex. 1001, 2:6–32. In that regard, the specification repeatedly refers to the ability of the claimed compositions to remain stable after high-temperature sterilization procedures (such as autoclaving) or shelf-storage storage for prolonged lengths of time. *See, e.g., id.* at 2:42–49 (contrasting the “enhanced stability” of the claimed compositions “relative to conventional HA-based compositions including” “lidocaine” “when subjected to sterilization techniques such as autoclaving” or “when stored for long periods of time at ambient temperature”);

The specification expressly defines the claimed “stable” lidocaine-containing HA-based composition by its ability to “resist degradation” (such as “transparent appearance, pH, extrusion force,” and both “HA” and “lidocaine” concentration” “after effective autoclave sterilization.” *Id.* at 4:41–48. The

specification reveals that the inventors “believed that the high cohesivity of the precursor composition . . . acts to substantially or entirely prevent or impede any breakdown or degradation of the crosslinked HA in the composition with the addition of lidocaine.” *Id.* at 6:36–41. The inventors further “believed that such degradation may primarily occur because many, perhaps most, crosslinked HA based gels are conventionally manufactured in a manner that produces gels which are not sufficiently cohesive to prevent such degradation when lidocaine is added.” *Id.* at 6:42–46.

The specification contains express disclosure regarding “what [the inventors] actually invented and intended to encompass by” the ’475 patent claims. *Catalina Mktg. Int’l.*, 289 F.2d at 808. Specifically:

It has now been discovered that the addition of lidocaine to sufficiently crosslinked HA-based compositions does not cause substantial or significant degradation of the compositions, and the compositions maintain their integrity in terms of rheology, viscosity, appearance and other characteristics even when stored for a length period of time, for example, for a period of time of at least 6 months to a year or more, and even after being subject to sterilization procedures, for example, autoclaving.

Ex. 1001, 6:46–54. Against that backdrop, the specification describes “a surprising discovery that” “HA-based compositions including lidocaine can be manufactured in a manner in accordance with the invention to produce sterilization-stable, injectable HA/lidocaine compositions.” *Id.* at 6:55–58.

The specification also emphasizes stability as “a key benefit” that distinguishes the invention from compositions that were known in the art. *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 834 (Fed. Cir. 2003) (holding that preamble term was limiting where it pertained to “a key benefit of the invention”). The specification expressly relies on stability characteristics to distinguish the claimed invention from prior art compositions, which degrade when lidocaine is

included in the HA-based composition. *Id.* at 2:23–27 (“Unfortunately, HA-based injectable compositions which incorporate lidocaine during the manufacturing process are prone to partial or almost complete degradation prior to injection, particularly during high temperature sterilization steps” or “when placed in storage for any significant length of time.”), 2:42–49 (discussing “enhanced stability” of the claimed compositions “relative to conventional” compositions that contain both HA and lidocaine).

One final point pertaining to the “stable” limitation requires discussion. The specification makes clear that stability, in the context of the ’475 patent, relates to the “shelf life” of the composition “when stored for a lengthy period of time” prior to injection into a patient, for example, “for a period of time of at least 6 months to a year or more.” *Id.* at 6:51–53, 13:51; *see id.* at 2:26–27 (objective of invention is to provide “HA-based injectable compositions which incorporate lidocaine” that are not “prone to” degradation “when placed in storage for any significant amount of time”), 4:42–43, 5:33–38 (composition has “enhanced stability” “when stored at ambient temperature for an extended period of time”), 8:4–5 (the composition of the invention will “remain stable when stored for long periods of time at room temperature”).

Accordingly, we determine that the preamble term “stable” (Ex. 1001, 16:40) “breathes life and meaning into” claim 1 and, therefore, is limiting. *In re Wertheim*, 541 F.2d at 269. We adopt for purposes of this decision the following definition of “stable,” which is advanced by Petitioner:

soft tissue filler that is free of viable microorganisms as determined by a sterility test recognized by a regulatory authority, the filler can be sterilized by any method known in the art, and is resistant to degradation such that the composition maintains one or more of the following aspects: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine

concentration, after being effectively sterilized by autoclaving and subsequently stored at a temperature of at least about 25° C for at least about two months.

Pet. 11. That construction is not opposed by Patent Owner at this stage of the proceeding (Prelim. Resp. 3–4) and is substantially consistent with an express definition set forth in the specification. Ex. 1001, 5:17–20.

C. Analysis of the Asserted Patent Challenges

We address each of the seven asserted grounds of unpatentability in turn below.

1. Anticipation Based on Hunter

The Petition challenges the patentability of claims 1–7 and 9 as anticipated by Hunter. Pet. 12. Our discussion of claim 1 (from which claims 2–7 and 9 directly or indirectly depend) is dispositive. Hunter was before the Examiner during prosecution. See Ex. 1001 [56] (references cited during patent prosecution, including Hunter). Hunter discloses a composition comprising an HA component in combination with a hyaluronidase inhibitor (“HI”) and, optionally, an anesthetic such as lidocaine. *Id.* at 12–13 (citing Ex. 1004, Abstract, ¶ 314).

For the crosslinking component (BDDE), the Petition directs us to a reference (identified as “Beasley”) that is not prior art. Pet. 13. The Petition identifies Beasley in a list of “[a]dditional [d]ocuments [r]elied [u]pon” and assigns it a publication date in “2009,” which is after the effective filing date of the ’475 patent. Pet. 4; see Ex. 1001 [60] (first provisional application was filed on August 4, 2008). The Petition relies on Beasley to establish that the HA-HI gel composition of Hunter contains HA that is crosslinked with BDDE. Pet. 13 (claim chart for claim 1, citing Beasley for the claim limitation that requires an HA component that is crosslinked with BDDE). The Petition also relies on Beasley to establish that Hunter’s HA-HI composition meets the limitation of claim 1 that

requires “about 10% uncrosslinked HA by volume.” *Id.* The Petition, however directs us to no persuasive evidence that that the gel marketed under the tradename Restalyne in 2009 (as disclosed in Beasley) would have been identical to the gel described by Hunter in 2004. Ex. 1004, [60] (provisional application filed Aug. 13, 2004), ¶ 297 (Hunter, discussing a gel marketed under the Restalyne tradename, but providing no information that the HA component was crosslinked with BDDE).

Further, the Petition does not show sufficiently that Hunter anticipates a “stable” composition as required by claim 1. Ex. 1001, 16:40. For reasons set forth in our discussion of claim construction, based on the information presented, we determine that the term “stable” is limiting in the preamble of claim 1. *See supra.* As we explain above, we adopt for purposes of this decision the interpretation of “stable” that is advanced in the Petition, namely:

soft tissue filler that is free of viable microorganisms as determined by a sterility test recognized by a regulatory authority, the filler can be sterilized by any method known in the art, and is resistant to degradation such that the composition maintains one or more of the following aspects: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration, after being effectively sterilized by autoclaving and subsequently stored at a temperature of at least about 25° C for at least about two months.

Pet. 11.

The specification makes clear that stability, in the context of the '475 patent, relates to the “shelf life” of the composition “when stored for a lengthy period of time” prior to injection into a patient. Ex. 1001, 7:41–42, 14:61; *see id.* at 2:26–27 (objective of invention is to provide “HA-based injectable compositions which incorporate lidocaine” that are not “prone to” degradation “when placed in storage for any significant amount of time”), 5:14–15, 6:18–19 (a stable composition “is

resistant to degradation” “when stored at ambient temperature for an extended period of time”), 8:62–63 (explaining that the composition of the invention will “remain stable when stored for long periods of time at room temperature”).

The Petition, however, attempts to make out that Hunter anticipates the “stable” composition of claim 1 by directing us to disclosure that Hunter’s composition “can result in increased durability and reduction in the number of subsequent repeat injections” in a patient after the composition is injected under the skin. Pet. 13 (citing Ex. 1004 ¶¶ 179, 295). We agree with Patent Owner that the disclosures in Hunter cited in the Petition (*see id.*) relate “solely to the stability of the [] composition in vivo following implantation.” Prelim. Resp. 12. “As such, the paragraphs of Hunter cited by [Petitioner] say nothing about whether” Hunter’s “composition is stable under [Petitioner’s own] proposed construction” (Prelim. Resp. 12), which requires the “stable” composition to retain certain characteristics or properties (“transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration”) after the composition is “effectively sterilized by autoclaving and subsequently stored at a temperature of at least about 25° C for at least about two months.” Pet. 11 (Petitioner’s proposed claim construction).

According, we determine that the Petition does not show sufficiently that Petitioner is reasonably likely to prevail at trial in showing that at least one challenged claim is anticipated by Hunter.

2. Obviousness Based on Lupo and Toth or Kinney

Petitioner contends that claims 1–9 and 27–30 would have been obvious at the time of the invention over Lupo in combination with Toth or Kinney. Pet. 9 (grounds chart), 29–42 (argument and evidence, including claim charts). Lupo, Toth, and Kinney were not before the Examiner during patent prosecution.

Pet. 15; Ex. 1001 [56] (references cited during patent prosecution). We first address Patent Owner's argument that Lupo and Toth do not qualify as printed publications. We then turn to independent claims 1 and 27.

(a) Printed Publication Status of Lupo and Toth

As an initial matter, Patent Owner points out that the Petition describes each of Lupo and Toth as an "[a]bstract of a poster" presented at a conference (Pet. 4, table of exhibits). See Prelim. Resp. 9. In Patent Owner's view, the Petition fails to show sufficiently that these conference posters "were ever actually disseminated before the critical date." *Id.* at 10. However, both Lupo and Toth appear to have been published in the Journal of the American Academy of Dermatology in February 2007, more than one year before the effective filing date of the '475 patent. Ex. 1015, 1; Ex. 1019, 1; see Ex. 1001 [60] (reflecting the August 4, 2008 filing date of provisional application for the '475 patent). On this record, we are not persuaded to deny this ground based on a failure to show sufficiently, for purposes of trial institution, that Lupo or Toth are not printed publications. Ex. 1015, 1; Ex. 1019, 1. We, thus, turn to the merits of the ground.

(b) Claims 1–9 and 27–30

The Petition does not show sufficiently that independent claims 1 or 27 (from which each of the other claims challenged in this ground depends) would have been obvious from the combined disclosures of Lupo and Toth or Kinney. Our analysis of claims 1 and 27 is dispositive of this ground.

Lupo is a single-paragraph abstract that refers to a crosslinked HA-based composition but does not disclose BDDE as the crosslinking agent. Ex. 1015 (entry P2909, single paragraph abstract). The Petition directs us to two other documents, identified only as "Allemann" and "Juvederm Summary," which are not established as prior art and, further, are presented without sufficient

explanation regarding how or why they show that Lupo necessarily discloses a composition comprising an HA component that is crosslinked with BDDE.

Pet. 15.

Further, the Petition repeatedly relies on disclosure from the first provisional application for the '475 patent as well as U.S. Patent No. 8,357,795 ("the '795 patent") (which is the subject of related Case IPR2017-01906 (*see supra* at n.1).

Pet. 16. Those documents are not established as prior art to the '475 patent, yet the Petition repeatedly cites them in this ground to support the unpatentability of the claims. *See, e.g.*, Pet. 15 (heading), 16 (relying on the first provisional application and the '795 patent for disclosure of the degree of crosslinking in Lupo's HA-based composition), 21 (reasserting reliance on the first provisional application and the '795 patent), 24 (claim chart for claim 27).

In addition, Petitioner acknowledges that Lupo discloses HA-based compositions that "do not contain lidocaine." Pet. 17. The Petition argues that a person of ordinary skill in the art "would have been highly motivated to combine lidocaine, with HA formulations crosslinked with BDDE such as Lupo's 'next generation' HA fillers (J30, J30HV, or J24JV)" in order to "reduce pain and increase tolerability upon injection of the filler, and enhance product acceptability." *Id.* at 18–19. The Petition, however, directs us to no evidence (such as the declaration of Dr. Prestwich) to support that proposition. *Id.* We will not search the record for evidence that may support that bare attorney argument. *See* 37 C.F.R. § 42.22(a)(2) (a petition must include "[a] full statement of the reasons for the relief requested"); *DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (Fed. Cir. 1999) ("A brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the record.").

The Petition also rests on conclusory attorney argument that “the prior art teaches the identical composition” specified in the challenged claims and, thus, necessarily (that is, inherently) possesses the same properties. *Id.* at 16–17 (bridging sentence). On that basis, Petition asserts that “Lupo teaches a stable, sterile soft tissue filler (dermal filler) containing HA-BDDE and about 10% uncrosslinked HA, and the HA-BDDE has a degree of crosslinking of 4–6%.” *Id.* That argument is insufficient to make out that the modified composition of Lupo necessarily would exhibit the degree of stability required by the challenged claims. *See id.* (conclusory analysis in bridging paragraph). Further, Petitioner’s inherency theory (based on bare attorney argument that “the prior art teaches the identical composition”) is flawed, where in the very next sentence, the Petition admits that Lupo “does not contain lidocaine.” Pet. 17. It is flawed also because Lupo does not indicate that its gel is crosslinked with BDDE. Ex. 1015 (P2909, single paragraph abstract).

We decline to institute trial on this ground because the Petition fails to explain adequately why or how a person of ordinary skill in the art would have been led to combine Lupo with Toth or Kinney to attain the invention of claim 1, including the feature that requires a “stable” composition. Ex. 1001, 19:31.

3. Anticipation Based on Levy

Petitioner challenges claims 1, 4, 5, 8, 9 and 27–29 as anticipated by Levy in view of six other documents, including the first provisional application for the ’475 patent, which is not shown to qualify as prior art. Pet. 26. Levy was not of record during patent prosecution. *Id.*; Ex. 1001 [56] (list of references cited during patent prosecution). We first address Patent Owner’s challenge to the printed publication status of Levy. We then turn to the merits of the challenge.

(a) Printed Publication Status of Levy

As an initial matter, Patent Owner points out that the Petition describes Levy as an “[a]bstract of a poster” presented at a conference (Pet. 4, table of exhibits). See Prelim. Resp. 9. In Patent Owner’s view, the Petition fails to show sufficiently that this conference poster was “ever actually disseminated before the critical date.” *Id.* at 10. However, Levy on its face reflects information suggesting that it was published in a “final program” to “3500 participants” at a conference held on August 10–12, 2008; that is, prior to the effective filing date of the ’475 patent. Ex. 1007, 2; see Ex. 1001 [60] (reflecting the August 4, 2008 filing date of provisional application for the ’475 patent). On this record, we are not persuaded to deny this ground based on a failure to show sufficiently that Levy is a printed publication. See Ex. 1007, 2 (Levy, bearing indications of public availability). We next turn to the merits of the challenge.

(b) Claims 1, 4, 5, 8, 9, and 27–29

Similar to the ground based on Lupo, the Petition acknowledges that Levy discloses an HA-based composition that “does not contain lidocaine.” Pet. 26. The Petition, moreover, does not identify disclosure adequate to show that Levy’s composition includes BDDE as the crosslinking component. *Id.* at 27 (claim chart, relying on two references, identified as “Ballin” (Ex. 1050, bearing publication date of 2013) and “Beasley” (Ex. 1044, bearing publication date of 2009), which are not established as prior art).

Further, Petitioner raises no argument that meaningfully distinguishes the challenge based on Levy from the challenge based on Lupo. *Id.* at 26–28. Instead, Petitioner directs us to the ground based on Lupo for information necessary to the challenge based on Levy. See *id.* at 26 (referring to argument “discussed under Ground 2”). Our reasons for declining to institute trial on the ground based on

Lupo apply with equal force to the ground based on Levy. *See supra*. For example, in support of the ground based on Levy, the Petition advances disclosure from the first provisional application for the '475 patent as if it were prior art (*see, e.g.*, Pet. 46 (claim chart)) and rests on conclusory argument to establish an inherent disclosure (*see id.* at 47 (arguing, without citation to evidence, that Levy's composition "must [] have a shelf-life of about 24 months, and necessarily have an extrusion force that is substantially constant for at least 9 months")). On this record, the Petitioner is not reasonably likely to prevail at trial with respect to at least one claim that is the subject of the challenge based on Levy.

4. Obviousness Based on Lupo, Toth, Kinney, and Reinmuller I

The Petition challenges claims 18 and 31–37 based on obviousness in view of Lupo, Toth, Kinney, and Reinmuller I. Pet. 28–35. For reasons stated above in our discussion of the ground based on Lupo, Toth, and Kinney, this ground unpersuasively advances the disclosures of Beasley (which is not shown to qualify as prior art) to make out limitations pertaining to crosslinking with BDDE. *See, e.g.*, Pet. 31 (claim chart for claim 18), 32 (claim chart for claim 32).

Reinmuller I is submitted in German. Ex. 1002. In view of that fact, we agree with the Petitioner that Reinmuller I is "not of record." Pet. 28. Instead, the Petition directs us to "U.S. Pat. No. 7,902,171," which issued on March 11, 2011 (Ex. 1003), "as the English equivalent" of the German document. Pet. 4 (table of references). The Petition does not show sufficiently that this document is prior art and, moreover, directs us to page and line numbers in "Reinmuller II" that do not support the propositions for which they are cited. Pet. 28 (citing "4:62–62" and "7:1–8," which do not take us to relevant disclosure in Exhibit 1003). In any event, Petitioner submits that "Reinmuller I does not describe HA crosslinked with

BDDE,” therefore, the Petition fails to explain how that reference cures deficiencies in the combined disclosures of Lupo, Toth, and Kinney. Pet. 28.

Further, this ground relies on information that allegedly pertains to the durability of HA-compositions after injection into a patient (“longer-lasting corrections that other HA fillers” in patients post-injection (*id.* at 31, claim chart pertaining to claim 18’s preamble) that is insufficient to make out a composition that is “stable” during storage prior to injection, as required by the challenged claims. *Id.* at 31–33 (claim charts, for “stable” limitation, tying all claims to the argument presented for claim 18). We are not persuaded, therefore, that the Petition demonstrates a reasonable likelihood that Petition would prevail at trial with respect to any claim challenged in this ground.

5. Obviousness Based on Debacker and Sadozai

The Petition alleges that claims 1–4, 8, 9, and 34–36 would have been obvious over Debacker in view of Sadozai. Pet. 35. The Petition states that both references were before the Examiner during patent prosecution. *Id.* at 35, 36.

Debacker discloses an HA component that may be crosslinked with BDDE. Pet. 35; Ex. 1009, 3:11–21, 4:21–34, 8:20–33. Debacker, however, “does not disclose the use of lidocaine.” Pet. 36. The Petition relies on Sadozai’s disclosure of lidocaine in a composition that contains an HA component that is crosslinked, not with BDDE, but with a different crosslinking agent described as “BCDI.” *Id.*

The Petition asserts that lidocaine has a “synergistic effect” on rheological properties of the BCDI-crosslinked HA-based composition in Sadozai’s composition. *Id.* As Patent Owner points out, however, Sadozai’s composition is crosslinked with a different agent and, further, is not shown to include any “uncrosslinked HA” as required by the challenged claims. Ex. 1001, 16:43 (independent claim 1), 18:45 (independent claim 34); *see* Prelim. Resp. 14 (citing

Ex. 1025 ¶ 25 (“The invention is directed to crosslinked HA compositions, their preparation, and their methods of use.”)). On this record, we agree with Patent Owner that the Petition does not explain sufficiently how or why an ordinary artisan would have expected any synergistic effect of lidocaine in Sadozai’s composition to behave in the same way in a composition containing uncrosslinked HA as well as HA that is crosslinked with BDDE. Prelim. Resp. 14; see Pet. 36–38 (citing Ex. 1041 ¶¶ 128–135).

In a further attempt to show that a person of ordinary skill in the art would have been prompted to combine Sadozai with Debacker with a reasonable expectation of success to attain the claimed invention, the Petition raises five (5) additional references without identifying them by exhibit number, without addressing whether they qualify as prior art, and without directing us to specific disclosures within them by pin citation. Pet. 37. Petitioner should not expect the Board to search the record to piece together what may support a challenge. See 37 C.F.R. § 42.22(a)(2) (a petition must include “[a] full statement of the reasons for the relief requested”); *DeSilva*, 181 F.3d at 866–67 (“A brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the record.”).

On this record, the Petition fails to explain adequately how or why a person of ordinary skill in the art would have been led to combine Debacker and Sadozai with a reasonable expectation of success.

6. Obviousness Based on Debacker, Sadozai, and Reinmuller II

Petitioner challenges claims 5–7, 18, 27–33, and 37 based on the combined disclosures of Debacker, Sadozai, and Reinmuller II. Like Debacker and Sadozai, Reinmuller II was before the Examiner during patent prosecution. Pet. 42.

The Petition introduces Reinmuller II to overcome that “Debacker and Sadozai do not specifically teach the degree of crosslinking as that recited in” the challenged claims. Pet. 41. The Petition advances conclusory argument that “Reinmuller II teaches or suggests” a certain degree of crosslinking, while acknowledging that the reference “does not disclose what percentage of the HA is uncrosslinked HA.” *Id.* at 41–42. This ground is based on attorney argument directed to what an ordinary artisan would have understood or undertaken: For example, the Petition argues (without directing us to evidence) that an ordinary artisan “would have been highly motivated to combine the teachings of” the asserted references and “to use a degree of crosslinking” allegedly suggested by Reinmuller II in a composition of Debacker as modified to include Sadozai’s lidocaine. *Id.* at 43; *see id.* at 41–43 (for several pages of unsupported attorney argument). Here again, we will not search the record to discern whether any evidence supports these conclusory arguments.

On this record, we determine that Petitioner is not reasonably likely to prevail at trial with respect to any claim challenged in this ground. We decline to institute trial on that basis.

7. Obviousness Based on Expert Anti-Aging, Sadozai, and Lebreton

Petitioner alleges that claims 19–26 would have been obvious over the combined disclosures of Expert Anti-Aging, Sadozai, and Lebreton. Pet. 48. The Petition directs us to eight (8) other references in an attempt to make out certain claimed features that are not expressly disclosed in Expert Anti-Aging, Sadozai, or Lebreton. *Id.* The Petition does not address whether those additional references qualify as prior art. *Id.* Those additional references include the first provisional application for the ’475 patent and the related ’795 patent, which are not established as prior art against the ’475 patent. *Id.* All of the arguments presented

with respect to those eight (8) additional references are advanced without a single citation to the declaration of Dr. Prestwich or any other competent evidence pertaining to how an ordinary artisan would have understood or applied them before the critical date. *Id.*

The HA-based composition of Expert Anti-Aging “does not contain lidocaine.” Pet. 49. Neither does the composition of Lebreton, and it is unclear why that reference is cited in this ground. *Id.* Petitioner argues “[f]or reasons similar to those under Grounds 2, 4, 5, and 6, a [person of ordinary skill in the art] would have been highly motivated to add 0.3% (w/v) lidocaine, such as that taught by Sadozai, to [the HA-based composition] taught by Expert Anti-Aging, with a reasonable expectation of success.” *Id.* (citing Ex. 1041, ¶¶ 120–127, 152–156).

The Petition fails to direct us to persuasive evidence that a person of ordinary skill in the art would have expected the lidocaine in Sadozai’s composition—which contains HA crosslinked with BCDI and no suggestion to include uncrosslinked HA—to behave the same way in a composition “that included HA crosslinked with BDDE in combination with uncrosslinked HA.” Prelim. Resp. 16; see Pet. 49 (citing Ex. 1041, ¶¶ 120–127, 152–156) (failing to adequately address differences between the compositions of Sadozai and Expert Anti-Aging). On this record, the Petition does not show sufficiently why or how a person of ordinary skill in the art would have been led to modify the applied references with a reasonable expectation of success to attain the claimed invention.

III. CONCLUSION

Taking account of the information presented in the Petition, the Preliminary Response, the Reply, and the Sur-Reply, for reasons stated above, we determine that Petitioner has not shown a reasonable likelihood of prevailing at trial with respect to any challenged claim of the ’475 patent.

IV. ORDER

Accordingly, it is:

ORDERED that the Petition is *denied* and no trial is instituted.

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