

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 IPR2017-01906

Patent 8,357,795 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 1–11, 22, 26–38, 40, and 41 of U.S. Patent No. 8,357,795 B2. Ex. 1001 (“the ’795 patent”). Paper 1 (“Pet.”). Patent Owner filed a Preliminary Response. Paper 10 (“Prelim. Resp.”). With Board preauthorization, Petitioner filed a Reply (Paper 12) and Patent Owner filed a Sur-Reply (Paper 14) limited to “two narrow evidentiary issues identified by Petitioner in Exhibit 3001.” Paper 11; see Ex. 3001 (identifying those two issues, pertaining to the printed publication status of an asserted prior art reference that is at issue in this case and the translation declaration of a different reference applied in a related proceeding¹). 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 ’795 patent. Pet. 1; Paper 5, 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 IPR2017-02002, 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 IPR2014–01422), which was terminated by joint motion on June 19, 2015. Pet. 1; Paper 5, 2. In addition, Patent Owner identifies several pending and one prior continuation applications that claim priority through the '795 patent. Paper 5, 3.

B. The '795 Patent (Ex. 1001)

The '795 patent is titled “Hyaluronic Acid-Based Gel Including Lidocaine.” Ex. 1001, [54]. The '795 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 '795 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 ’795 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 ’795 patent is directed to a “stable” HA-composition that includes lidocaine and a method of preparing that “stable” composition. *Id.* at 5:12–20, 6:20–27 (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, or about 36 months or greater”—“even after being subjected to sterilization procedures” such as “autoclaving.” *Id.* at 7:36–46. The specification of the ’795 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 6:9–19.

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 19:23 (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 7:3–12. 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, for example, no greater than about 5% free HA material.” *Id.* at 7:12–15.

The ’795 patent explains: “Without intending to be bound by any particular theory of operability, it is believed that the 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 7:26–31. 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 7:32–36.

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 lengthy period of time,” for example, “about 36 months or greater,” and “even after being subjected to sterilization” by “autoclaving.” *Id.* at 7:36–46. “Such cohesive gels” may be “monophasic, or substantially single-phase compositions, in that less than about 1% to about 10% of the composition comprises free HA.” *Id.* at 7:61–65.

The specification further describes “the kinetic release of lidocaine from cohesive HA gels.” *Id.* at 17:8–9. In that regard, the specification discloses an experimental protocol and “in vitro study” useful for determining whether lidocaine “is freely released from the gels when placed in the skin.” *Id.* at 17:10–13, 43–44; *see generally id.* at 17:4–45 (Example 5, “Kinetic Release”).

C. Illustrative Claims

Claims 1 and 22 are illustrative and are reproduced below:

1. A soft tissue filler composition comprising:

a hyaluronic acid (HA) component crosslinked with a crosslinking agent selected from the group consisting of 1,4- butanediol diglycidyl ether (BDDE), 1,4-bis(2,3- epoxypropoxy)butane, 1,4-bisglycidyl ether, 1,2-bis(2,3-epoxypropoxy)ethylene and 1-(2,3-epoxypropyl)-2,3-epoxycyclohexane, and 1,4-butanediol diglycidyl ether;

wherein the HA is not crosslinked to a non-HA biopolymer; and
lidocaine combined with said crosslinked HA component;

wherein the lidocaine is freely released *in vivo*; and

wherein the composition is sterile.

Ex. 1001, 19:20–32 (indentation added).

22. A cohesive soft tissue filler composition, the composition comprising:

a hyaluronic acid (HA) component crosslinked with 1,4-butanediol diglycidyl ether (BDDE); and

unbound lidocaine HCL combined with the crosslinked HA component,

wherein said cohesive soft tissue filler composition has an extrusion force of between about 10 N and about 13 N and has a viscosity of between about 5 Pa*s and about 450 Pa*s after sterilization.

Id. at 20:35–44 (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), alleging the following dates of publication (Pet. 4, table of exhibits):

(1) Ele vess, Summary of Safety and Effectiveness, published Jan. 10, 2007, Ex. 1017 (“Ele vess Summary”);

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

(3) Wang, W.O. 2005/112888, published Dec. 2, 2005, Ex. 1026 (“Wang”);

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

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

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

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

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)
Eleves Summary	§ 102(b)	26–38
Hunter	§ 102(b)	1–3, 6, 8, 40, 41
Wang	§§102(b), 103(a)	1, 3–6, 8, 22, 40
Lupo, Toth, Kinney	§ 103(a)	1–11, 22, 40, 41
Kinney	§§ 102(b), 103(a)	29–31, 33, 37, 38
Levy	§ 102(a)	1–3, 6–8, 11, 22, 40, 41

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 '795 patent is unpatentable. For reasons that follow, we determine 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. 9–10 (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 795, 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 even under Petitioner’s constructions. Prelim. Resp. 3. We adopt for

purposes of this decision the following definition of “stable,” which is advanced by Petitioner:

a sterile composition that 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 stored at a temperature of at least about 25° C for a specified period of time.

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

One final point pertaining to the “stable” limitation requires discussion. The specification makes clear that stability, in the context of the ’795 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 about 6 months” and, in some cases, “about 36 months or greater.” *Id.* at 7:41–44, 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, 6:14–19 (composition has “enhanced stability” “when stored at ambient temperature for an extended period of time”), 8:62–63 (the composition of the invention will “remain stable when stored for long periods of time at room temperature”).

C. Analysis of the Asserted Patent Challenges

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

1. Printed Publication Status of the Elevess Summary

Petitioner asserts that claims 26–38 of the ’795 patent are anticipated by the disclosure of the Elevess Summary. Pet. 9, 14–19. We deny trial on this ground because Petitioner has not shown sufficiently that the Elevess Summary is a

“printed publication” that was “sufficiently accessible to the public interested in the art” before the critical date. *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989). The touchstone of public accessibility is whether an ordinary artisan “exercising reasonable diligence” would have been able to locate the document prior to the critical date. *SRI Int’l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008). Petitioner availed itself of two opportunities to make out that showing, but has not done so adequately. *See* Pet. 4, 14; Reply 1–5.

Petitioner alleges that the Elevess Summary is an FDA Premarket Approval (“PMA”) document summarizing “the safety and effectiveness of an injectable dermal filler.” Pet. 14; *see* Ex. 1005, 1² (cover page). Petitioner shows sufficiently that the effective filing date of the ’795 patent is August 4, 2008, and that, therefore, the Elevess Summary would be a prior art printed publication if it was publicly available prior to the critical date of August 4, 2007. *See* Pet. 2–3 (asserting that the effective filing date of the ’795 patent is August 4, 2008); *see* Ex. 1001 [60] (reporting filing date of August 4, 2008, for the first provisional application for the ’795 patent); *see also* Pet. 9 (grounds chart, asserting that the Elevess Summary is prior art under 35 U.S.C. § 102(b)).

The Petition does not show sufficiently, however, that the Elevess Summary was available to interested persons exercising reasonable diligence prior to the critical date. On that point, the Petition, in the table of exhibits, sets forth two internet links beneath the Elevess Summary—links that appear to relate to an FDA website and an archived Wayback Machine webpage. Pet. 4. The Petition includes no discussion of those internet links. Pet. 4, 14. Instead, the Petition

²² We refer to the original page numbering of exhibits, not those added by a party.

advances bare attorney argument that the “Ele vess Summary was published online at least by January 10, 2007.” Pet. 14.

Patent Owner, for its part, comes forward with argument and evidence casting doubt on whether the internet links set forth in the Petition’s table of exhibits establish sufficiently that interested persons, exercising reasonable diligence, would have located the Ele vess Summary prior to the critical date. Prelim. Resp. 10–11. First, Patent Owner correctly observes that “[a]rguments of counsel cannot take the place of factually supported objective evidence.” *Id.* at 6 (citing *Estee Lauder Inc. v. L’Oréal, S.A.*, 129 F.3d 588, 596 (Fed. Cir. 1997)). Second, Patent Owner identifies evidence that the link to the FDA website (*see* Pet. 4) leads to a message that the “page was captured on [] Jan 12, 2017.” Prelim. Resp. 11 (citing Ex. 2001). Third, Patent Owner directs us to evidence that the archived Wayback webpage identified in the Petition (*see* Pet. 4) leads only to error messages. Prelim. Resp. 11 (citing Exs. 2002, 2003).

Over Patent Owner’s objection, we determined that the interests of justice favored providing Petitioner an opportunity to respond to the evidence, presented in the Preliminary Response, which undercuts the Petition’s bare attorney argument that the Ele vess Summary qualifies as a printed publication. Paper 11 (providing Petitioner an opportunity to file a Reply and Patent Owner to file a Sur-Reply on that issue). In the Reply, however, Petitioner abandons the evidence presented in the Petition, does not address the evidence presented in the Preliminary Response, and instead advances an entirely new theory of public accessibility. Reply 1–5 (citing Exs. 1067, 1068, 1069, and 1070). Petitioner’s Reply to the Preliminary Response is not the proper place to raise such information, which should have been presented in the Petition. Because the argument and evidence presented in the Reply exceeds the scope of a proper reply,

we have discretion to exclude it. 37 C.F.R. § 42.23(b) (“A reply may only respond to arguments raised in the corresponding opposition or patent owner response.”).

Even entertaining the new theory presented for the first time in the Reply, however, we determine that Petitioner fails to establish sufficiently that the Elevess Summary would have been publicly available prior to the critical date. Petitioner directs us to four new documents: (1) a letter from the Department of Health & Human Services to Anika Therapeutics, Inc., dated December 6, 2006 (Reply, 2 and n.2 (citing Ex. 1067)); (2) a copy of FDA guidelines pertaining to the PMA Review Process (*id.* at 2, 3 (citing Ex. 1068)); (3) an entry from the Federal Register that allegedly represents a quarterly listing of approved PMAs (*id.* at 3 (citing Ex. 1069)); and (4) a document that allegedly shows that the Elevess Summary “remains accessible through [the] FDA’s PMA database” (*id.* at 4 (citing Ex. 1070)).

That new evidence is accompanied by no witness testimony, or any other competent information, tending to establish the relevance of the new documents asserted for the first time in the Reply. Reply 1–5. Here again, Petitioner relies on conclusory statements of counsel. *Id.* Critically lacking in the Reply is any persuasive evidence (such as testimony from Dr. Prestwich or any other person competent to opine from the perspective of an ordinary artisan) tending to establish that interested persons, exercising reasonable diligence, would have routinely examined FDA quarterly listings of PMA approvals, such as the FDA quarterly listing purportedly represented in Exhibit 1069. Reply 3.

Instead, Petitioner advances bare attorney argument that “because the Notice of Approval for PMA Application No. P05003 was issued December 20, 2006 ***as disclosed in the Elevess Summary***, a [person of ordinary skill in the art] would readily understand that the Elevess Summary would be ‘published on the internet’

(Ex. 1068) very shortly after the December 20, 2006 approval date.” *Id.* (emphasis added). The suggestion that the issue date of “December 20, 2006 ***as disclosed in the Elevess Summary***” would alert interested persons that they should peruse the FDA’s quarterly listings at about that time (*id.*) is, of course, a circular argument that depends upon a showing that the Elevess Summary would have been available to interested persons prior to the publication of the FDA quarterly listing, which allegedly announced publication of the Elevess Summary (Ex. 1069).

In any event, the record does not include information sufficient to show that interested persons, exercising reasonable diligence, would have routinely reviewed the FDA’s quarterly listings and, thereby, would have discovered the quarterly listing identified as Exhibit 1069. Reply 1–3. On that point, the Reply directs us to an approval letter that bears no indication that it was ever publicly disseminated. Reply 2 (citing Ex. 1067). On this record, it is unclear how the letter would have alerted interested persons that the Elevess Summary “would be ‘published on the Internet’” “very shortly after the December 20, 2006 approval date.” Reply 3.

We agree with Patent Owner that the Reply rests on bare attorney argument regarding what interested persons would have done or understood from Exhibits 1067, 1068, 1069, and 1070. Sur-Reply 2–3; *see, e.g.*, Reply 1, 2 (twice referring, without evidence, to what a person of ordinary skill in the art “would readily understand” from those exhibits), 4 (referring, without evidence, to the FDA’s PMA database as “a very well-known website to a [person of ordinary skill in the art]”). The FDA quarterly listing advanced by Petitioner (Exhibit 1069) reveals only that “Anika Therapeutics, Inc.” had received an approval for a “Cosmetic Tissue Augmentation Product” on December 20, 2006. Ex. 1069. That approval entry is one among a list of approvals pertaining to “a wide variety of medical devices,” including “excimer lasers, stents, and breast implants.” Sur-

Reply 2. Even if interested persons would have routinely scanned the FDA’s quarterly listings (and there is no competent evidence of that on this record), Petitioner fails to advance any evidence tending to show that interested persons would have recognized “Anika Therapeutics, Inc.” as a dermal filler manufacturer or would have understood the entry identified as a “Cosmetic Tissue Augmentation Product” as pertaining to an HA-based dermal filler. *See* Reply 1–5.

Petitioner identifies a statement in Exhibit 1069 that informs: “Persons with access to the Internet may obtain the documents” pertaining to the quarterly notice at a link identified as “<http://www.fda.gov/cdrh/pmapage.html>.” Reply 3–4. From there, Petitioner advances conclusory attorney argument that “it is clear that [the] Ele vess Summary constitutes a printed publication.” *Id.* at 4. Petitioner further argues that Exhibit 1069 is “self-authenticating” as a public record. *Id.* at 4 n.4.

Petitioner’s argument and evidence is unpersuasive. Even if we accept that interested persons would have discovered the internet link provided in Exhibit 1069 (and again, there is no competent evidence of that on this record), Petitioner identifies only indirect proof that the link published in Exhibit 1069 would have led one to a set of documents that included the Ele vess Summary. Reply 2 (citing Ex. 1067 (approval letter); Ex. 1068 (PMA process)). The record is devoid of evidence sufficient to identify the documents that would have been accessible from this general link (identified as a “pmapage” (Ex. 1069))—much less whether or how any documents available by clicking on that link would have been catalogued or indexed prior to the critical date.

On that point, the Reply is silent on whether or how the documents (which pertained to “a wide variety of medical devices” including “excimer lasers, stents, and breast implants” (Sur-Reply 2)) would have been organized. The record does not include evidence from which we reasonably can conclude that any documents,

accessible by clicking on this link, would have been organized in a manner that would have allowed interested persons, exercising reasonable diligence, to locate the Ele vess Summary prior to the critical date (if, in fact, the Ele vess Summary was among the documents accessible by clicking on the link). Reply 1–5.

In sum, Petitioner does not show sufficiently (1) that interested persons, exercising reasonable diligence, would have located Exhibit 1069 prior to the critical date; (2) that the set of documents accessible from the internet link identified in Exhibit 1069 would have included the Ele vess Summary; or (3) that the set of documents accessible from the internet link identified in Exhibit 1069 would have been catalogued or indexed in a manner that would have allowed interested persons, exercising reasonable diligence, to locate the Ele vess Summary prior to the critical date. Reply 1–5.

On this record, Petitioner fails to demonstrate adequately that the Ele vess Summary was publicly available to interested persons prior to the critical date. Accordingly, we deny trial on the challenge that is based on the Ele vess Summary.

2. Anticipation Based on Hunter

The Petition challenges the patentability of claims 1–3, 6, 8, 22, 40 and 41 as anticipated by Hunter. Pet. 19. Hunter was before the Examiner during patent 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 20 (citing Ex. 1004, Abstract, ¶ 314).

(a) Independent Claim 1 (and Claims that Depend Therefrom)

We first address claim 1 (and claims 2–3, 6, 8, 40, and 41, which depend from claim 1). 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 of “2009,” which is after the effective filing date of the ’475 patent. Pet. 5; *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. 20; *see id.* at 22 (claim chart for claim 1, citing Beasley for the claim limitation that requires an HA component that is crosslinked with BDDE). Petitioner directs us to no persuasive evidence 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 name, but providing no information that the HA component was crosslinked with BDDE).

Nor does the Petition show sufficiently that Hunter anticipates the limitation in claim 1 requiring a composition “wherein the lidocaine is freely released in vivo” (after injection in a patient). Ex. 1001 19:31. On that point, we agree with Patent Owner that the Petition fails to address adequately how the presence of HI in Hunter’s composition would affect the free release of lidocaine from the HA gel in vivo. *See* Pet. 20–21; Prelim. Resp. 14–15 (pointing out that the Petition includes no showing that the lidocaine in Hunter’s composition “would necessarily be ‘freely released’ in vivo” where Hunter discloses “very different compositions” that include both “hyaluronic acid and an inhibitory compound” that “can inhibit the activity of hyaluronidase” (quoting Ex. 1004, 11)).

The Petition further avers that lidocaine “would be inherently freely released from the HI-HA product of Hunter” but, in terms of evidentiary support, directs us to declaration testimony that stops short of supporting that proposition. Pet. 21

(citing Ex. 1041 ¶¶ 143–145). Dr. Prestwich states that lidocaine in Hunter’s composition “should freely diffuse from the implant” because “any interaction of the protonated form [of] lidocaine with the polyanion HA” in Hunter’s composition “would be very weak.” Ex. 1041 ¶ 144. That opinion is based on Dr. Prestwich’s assessment of the pH of the HA gel that is used in Hunter’s composition. Pet. 22 (claim chart, citing Ex. 1004 ¶ 247). But as Patent Owner observes, the Petition identifies “no evidence” of “what would happen to the pH of” the HA gel “after the HI is added;” nor does the Petition address how the pH would be affected “if lidocaine were added to the composition.” Prelim. Resp. 15.

Dr. Prestwich’s opinion that Hunter discloses a composition in which lidocaine “should freely diffuse from the implant” in vivo (Ex. 1041 ¶ 144) is “the very kind of probability and possibility that is insufficient to establish inherency.” Prelim. Resp. 15; *see In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”) (citation omitted). Dr. Prestwich does not testify (much less direct us to objective proof, such as experimental data) that a free release of lidocaine would necessarily occur in vivo when HI is included in the HA-based composition—instead, he states only that this result “should” occur. Ex. 1041 ¶ 144.

(b) Independent Claim 22

Like claim 1, claim 22 requires an HA component that is crosslinked with BDDE. Ex. 1001, 20:37–38. The Petition refers us back to the claim chart for claim 1 to make out this limitation of claim 22. Pet. 25. For reasons set forth above, the Petition’s reliance on Beasley (which is not prior art, and is not shown to disclose an HA-based composition that is identical to the HI-HA gel disclosed in

Hunter) is insufficient to show that Hunter discloses an HA component that is crosslinked with BDDE. *See supra*.

Claim 22 also requires, among other things, a “cohesive soft tissue filler composition” that “has an extrusion force of between about 10 N and about 13 N and,” further, “a viscosity of between about 5 Pa*s and about 450 Pa*s after sterilization.” Ex. 1001, 20:41–44. Regarding claim 22, we agree with Patent Owner that Petitioner’s reliance on “reasons discussed” “regarding claims 1 and 6” is insufficient to support trial institution, given that neither of those claims recites the physical properties, pertaining to extrusion force and viscosity after sterilization, that are specified in claim 22. *Compare* Pet. 25, with Prelim. Resp. 16. “With respect to inherency, [Petitioner] never explains how or why Hunter’s HA-HI compositions, if combined with lidocaine, would necessarily exhibit those properties.” Prelim. Resp. 16; *see* Pet. 25 (nowhere addressing those limitations of claim 22). Accordingly, we determine that Petitioner fails to make out the threshold showing for review of claim 22 based on anticipation by Hunter.

3. Anticipation or Obviousness Based on Wang

Petitioner asserts that claims 1, 3–6, 8, and 40 are unpatentable as anticipated by, or obvious from, the disclosure of Wang.³ Pet. 25–29. Like Hunter, Wang was of record during the patent prosecution. Pet. 25; Ex. 1001 [56] (references cited during patent prosecution, including Wang).

³ Although the grounds chart in the Petition identifies independent claim 22 as challenged based on Wang (Pet. 9), claim 22 is not identified in the heading pertaining to that ground (Pet. 25). The Petition, moreover, advances no argument or evidence with respect to claim 22 in the challenge based on Wang (*id.* at 25–29). Given that circumstance, we find that Petitioner fails to show sufficiently that claim 22 would have been obvious over, or anticipated by, the disclosure of Wang.

Petitioner argues that Wang discloses an HA-BDDE composition that may include lidocaine. Pet. 25–26. We deny this ground because, like the ground based on Hunter, the Petition fails to show sufficiently that Wang discloses or suggests a composition “wherein the lidocaine is freely released in vivo” as required by claim 1. Ex. 1001 19:31. Claim 2–6, 8, and 40 depend directly or indirectly from claim 1; therefore, the Petition fails to meet the threshold showing for review with respect to any claim that is challenged based on Wang. Our discussion of claim 1 is dispositive of this ground.

For the limitation of claim 1 that requires a composition “wherein the lidocaine is freely released in vivo” (Ex. 1001 19:31), the Petition advances bare attorney argument. Specifically, in the claim chart pertaining to this limitation, the Petition cites no persuasive evidence (such as the declaration of Dr. Prestwich) in support of the conclusory assertion that “HA would not interact with lidocaine to an extent to thereby prevent the free release of lidocaine from the HA gel in vivo.” Pet. 27; *see also id.* at 26 (repeating this bare attorney argument).

The Petition contains a single additional sentence on point: “Thus, lidocaine is inherently freely released from the HA-BDDE gel of Wang.” *Id.* at 26 (citing Ex. 1041 ¶ 152). When we turn to the evidence cited in support of that proposition, however, which is a single paragraph from the declaration of Dr. Prestwich, we find material that does not support the proposition. Ex. 1041 ¶ 152 (nowhere asserting that lidocaine is freely released from Wang’s HA-based composition).

Nevertheless, we examined the paragraphs of the declaration that immediately surround the paragraph cited in the Petition. *See* Ex. 1041 ¶¶ 151, 153. We discovered a discussion of the pH of the HA gel used in Wang (*id.* at ¶ 151) as well as a statement that “lidocaine would be inherently freely released

from the injectable gel of Wang for reasons similar to those discussed in detail for the implant of Hunter” (*id.* at ¶ 153). Although Dr. Prestwich does not provide a pin cite to Wang, he appears to rely on disclosure pertaining to the pH of Wang’s HA component alone (before lidocaine is added) in forming his opinion that lidocaine would be freely released in vivo from the lidocaine-containing HA gel. *Id.*; see Ex. 1026, 5:3–6 (Wang, explaining that the HA component is buffered to a pH of 7.4), 7:3–6 (Wang, explaining that lidocaine, thereafter, may be added to the HA component). Dr. Prestwich does not address what would happen to the pH if one were to add lidocaine to the HA component. Ex. 1041 ¶ 153. On the contrary, Dr. Prestwich assumes a free release of lidocaine from a lidocaine-containing gel, based on pH, but applies in his analysis the pH of the HA component alone (before addition of lidocaine). *Id.* Nothing in the ’795 patent suggests that the kind of analysis provided by Dr. Prestwich is sufficient to establish that required kinetic property. Ex. 1041 ¶¶ 152–153; *compare* Ex. 1001, 17:6–45 (kinetic release study, providing an experimental method for assessing whether lidocaine is freely release in vivo from a lidocaine-containing HA gel).

In addition, we agree with Patent Owner that Dr. Prestwich’s opinion is at odds with an express disclosure in Wang. Prelim. Resp. 17. Wang discusses the optional use of therapeutically active additives, including lidocaine, but states that the additives “may be bound, either physically or chemically, to the crosslinked gel using methods well known in the art.” Ex. 1026 7:8–10. Dr. Prestwich does not address that disclosure, even though he cites the immediately preceding line in Wang. Ex. 1041 ¶ 152 (citing Ex. 1026 7:7). We agree with Patent Owner that the disclosure, which Dr. Prestwich ignores, “suggests that lidocaine, if included, would not be freely released in vivo.” Prelim. Resp. 17; see Ex. 1026 7:8–10 (contemplating the addition of lidocaine that is “bound, either physically or

chemically, to the crosslinked gel”). That disclosure undercuts Dr. Prestwich’s opinion that Wang discloses or suggests a composition in which lidocaine “inherently” is freely released in vivo. See Ex. 1041 ¶ 153 (for that opinion).

On this record, we find that the challenge based on Wang rests on “the very kind of probability and possibility that is insufficient to establish inherency.” Prelim. Resp. 15; see *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (“Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”)

4. Obviousness Based on Lupo and Toth or Kinney

Petitioner contends that claims 1–11, 22, 40, and 41 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 of record during patent prosecution. Pet. 29; 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 22.

(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. 12. 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 13. 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 ’795 patent. Ex. 1015, 1; Ex. 1019, 1; see Ex. 1001 [60] (reflecting the August 4, 2008 filing date of provisional application for the ’795 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) Independent Claim 1 (and Claims that Depend Therefrom)

The Petition does not direct us to information sufficient to show that independent claim 1 (or claims 2–11, 40, or 41, which directly or indirectly depend from claim 1) would have been obvious over the combined disclosures of Lupo and Toth or Kinney. Claim 1 requires an HA-based component that is crosslinked with BDDE. Ex. 1001, 19:20–26.

Lupo is a single-paragraph abstract that refers to a crosslinked HA-based composition but does not disclose BDDE. Ex. 1015 (entry P2909, single paragraph abstract). The Petition relies on two other documents in an attempt to show that products described by the same tradename as Lupo’s gel were crosslinked with BDDE. Pet. 37 (claim chart, citing two documents described as “Allemann” and “Gold”). The Petition, however, directs us to no persuasive evidence that the products described in those two additional documents are identical to the HA-based composition disclosed in Lupo. *Id.* The Petition, therefore, fails to show sufficiently that the HA-based gel disclosed in Lupo was crosslinked with BDDE.

Further, claim 1 requires an HA-based composition that contains lidocaine, “wherein the lidocaine is freely released in vivo.” Ex. 1001, 19:31. Petitioner acknowledges that Lupo’s composition does not contain lidocaine. Pet. 32. The Petition argues (without providing any pin cites) that Toth and Kinney (as well as twelve (12) other references, all asserted without pin cites) suggest adding lidocaine to Lupo’s HA-based composition. *Id.*

The Petition contends that the modified composition of Lupo would “inherently” meet the claim 1 limitation requiring that “the lidocaine is freely released in vivo.” Pet. 31; *see* Ex. 1001 19:31 (for the claim limitation). By way of evidentiary support, however, the Petition does not identify disclosure in any prior art reference, but instead directs us to disclosure from “the priority documents for the ’795 patent.” Pet. 31; *see id.* at 38 (claim chart, directing us to the first provisional application for the ’795 patent for disclosure of a composition “wherein the lidocaine is freely released in vivo”).

On this record, the Petition does not show sufficiently that the asserted prior art would have suggested a composition wherein lidocaine inherently (that is, necessarily) is freely released in vivo. Like the grounds based on Hunter and Wang, the ground based on Lupo depends on a showing of inherent disclosure of that claim limitation. *See* Pet. 31–32 (attempting to make out a showing of inherency) (citing Ex. 1041 ¶¶ 58–65). On that point, the Petition directs us to declaration testimony (*id.*) that sets forth a chart identifying lidocaine-containing HA-based gels that allegedly were available “before and after” the effective filing date of the ’795 patent (Ex. 1041 ¶ 63). The cited testimony, however, does not include opinion (much less persuasive objective proof) that an ordinary artisan would have been led to combine any particular combination of references to arrive at a composition “wherein the lidocaine is freely released in vivo” (Ex. 1001 19:31). *See* Ex. 1041 ¶¶ 58–65 (nowhere addressing the free release of lidocaine in vivo); *see also* Pet. 38 (claim chart, relying on first provisional application for disclosure of the free release of lidocaine in vivo).

In addition, without directing us to any supporting evidence (such as the declaration of Dr. Prestwich), the Petition advances a conclusory argument that an ordinary artisan “would have had a reasonable expectation of success to obtain”

the composition of claim 1 from Lupo “in view of the teachings from Toth and Kinney.” *Id.* at 34. We will not search the record (including Dr. Prestwich’s declaration) to ascertain whether any evidence supports that bare argument. *Id.* 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 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.”).

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 with a reasonable expectation of success to attain the invention of claim 1, including the feature that requires a composition “wherein the lidocaine is freely released in vivo.” Ex. 1001, 19:31.

(c) *Claim 22*

Claim 22 is directed to “[a] cohesive soft tissue filler composition” that, among other things, comprises “unbound lidocaine HCL combined with [a] crosslinked HA component.” Ex. 1001, 20:35–40. The “said cohesive soft tissue filler composition” is characterized by “an extrusion force of between about 10 N and about 13 N and,” further, “has a viscosity of between about 5 Pa*s and about 450 Pa*s after sterilization.” *Id.* at 20:41–44.

Petitioner relies on the first provisional application for the ’795 patent to establish that Lupo’s composition is “cohesive.” Pet. 41 (claim chart). But the Petition does not aver that the provisional application is prior art to the ’795 patent. *Id.* Further, for the limitation pertaining to extrusion force, the Petition rests on a conclusory argument that “the claimed extrusion force can always be obtained with any sterile soft tissue filler composition of claim 1 when one varies the dimensions

of the syringe and needle.” Pet. 39 (discussing claim 6); *see id.* at 41 (claim chart, directing us to argument on page 39 of the Petition, which pertains to claim 6). In an attempt to make out the limitation pertaining to viscosity, the Petition again directs us to the first provisional application of the ’795 patent. Pet. 39 (discussing claim 7); *see id.* at 41 (claim chart, directing us to argument on page 39 of the Petition, which pertains to claim 7).

We are not persuaded that bare attorney argument, or the disclosure of the first provisional application for the ’795 patent (which has not been established as prior art), is sufficient to show that claim 22 would have been obvious over the combined disclosures of Lupo and Toth or Kinney. Accordingly, we decline to institute trial based on that challenge.

5. Anticipation or Obviousness Based on Kinney

Petitioner argues that claims 29–31, 33, 37, and 38 are anticipated by, or obvious from, the disclosure of Kinney. Pet. 9, 42. These challenged claims require a composition that, among other things, “is stable during storage under ambient conditions for at least 3 months” (claim 29), “for at least 6 months” (claim 30), or “for at least 9 months” (claim 31); or is “stable to autoclaving” (claim 28, from which claims 33, 37, and 38 depend) and “wherein the HA concentration is substantially constant during storage under ambient conditions for at least 3 months” (claim 33), has “an extrusion force that is substantially constant during storage under ambient conditions for at least 3 months” (claim 37), or “wherein the lidocaine is freely released in vivo” (claim 38). Ex. 1001, 21:19–22:16).

We address each claim in turn below.

(a) *Claim 29*

We first address Petitioner’s challenge to claim 29, which specifies a composition that “is stable during storage under ambient conditions for at least 3

months.” *Id.* at 21:22–23. As we explained in our discussion of claim construction, we adopt for purposes of this decision the interpretation of “stable” that is advanced in the Petition, namely:

a sterile composition that 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 stored at a temperature of at least about 25° C for a specified period of time.

Pet. 11. As also explained in our claim construction analysis, the specification makes clear that stability, in the context of the ’795 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, 6:14–19 (composition has “enhanced stability” “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”).

For the stability limitation of claim 29, although the citation to Kinney in the Petition is less than clear (*see infra*, n. 4), we presume that the Petition attempts to direct us to disclosure in Kinney that relates to the persistence of an HA gel in a patient “post injection.” Pet. 43 (citing Ex. 1016, 748).⁴ The Petition identifies no information tending to establish that Kinney’s composition “is stable during

⁴ The Petition cites page 749 of Kinney (Ex. 1016), but that asserted prior art reference concludes on page 748. Ex. 1016, 748. In the interests of reaching a fair result, we reviewed the exhibit to discover a pertinent disclosure, which appears in the paragraph immediately preceding the conclusion on page 748 of Kinney. *Id.*

storage under ambient conditions for at least 3 months” within the meaning of claim 29.

(b) Claims 30, 31, and 33

The Petition presents no arguments specific to the limitations recited in claims 30, 31, or 33. Pet. 44. Petitioner’s single-sentence analysis points us only to “reasons discussed immediately above.” *Id.* (citing Ex. 1016, 749⁵; Ex. 1041 ¶ 181). We have examined the evidence cited in support of that statement, however, and are persuaded that Petitioner means to rely on the same disclosure in Kinney, advanced in support of the unpatentability of claim 29, pertaining to the persistence of an HA-based composition in a patient “post-injection.” Ex. 1041 ¶ 181 (Dr. Prestwich, referring to Kinney’s disclosure of “post-injection” stability; see Ex. 1016, 748 (discussing post-injection “persistence” of Kinney’s HA-based composition in patients). The Petition’s reliance on “reasons discussed above” that pertain to the limitations of claim 29 are insufficient to establish the unpatentability of the different limitations set forth in claims 30, 31, and 33. Pet. 44.

On this record, the Petition does not advance evidence sufficient to show that the limitations of claims 30, 31, or 33 (which differ from those set forth in claim 29) are unpatentable over Kinney. To the extent that those claims, like claim 29, relate to a “stable” HA-based composition including lidocaine (Ex. 1001, 5:12), we determine on this record that the stability required by claims 30, 31, and 33 (like claim 29) relate to “shelf life” during storage prior to injection (*id.* at 14:60-64) and not to post-injection “persistence” in a patient (Ex. 1016, 748).

In the alternative, we find that the Petition sets forth insufficient analysis of claims 30, 31, and 33 to meet the threshold showing required to support institution

⁵ There is no page 749 in Kinney (Ex. 1016).

of an *inter partes* review. Pet. 44 (failing to particularly point out or explain the challenge in the context of the limitations specific to claims 30, 31, and 33).

Accordingly, on this record, we determine that Petitioner is not reasonably likely to prevail at trial in showing that any of these claims is unpatentable over Kinney.

(c) Claims 37 and 38

For the “substantially unbound” limitation of claims 37 and the “freely released in vivo” limitation of claim 38, the Petition rests on conclusory attorney argument that Kinney’s disclosure of “a relatively pain-free injection” establishes that the lidocaine is “substantially unbound” in the composition. *Id.* (citing Ex. 1016, 742, 748). The Petition does not direct us to evidence that connects a pain-free injection to “substantially unbound” lidocaine. *Id.* We deny this ground because it is based on bare attorney argument, which cannot take the place of evidence lacking in the record. *See, e.g., In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997); *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

6. Anticipation Based on Levy

Petitioner challenges claims 1–3, 6–8, 11, 22, 40, and 41 as anticipated by Levy in view of five (5) other documents, including the first provisional application for the ’795 patent, which is not shown to qualify as prior art. Pet. 44. 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. 12. 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 13. 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 ’795 patent. Ex. 1007, 2; *see* Ex. 1001 [60] (reflecting the August 4, 2008 filing date of provisional application for the ’795 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 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 1–3, 6–8, 11, 22, 40, and 41

This ground addresses a sub-set of the same claims that are the subject of the challenge based on Lupo. Pet. 9 (grounds chart). Similar to the ground based on Lupo, the Petition acknowledges that Levy discloses an HA-based composition that “does not contain lidocaine.” Pet. 45. Nor does Levy disclose that the HA component is crosslinked with BDDE. Ex. 1007; *see* Pet. 46 (relying on documents identified only as “Prager” (Ex. 1049, an email communication bearing the date “Sun Mar 23 17:12:18 2014”) and “Gold” (Ex. 1040, an article bearing a copyright notice from 2007) for a suggestion to crosslink HA with BDDE).

The Petition raises no argument that meaningfully distinguishes the challenge based on Levy from the challenge based on Lupo. Pet. 44–47. Instead, Petitioner twice directs us to arguments set forth in the ground based on Lupo for information necessary to make out the challenge based on Levy. *See id.* at 45 (referring to argument “discussed in detail under Ground 4”), 46 (referring to “reasons discussed more fully for the respective claims in Ground 4”).

Our reasons for denying 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 '795 patent as if it were prior art (*see, e.g.*, Pet. 46 (claim chart)) and rests on conclusory attorney argument in an attempt to make out an inherent disclosure (*see id.* at 47 (arguing 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"))). For these reasons, the Petition fails to demonstrate a reasonable likelihood that Petitioner would prevail at trial with respect to at least one claim that is the subject of the challenge based on Levy.

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 '795 patent.

IV. ORDER

Accordingly, it is:

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

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Patent 8,357,795 B2

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