

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SALVACION USA, INC.,
Petitioner,

v.

TRUTEK CORP.,
Patent Owner.

IPR2024-00711
Patent 8,163,802 B2

Before ERICA A. FRANKLIN, ULRIKE W. JENKS, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Salvacion USA, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–3 and 8 of U.S. Patent No. 8,163,802 B2 (Ex. 1002, “the ’802 patent”). Paper 2 (“Pet.”). Trutek Corp. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314. Upon considering the parties’ arguments and evidence, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of all claims and all grounds asserted in the Petition.

A. *Real Parties-in-Interest*

Petitioner identifies itself, Pharmhealth Technologies, Inc., and Salvacion Co. Ltd. as the real parties-in-interest. Pet. 1. Patent Owner identifies itself as the real party-in-interest. Paper 5, 1.

B. *Related Matters*

The parties relay that Patent Owner has asserted the ’802 patent against Petitioner in *Trutek Corp. v. Cho, et al.*, Case No. 2:23cv3709 (D.N.J. 2023); *Trutek Corp. v. Bluewillow Biologics, Inc.*, Case No. 2:21cv10312 (E.D. Mich. 2021); and *Matrixx Initiatives, Inc. v. Trutek Corp.*, Case No. IPR2020-01592 (PTAB Sept. 4, 2020). Pet. 1; Paper 5, 1–2. Patent Owner also lists as related matters *Trutek Corp. v. Matrixx Initiatives, Inc., et al.*, Case No. 3:19cv17647 (D.N.J. 2019) and *Trutek Corp. v. Bluewillow Biologics, Inc.*, Appeal No. 24-1555 (Fed. Cir. 2024). Paper 5, 1.

C. The '802 patent

The '802 patent is directed to electrostatically charged nasal application products that reduce the inflow of airborne contaminants to the nasal passages, by capturing the contaminants, such as viruses, bacterial, and other harmful microorganisms or toxic particulates, and keeping them from entering the body, while also inactivating them to render them harmless. Ex. 1001, 1:67–2:7. According to the Specification,

[t]his formulation, when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidal agent renders microorganisms coming in contact [with] the substrate or skin less harmful.

Id. The Specification provides exemplary formulations which comprise a quaternary thickener, e.g., a polyquaternary ammonium compound, and a biocidal agent. *Id.* at 5:55–10:5. The Specification explains that benzalkonium chloride may also serve the same function as a quaternary thickener, but that it is also a cationic agent and a biocide. *Id.* at 5:25–26.

The '802 patent recognizes that other patents have “describe[d] electrostatically charged compositions that may be applied externally in the vicinity of the nostril and attract oppositely charged materials that would otherwise be inhaled.” *Id.* at 2:42–45. According to the Specification those compositions “cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as microorganisms that are motile within the air stream.” *Id.* at 2:45–52. Further, the Specification states that particles held captive by the former compositions could become dislodged and inhaled when blowing or wiping the nose. *Id.* at 2:52–58.

D. Challenged Claims

Challenged claims 1–3 and 8 of the '802 patent are set forth below.

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

- a) electrostatically attracting the particulate matter to the thin film;
- b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
- c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidal agent, and wherein said formulation, once applied:

- a) electrostatically attracts the particulate matter to the thin film;
- b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
- c) inactivates the particulate matter and renders said particulate matter harmless.

3. The formulation of claim 2 wherein the at least one cationic agent is a polymeric quaternary ammonium compound.

8. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of

nasal passages of the individual in a thin film, said formulation comprising:

- a) at least one biocidic agent, and
- b) at least one quaternary thickener.

Ex. 1001, 10:19–51; 11:1–7.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–3 and 8 are unpatentable on the following grounds:

Claims Challenged	35 U.S.C. § ¹	References
1–3, 8	102(b)	Chen ²
1–3, 8	103	Chen
1–3, 8	102(b)	Baker ³
1–3, 8	103	Baker
1–3, 8	102(b)	Wahi '005 ⁴
1–3, 8	103	Wahi '005
1, 2, 8	102(b)	Rolf ⁵
1, 2, 8	103	Rolf
2	103	Rolf, Wahi '005

¹ The Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. § 102(b) and §103, effective March 16, 2013. The earliest claimed priority date for the '802 patent is before the effective date of the applicable AIA amendment. *See* Ex. 1002, (60).

Accordingly, we apply the pre-AIA version of § 102(b) and §103.

² Chen, U.S. Patent App. Pub. 2005/0232895 A1, published October 20, 2005 (Ex. 1005, “Chen”).

³ Baker, Jr. et al., U.S. Patent 6,559,189 B2, issued May 6, 2003 (Ex. 1006, “Baker”).

⁴ Wahi et al., U.S. Patent 6,844,005 B2, issued January 18, 2005 (Ex. 1007, “Wahi '005”).

⁵ Rolf, U.S. Patent App. Pub. 2004/0071757 A1, published April 15, 2004 (Ex. 1008, “Rolf”).

Petitioner also relies upon the Declaration of Kinam Park, Ph.D. (Ex. 1002).

II. ANALYSIS

A. *Person of Ordinary Skill in the Art*

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that a person of ordinary skill in the art (“POSITA”) at the time the application for the ’802 patent was filed “would have had at least an undergraduate degree in pharmacy, chemistry, biochemistry, biomedical engineering or a closely related field, such that the POSITA generally understand pharmaceutical formulation.” Pet. 12. Additionally, Petitioner asserts “[a] POSITA would be familiar with the chemical ingredients in the [’802] Patent, biocidal agents, and cationic agents, have knowledge of airborne particles including viruses and bacteria, and understand electrostatic fields, electrostatic attraction and repulsion, adhesion and cohesion.” *Id.* (citing Ex. 1002 ¶¶ 38, 39).

Patent Owner does not specifically address or dispute Petitioner’s proposed definition of a person of ordinary skill in the art. *See generally* Prelim. Resp.

At this stage of the proceeding, we adopt Petitioner’s proposed level of ordinary skill in the art as we find it consistent with the cited prior art and it is undisputed on this record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate

level and a need for testimony is not shown” (*quoting Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b); 37 C.F.R. § 100(b). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

The parties propose constructions for a number of claim terms. Pet. 14–16; Prelim. Resp. 7–12. We address those proposals to the extent that express construction of the term is necessary for purposes of deciding whether to institute an *inter partes* review of the challenged claims. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (Only those terms that are in controversy need be construed, “and only to the extent necessary to resolve the controversy.”).

1. Preamble

We begin by addressing Patent Owner’s contention that the preambles of independent claims 1, 2, and 8 are limiting. Prelim. Resp. 7. According to Patent Owner, for these claims, the preamble “recites specific steps in the process that are not recited in the body of the claim or are recited in a way

that is enhanced in the body,” including “electrostatically inhibiting; harmful particulate matter; infecting an individual through nasal inhalation; formulation is applied to the skin or tissue of nasal passages; and a thin film.” *Id.* Petitioner does not allege any contention regarding whether the preamble is limiting. *See* Pet. 14–16.

Based on our review, we agree with Patent Owner that the preamble of independent claims 1, 2, and 8 limits the challenged claims as both the preamble and the body have been used to define the subject matter claimed. *See Allen Engineering Corp., v. Bartell Industries, Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). In particular, the preamble is “necessary to give life, meaning and vitality” to the claim, *see id.*, because it provides the only description in the claim for the application site of the formulation, i.e., “to skin or tissue of nasal passages,” and how the formulation is applied, i.e., “in a thin film.” *Id.*

2. “biocidic agent” and “cationic agent”

Independent claims 2 and 8 recite formulations comprising at least one “biocidic agent.” Petitioner asserts that this term means “an agent which has the capacity to neutralize, inactivate, render harmless or kill airborne particles, which include microorganisms, for example viruses and/or bacteria.” Pet. 14. Patent Owner asserts that the term refers to “a chemical substance that destroys or inhibits the growth or activity of living organisms.” Prelim. Resp. 12 (citing Merriam-Webster Dictionary).

Independent claim 2 recites a formulation comprising at least one “cationic agent.” Dependent claim 3 recites that the “cationic agent is a polymeric quaternary ammonium compound.” Patent Owner asserts that a “cationic agent” is “a chemical substance that creates a positive electrostatic

charge.” Prelim. Resp. 12. Petitioner does not propose a construction for this term.

Based on our review, we determine that an explicit construction is not necessary for purposes of our determination whether to institute an *inter partes* trial, as there is no dispute as to whether the prior art discloses formulations comprising a biocidic agent and a cationic agent.

3. “adequate impermeability”

Independent claims 1 and 2 recite “adjusting the cohesion of the formulation to provide adequate impermeability to the thin film.” Petitioner asserts “adequate impermeability” refers to the “thin film holding harmful particles in place and inhibiting them from penetrating the thin film and contacting the skin or tissue of an individual’s nasal passages. This is done by varying the concentration of ingredients . . .[,] thereby adjusting the adhesion and cohesion of the thin film.” Pet. 15. Patent Owner asserts that the term refers to “the thin film inhibiting harmful particles from penetrating the thin film and contacting the [skin] or tissue of an individual’s nasal passages.” Prelim. Resp. 12.

At this stage in the proceeding, based upon our review of the current record and examination of the claim language and the written description, we determine that the record supports finding that, in the context of the challenged claims, “adequate impermeability” requires sufficient cohesion of the formulation to inhibit harmful particles from penetrating the thin film and contacting the skin or tissue on which the film is applied. The term “adequate impermeability” occurs only in the claims of the ’802 patent. Along with that term, the claim language explains that the thin film is meant to stick to the skin or tissue and to hold the particulate matter in place. The claim language also explains that the cohesion of the formulation is adjusted

to provide adequate impermeability to the thin film. Thus, it is reasonable to consider the recited impermeability is a function of the cohesive properties of the thin film and that the such impermeability refers to a property of the thin film, i.e., inhibiting the penetration or passage of matter through it onto the skin or tissue at the application site.

4. “*skin or tissue of nasal passages of the individual*”

Independent claims 1, 2, and 8 recite that the formulation is applied “to skin or tissue of nasal passages.” Petitioner asserts that this phrase means “skin in or near the area of the nasal passages or tissues of the nasal passages.” Pet. 15.

Further, Petitioner asserts that the term “[s]kin” itself means skin near the nasal passages because independent claims 1, 2, and 8 each state that the formulations and method are “for electrostatically inhibiting harmful particulate matter from infecting an individual through *nasal inhalation*.” *Id.* (quoting Ex. 1001, 10:19–21; 10:34–36, 11:1–3) (emphasis added by Petitioner). Petitioner refers to a passage in the ’802 patent describing the “object of the invention” as composition applied to “the exterior region around the nostril and/or slightly inside the edge of the nostril.” *Id.* (quoting Ex. 1001, 2:62–65). Petitioner contends that “[l]ogically, the formulations applied in a thin film must be on the exterior region around the nostril (i.e., skin) and/or slightly inside the edge of the nostril which is the tissue of nasal passages in order to prevent nasal inhalation.” *Id.* (citing Ex. 1002 ¶ 71).

Patent Owner does not address Petitioner’s proposed construction of this claim phrase or provide one of its own. *See* Prelim. Resp. 6–12.

Based on the current record, an explicit construction of this claim phrase is not necessary for purposes of our determination whether to institute

an *inter partes* trial, as there is no dispute as to whether the prior art discloses this element.

5. “*harmful particulate matter*”

The term “harmful particulate matter” appears in the preamble of independent claims 1, 2, and 8. Patent Owner asserts that this term refers to “particles that are capable of infecting human beings.” Prelim. Resp. 8. Patent Owner does not cite to any support for this proposed construction. In any event, we determine that this term need not be expressly construed for purposes of deciding whether to institute an *inter partes* review of the challenged claims, as there is no dispute that centers on the meaning of this term.

6. “*electrostatically inhibiting*” and “*electrostatically attracting/attracts*”

The preamble of independent claims 1, 2, and 8 recite the term “electrostatically inhibiting.” Claim 1 additionally recites that the formulation “electrostatically attracting” the particulate matter to the thin film, while claim 2 recites that the formulation “electrostatically attracts” the same. Patent Owner asserts the term “electrostatically” refers to “static electricity,” and “utilizing electrically charged particles.” Prelim. Resp. 7 (citing Merriam-Webster Dictionary). Patent Owner asserts that “[i]t is well known that in an electrostatic field, oppositely charged particles attract each other, and similarly charged particles repel each other.” *Id.* at 7–8. Patent Owner proposes that the term “electrostatically inhibiting” means “using an electrostatic field to attract or repel harmful particles.” Prelim. Resp. 9. From what we can decipher, Patent Owner asserts further that “electrostatically attracts” refers to a formulation with a static charge which attracts harmful

particles with an opposite charge. *Id.* at 8. Petitioner does not propose constructions for these terms.

At this stage in the proceeding, based upon our review of the current record and examination of the claim language and the written description, we determine that the record supports finding that “electrostatically inhibiting” refers to the claimed process of using an electrostatic field to attract the charged particulate matter and then inactivating the matter to render it harmless. From our perspective, the claims themselves support this construction as they expand upon the term “electrostatically inhibiting” with specific means for achieving such inhibition. Specifically, claims 1 and 2 recite electrostatically attracting the particulate matter, holding the matter in place, and inactivating the matter. Although claim 8 does not recite those actions, it nevertheless recites a formulation comprising two agents responsible for achieving those actions, i.e., a quaternary thickener (cationic agent) and a biocidal agent.

Additionally, the Specification supports our construction as it describes the use of “an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless.” Ex. 1001, 3:36–40.

7. “*adhesion*” and “*cohesion*”

Patent Owner asserts that “adhesion” is “the tendency of dissimilar particles or surfaces to cling to one-another.” Prelim. Resp. 10. Patent Owner asserts that “cohesion” refers to “the tendency of similar or identical particles or surfaces to cling to one-another.” *Id.* Petitioner does not propose constructions for these terms.

At this stage in the proceeding, based upon our review of the current record and examination of the claim language and the written description, we determine that the record supports finding that a skilled artisan would understand the ordinary and customary meaning of the term “adhesion” the tendency of dissimilar substances to adhere or stick together. Similarly, the skilled artisan would understand the ordinary and customary meaning of the term “cohesion” is the tendency of similar or identical substances to adhere or stick together. These terms occur only in the claims of the ’802 patent. In that context, the claim language provides support for these constructions because the claims explain that the *adhesion of thin film* permits it to “stick” to the skin or tissue and that the *cohesion of the formulation* provides the adequate impermeability to the thin film.

8. “*inactivates*” and “*inactivating*”

Patent Owner discusses the dictionary definition of the terms “inactivates,” “inactivating,” and “inactive.” Prelim. Resp. 12. Petitioner does not propose a claim construction for these terms. Insofar as Patent Owner intended to propose the asserted dictionary definitions as its claim constructions, we do not find it necessary to explicitly construe these terms as there is no dispute between the parties that centers on the meaning of these terms.

C. *Anticipation by or Obviousness over Chen*

Petitioner asserts that Chen anticipates claims 1–3 and 8. Pet. 16–28. Alternatively, Petitioner asserts that “[i]n the event that one or more of claims 1-3 or 8 are not found to be anticipated by Chen, claims 1-3 and 8 would nevertheless have been obvious over Chen.” *Id.* at 16. Patent Owner disagrees. Prelim. Resp. 24–41.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Schering Corp. v. Geneva Pharms*, 339 F.3d 1373 (Fed. Cir. 2003) (quoting *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987)). It is well settled that “a reference can anticipate a claim even if it ‘d[oes] not expressly spell out’ all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would ‘at once envisage’ the claimed arrangement or combination.” *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (quoting *In re Petering*, 301 F.2d 676, 681 (1962)).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). “An obviousness determination requires finding both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016)).

I. Chen

Chen discloses antiviral compositions comprising a cationic polymer, and a cationic surfactant. Ex. 1005 ¶¶ 55–56. Chen teaches that the cationic polymer may be chitosan or may be selected from the “the group of poly((meth)acrylic acid) based copolymers with cationic groups,” including

quaternary amines. *Id.* ¶¶ 55, 76, 78–81. Chen explains that cationic surfactants are also useful for the antiviral compositions, including “those in the form of . . . quaternary ammonium salts,” e.g., “cetyl trimethyl ammonium chloride . . . and alkylbenzyl dimethyl ammonium chloride (such as benzalkonium or benzethonium type preservative, disinfectant and fungicide).” *Id.* ¶¶ 82–84; *see also id.* ¶ 97. Chen discloses that benzalkonium chloride is also “a surface-active germicide for many pathogenic nonsporulating bacteria and fungi.” *Id.* ¶ 86.

Chen teaches that its composition is applied “in and around the site of intended treatment,” including “treatment on the nasal mucous membrane.” *Id.* ¶ 110. Chen teaches the use of “[a]ny methods appropriate for . . . administering a pharmaceutical composition to a subject” that “generally cause the formulation to coat and remain in contact with those membranes or skin surfaces for a period of time, like a chemical barrier at those sites.” *Id.* ¶ 112. Chen provides an exemplary formulation that is “a viscous gel, which provides excellent muco-adhesiveness by forming a physical barrier over the mucous membrane for a prolonged period of time.” *Id.* ¶ 121, Example 1.

2. Discussion

As noted by Petitioner, *see* Pet. 23, claim 1 is identical to claim 2, except that claim 1 recites a method for electrostatically inhibiting harmful particular matter using a formulation, without reciting the components of the formulation, whereas claim 2 recites a formulation for such inhibition comprising at least one cationic agent and at least one biocidal agent. *Compare* claim 1 *with* claim 2. As claim 2 explicitly recites the formulation components, we begin with Petitioner’s assertion that Chen disclosed each element of claim 2.

Petitioner asserts that Chen teaches the preamble is claim 2, i.e., “[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation,” by disclosing an antiviral composition that is administered to the skin or nasal membrane. *Id.* at 17 (citing Ex. 1005 ¶ 44). Additionally, Petitioner asserts that Chen discloses that its composition comprises a cationic polymer. *Id.* (citing Ex. 1005 ¶ 78). According to Petitioner’s declarant, Dr. Park, such a composition would function to electrostatically inhibit harmful particulate matter from infecting an individual through nasal inhalation. *See id.* (citing Ex. 1002 ¶ 112).

Petitioner asserts that Chen discloses that its formulation is applied to the skin or tissue of nasal passages in a thin film, as required by claim 2, because Chen explicitly teaches administering the composition locally, such as to skin or to nasal membrane. *Id.* (citing Ex. 1005 ¶ 44). Additionally, Petitioner asserts that Chen describes its formulations as providing “muco-adhesiveness by forming a physical barrier over the mucous membrane.” *Id.* at 18 (citing Ex. 1005 ¶¶ 121, 148). Further, Petitioner asserts that Chen discloses that its compositions may be applied locally as a paste, gel, lotion, cream, or ointment. *Id.* (citing Ex. 1005 ¶ 111). According to Dr. Park, a skilled artisan would understand that such dosage forms would be applied in a thin film. *Id.* (citing Ex. 1002 ¶ 115).

Petitioner asserts also that Chen discloses that its formulation comprises “at least one cationic agent,” as required by claim 2, by disclosing the use of cationic polymers, including poly(methyl methacrylate-*b*-N-methyl-4-vinyl pyridinium iodide), which Dr. Park explains is a polymeric quaternary ammonium compound. (Ex. 1005 ¶ 78, Ex. 1002 ¶ 117). Petitioner asserts that Chen also discloses that its formulation comprises “at least one biocidal agent,” as required by claim 2, by teaching the use of

benzalkonium chloride (BAC), which is the same biocidal agent recognized in the '802 patent. *Id.* at 18–19 (citing Ex. 1005 ¶ 86, Ex. 1001, claims 7, 9).

Further, Petitioner's declarant testifies that Chen's formulation "once applied [] electrostatically attracts the particulate matter to the thin film," as required by claim 2, because Chen's cationic agents, particularly the quaternary ammonium compound, necessarily electrostatically attracts particulate matter to the topical composition applied as a thin film. *Id.* at 19–20 (citing Ex. 1002 ¶ 127). Alternatively, Petitioner asserts that it would have been obvious to a skilled artisan that Chen's formulations comprising cationic polymers "would inherently electrostatically attract the particulate matter." *Id.* at 20 (citing Ex. 1002 ¶ 130).

Petitioner asserts that Chen's formulation "holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film," as required by claim 2. *Id.* According to Petitioner and Dr. Park, Chen's formulation functions in this way because Chen's cationic agent in the formulation attracts and holds particulate matter and the thin film comprising the cationic agent and formulated as a gel, lotion, cream, or ointment holds the particulate matter to the film. *Id.* (citing Ex. 1005 ¶ 38, Ex. 1002 ¶¶ 77, 134).

Petitioner asserts that Chen discloses adjusting the adhesion and cohesion of the formulation by exemplifying different formulations that "vary the concentration of ingredients." *Id.* at 21 (citing Ex. 1005 ¶ 97). For example, Petitioner compares Chen's compositions 12 and 14, which reflect an adjustment of the cationic polymer from 1.5 wt.% to 0.15 wt.%. *Id.* According to Petitioner and Dr. Park, "[c]hanging the amount of cationic polymer in a composition will change the adhesion and cohesion of a

formulation applied as a thin film.” *Id.* (citing Ex. 1002 ¶ 134).

Alternatively, Petitioner asserts that a skilled artisan would have found it obvious to modify Chen’s formulation, based on Chen’s teachings and suggestions, so that the formulations would hold the particulate matter and would have adequate impermeability to prevent the viruses from reaching the skin, tissue, or mucosa of the nasal passages, with a reasonable expectation of success. *Id.* (citing Ex. 1002 ¶ 140).

Petitioner asserts that Chen’s formulation “inactivates the particulate matter and renders said particulate matter harmless,” as required by claim 2, because those actions are achieved by the biocidal agent, BAC, in Chen’s formulation. *Id.* at 22 (citing Ex. 1002 ¶ 143). Alternatively, Petitioner asserts that a skilled artisan would have understood that the time of the invention that Chen’s formulations comprising a biocidal agent inherently inactivate the particulate matter and render that matter harmless. *Id.*

Claim 3 depends from claim 2 and further recites “wherein the at least one cationic agent is a polymeric quaternary ammonium compound.”

Petitioner asserts that Chen expressly discloses a polymeric quaternary ammonium compound, i.e., poly(methyl methacrylate-*b*-N-methyl-4-vinyl pyridinium iodide). *Id.* at 23 (citing Ex. 1005 ¶ 78, Ex. 1002 ¶ 149). Further, Petitioner asserts that if claim 3 is not found anticipated by Chen, then Chen renders the claim obvious because all elements of claim are taught or suggested by Chen and the claimed combination of those elements would have been obvious over Chen. *Id.*

For claim 1, Petitioner reiterates its discussion of claim 2 to support its assertion that Chen anticipates or renders obvious each element of claim 1. *See id.* at 23–26. Additionally, for this method claim, Petitioner relies on Chen’s disclosure of “a method of ameliorating viral infection comprising

administering to a subject in need thereof the composition described herein.” *Id.* at 24 (quoting Ex. 1005 ¶ 109).

Similarly, for claim 8, Petitioner reiterates its discussion of claim 2 to support its assertion that Chen anticipates or renders obvious each element of claim 8. *Id.* at 27–28. Additionally, Petitioner asserts that the polymeric quaternary ammonium compound in Chen’s compositions “would increase the thickness of the compositions,” and therefore function as “quaternary thickeners.” *Id.* at 27 (citing Ex. 1005 ¶ 78, Ex. 1002 ¶¶ 183–184).

At this stage in the proceeding, we determine that Petitioner’s foregoing assertions are supported by Chen and the testimony of Petitioner’s declarant, Dr. Park. In particular, based on the current record, we determine that Petitioner has shown sufficiently for institution that Chen discloses a method and formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation, wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film in a manner that satisfies each element of the challenged claims.

In particular, we find that Petitioner has also shown sufficiently for institution that Chen discloses antiviral compositions comprising a cationic agent, i.e., poly(methyl methacrylate-*b*-N-methyl-4-vinyl pyridinium iodide), which Dr. Park credibly explains is a polymeric quaternary ammonium compound that necessarily electrostatically attracts particulate matter in Chen’s formulation. Ex. 1002 ¶¶ 117, 127. Additionally, on the current record, we find persuasive Dr. Park’s testimony that a skilled artisan at the time of the invention would have understood that Chen’s formulation holds the particulate matter attracted by the cationic agent in place as a result of the cationic attraction of the polymeric quaternary ammonium compound and the adhesion of the thin film, which Chen discloses as being formulated

to stick to the mucous membrane or skin. Ex. 1002 ¶ 77; Ex. 1005 ¶ 38. For example, Chen discloses a formulation that is “a viscous gel, which provides excellent muco-adhesiveness by forming a physical barrier over the mucous membrane for a prolonged period of time.” *Id.* ¶ 121. We also find that Petitioner has shown persuasively that Chen discloses a biocidic agent, i.e., BAC, which Dr. Park credibly explains would inactivate the particulate matter attracted by the cationic agent in Chen’s formulation, rendering the matter harmless. Ex. 1002 ¶ 143.

In reaching our determination that Petitioner has also shown sufficiently for institution that Chen anticipates and/or renders obvious the challenged claims, we have considered Patent Owner’s arguments. As explained in the following discussion, however, we do not find those arguments sufficiently supported at this stage in the proceeding to deny the Petition. Patent Owner’s primary contentions with Petitioner’s reliance on Chen are: (1) Chen does not disclose attracting harmful particulate matter; and (2) Chen does not disclose holding the particulate matter in place. Prelim. Resp. 25–30. Based on the current record, we disagree with both contentions and address them below, in turn.

Patent Owner contends that “Chen did not anticipate electrostatic attraction of airborne harmful particulate matter.” Prelim. Resp. 25. According to Patent Owner, “Chen intended his formulation to act on viruses that may be in the vicinity and randomly enter the nasal passages and comes in direct contact with the viscous membrane” and “did not envision employment of an electrostatic field to attract the viruses.” *Id.* at 26. In support of that contention, Patent Owner refers to Chen’s teaching that “[b]y forming a viscous membrane over nasal mucous and by deactivating viruses on contact, the formulation of the present invention could provide an

effective means to prevent the virus from spreading.” *Id.* at 25–26 (quoting Ex. 1005 ¶ 115).

Patent Owner asserts that although the “inclusion of a cationic agent might attract some negatively charged viruses, no effort was made by Chen to perform this function effectively.” *Id.* at 27. According to Patent Owner, Dr. Park, Petitioner’s declarant, is “wrong in his opinion” that the cationic agent in Chen’s composition would attract and hold the virus.” *Id.* (citing Ex. 1002 ¶ 112). Patent Owner contends, “the Chen formulation must contain electrostatic charge carrying ingredients in sufficient concentration to accomplish the goal of electrostatic inhibition.” *Id.* at 39.

Based on the current record, we do not find Patent Owner’s argument persuasive. Insofar as Patent Owner alleges that Chen did not intend to employ a cationic agent as an agent that functions to attract negatively charged viruses, we do not find that contention supported by the record. Rather, Chen explicitly describes a “cationic polymer” as “any positively charged, pharmacologically acceptable molecule.” Ex. 1005 ¶ 77. In other words, Chen defines the polymer by referring to its property that is responsible for its ability to electrostatically attract viruses.

Further, without persuasive evidence to the contrary, we credit Dr. Park’s testimony that a skilled artisan at the time of the invention would have understood the cationic polymer in Chen’s formulation necessarily electrostatically attracts particulate matter. Ex. 1002 ¶¶ 117, 127. Patent Owner does not direct us to any evidence that electrostatically attracting harmful particulate matter requires a concentration of a cationic agent greater than what is disclosed in Chen.

Next, Patent Owner contends that Chen does not disclose holding the particulate matter in place in the same manner as required by the challenged

claims. Prelim. Resp. 29. Patent Owner asserts that although “Chen discloses that his formulation sticks to the nasal mucosa, the hold function was not disclosed anywhere in Chen’s specification or claims.” *Id.* Further, Patent Owner asserts that although Chen adds a viscosity modifier to the formulation, Chen “does not disclose how or why the viscosity is adjusted.” *Id.* Moreover, Patent Owner asserts that “adjusting cohesion is not the same as adjusting viscosity.” *Id.*

Based on the current record, we do not find Patent Owner’s argument persuasive. The challenged claims explain that holding the particulate matter in place is achieved by adjusting the adhesion and cohesion of the formulation. We have provided a preliminary construction for the claim term “adhesion,” i.e., the tendency of dissimilar substances to adhere or stick together. The claim language itself explains that the adhesion of the thin film permits it to stick to the skin or tissue. As Patent Owner acknowledges, Chen discloses that its formulation sticks to the nasal mucosa. Prelim. Resp. 29. Thus, at this stage in the proceeding, we agree with Petitioner that a person of skill in the art would have understood Chen’s disclosure that its formulation sticks to the nasal mucosa reflects an adjusted adhesion of the applied film.

We have also provided a preliminary construction for the term “cohesion,” i.e., “the tendency of similar or identical substances to adhere or stick together.” In the context of the claims, the cohesion contributes to holding the particulate matter in place by providing adequate impermeability to the thin film. In other words, the cohesive property of the formulation prevents the particulate matter attracted by the cationic agent from penetrating through the thin film of the formulation onto the skin to which the film is applied. At this stage in the proceeding, we credit Dr. Park’s

currently un rebutted testimony that a person of skill in the art would have understood that Chen's composition was formulated so that the particulate matter attracted to Chen's formulation would remain in place on the film and not penetrate through to the skin because the formulation cohesion was adjusted to provide adequate impermeability. Ex. 1002 ¶¶ 131–139. Dr. Park testifies that these adjustments are achieved by changing the amount of cationic polymer in the composition, as well as the viscosity of the composition. *Id.* ¶¶ 134–135, 137. Further, at this stage in the proceeding, we credit Dr. Park's testimony that a person of ordinary skill in the art would have understood that Chen's compositions would have adequate impermeability to prevent viruses or other harmful particulate matter attracted to the film from reaching the skin, as it would have been apparent that achieving Chen's antiviral activity would require this function. *Id.* ¶ 138.

Based on these same disclosures in Chen and testimony by Dr. Park, we find persuasive, on the current record, Petitioner's alternative argument that a person of ordinary skill in the art would have been motivated by Chen's teachings, with a reasonable expectation of success, to modify the properties of Chen's formulations, including the adhesion and cohesion, so that the formulation would hold the particulate matter in place by ensuring that it sticks to the film and does not permeate through the film to the skin, tissue, or mucosa of the nasal passages. Pet. 21; Ex. 1002 ¶ 140.

We have also considered Patent Owner's contention that Petitioner and Dr. Park rely on impermissible hindsight for the alternative obviousness argument. Prelim. Resp. 33. In particular, Patent Owner alleges that Dr. Park improperly "observes the Chen publication as it would be seen alongside the '802 Patent in 2024." *Id.* We do not find this argument persuasive as Patent

Owner has not explained or demonstrated that Dr. Park has improperly formulated his opinions. Rather, Dr. Park indicates in his declaration an understanding that his opinions regarding the knowledge or understanding of a person of skill must be in the context of what the skilled artisan would have known at the time of the claimed invention. *See, e.g.*, Ex. 1002 ¶ 10. In this regard, we note that Patent Owner will have an opportunity to pursue this issue and to further question Dr. Park about his declaration testimony by deposing him in this proceeding.

Additionally, Patent Owner contends that the products based on the '802 patent have been a commercial success and have met a long-felt but unmet need. *See* Prelim. Resp. 22–24, 37–38, 41. According to Patent Owner, “it can produce evidence that since 2012, Trutek has sold over seven million tubes of its product worldwide, said product being protected by the '802 Patent and having said patent number marked thereon.” *Id.* at 64. Because such evidence has not been identified, discussed, or included as part of the current record, we are unable to consider Patent Owner’s allegations of secondary considerations at this stage in the proceeding. *See Apple Inc. v. Samsung Elecs. Co. Ltd.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) (requiring consideration of objective indicia of nonobviousness “in every case where present”).

Accordingly, we determine that Petitioner has shown a reasonable likelihood of prevailing in its challenge of claims 1–3, and 8 as anticipated by, or obvious over Chen.

D. Remaining Grounds

In the remaining grounds, Petitioner asserts that claims 1–3 and 8 are also anticipated by and/or rendered obvious by each of Baker and Wahi '005. Pet. 28–50. Additionally, Petitioner asserts that claims 1, 2, and 8 are

anticipated by and/or rendered obvious by Rolf, and that claim 2 is rendered obvious by the combination of Rolf and Wahi '005. *Id.* at 50–60. Patent Owner disagrees. Prelim. Resp. 41–59.

We do not provide an analysis of these remaining grounds, as we have already determined that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of each of the challenged claims based upon similar teachings in Chen and over similar arguments raised by Patent Owner. In view of that determination, we institute *an inter partes* review of all the challenged claims based upon all grounds raised in the Petition.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has established a reasonable likelihood of prevailing in its assertion that at least one challenged claim of the '802 patent is unpatentable. Accordingly, we grant the Petition and institute the requested *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–3 and 8 of the '802 patent on all grounds set forth in the Petition is instituted, commencing on the entry date of this decision; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of review.

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