

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SALVACION USA, INC.,
Petitioner,

v.

TRUTEK CORP.,
Patent Owner

U.S. Patent No. 8,163,802
Issued: April 24, 2012

Title: ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL
APPLICATION, PRODUCT, AND METHOD

Inter Partes Review No. IPR2024-00711

**PETITION FOR INTER PARTES REVIEW
OF U.S. PATENT NO. 8,163,802**

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1001	U.S. Patent No. 8,163,802 (the “’802 Patent”)
1002	Declaration of Kinam Park, Ph.D.
1003	<i>Curriculum Vitae</i> of Kinam Park, Ph.D.
1004	File History of U.S. Patent No. 8,163,802
1005	U.S. Patent Publication No. 2005/0232895 (“Chen”)
1006	U.S. Patent No. 6,559,189 (“Baker”)
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1008	U.S. Patent Publication No. US 2004/0071757 (“Rolf”)
1009	U.S. Patent No. 5,674,481 (“Wahi ’481”)
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1015	Scheduling Order in <i>Cho</i> , ECF No. 75 (Feb. 28, 2024)
1016	Interim Procedure Memorandum issued by Director Vidal on June 21, 2022
1017	District of New Jersey, Judicial Caseload Profile, December 31, 2023, excerpted from fcms_na_distprofile1231.2023.pdf and downloaded from

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	https://www.uscourts.gov/statistics/table/na/Federal-court-management-statistics/2023/12/31-1 on March 11, 2024
1018	Rahn, O. and Van Eseltine, W.P., <i>Quaternary ammonium compounds</i> , Annual Review of Microbiology, 1, 173-192 (1947)
1019	Shelton et al., <i>Quaternary ammonium salts as germicides. I. Non-acylated quaternary ammonium salts derived from aliphatic amines</i> , J. Am. Chem. Soc., 68 (5): 753-755 (1946)
1020	Denyer, S.P., <i>Mechanisms of action of antibacterial biocides</i> , International Biodeterioration & Biodegradation 36(3-4): 221-245 (1995)
1021	Knowde Compound Summary for CelquatSC-240C
1022	Maillard, Jean-Yves, <i>Antimicrobial biocides in the healthcare environment: efficacy, usage, policies, and perceived problems</i> (2005)
1023	Block, Seymour S., <i>Disinfection, Sterilization, and Preservation</i> , (4th Ed. 1991)
1024	U.S. Patent Publication No. 2007/0243237 to Khaled et al.
1025	U.S. Patent Publication No. 2007/0134302 to Koenig et al.
1026	Moore et al., <i>Microbiological standards for nasal solutions</i> , Journal of Applied Bacteriology (1976)
1027	U.S. Patent No. 7,776,798 to Subramanian et al.
1028	Joint Letter in <i>Cho</i> , ECF No. 79 (May 22, 2024)
1029	U.S. Patent Publication No. 2007/0048356 A1 to Schorr et al.

I. INTRODUCTION

Salvacion USA, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of Claims 1-3 and 8 of U.S. Patent No. 8,163,802 (“the ’802 Patent”) (Ex. 1001), currently assigned to Trutek Corp. (“PO”). Claims 1-3 and 8 of the ’802 Patent should be found unpatentable and canceled, for the reasons below.

II. MANDATORY NOTICES

A. Real Party-in-Interest

Salvacion USA, Inc., Pharmhealth Technologies, Inc., and Salvacion Co. Ltd. are the real parties in interest for Petitioner.

B. Related Matters

The ’802 Patent has been asserted by PO against Petitioner in *Trutek Corp. v. Cho, et al.*, Case No. 2:23cv3709 (D.N.J. Jul. 11, 2023) (Ex. 1014). The ’802 Patent was also the subject of *Trutek Corp. v. Bluewillow Biologics, Inc.*, Case No. 2:21cv10312 (E.D. Mich. Feb. 10, 2021), now dismissed, and *Matrixx Initiatives, Inc. v. Trutek Corp.*, Case No. IPR2020-01592 (P.T.A.B. Sept. 4, 2020), now closed.

There are no other related matters.

C. Lead and Back-up Counsel

Petitioner provides the following designation of counsel:

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D. Service Information

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III. PAYMENT OF FEES

The PTO is authorized to charge all fees due during this proceeding to Deposit Account No. 220585.

IV. THE '802 PATENT

A. Scope and Content of the '802 Patent

The '802 Patent pertains to “electrostatically charged multi-acting nasal application, product and method.” (Ex. 1001 1:1-3.)

The present invention relates to anti-microorganism, anti-viral/anti-bacterial products and methods that involve the use of products that restrict the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. Additionally, in the present invention, these electrostatically charged nasal application products are used to hold the contaminants including microorganisms, viruses, bacteria, and other harmful or toxic particulate outside the body and render them harmless.

(Ex. 1001 3:44-52.)

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

(Ex. 1001 10:19-33.)

Additionally, the '802 Patent describes

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.

(*Id.* 10:34-48)

Another formulation is also described in the '802 Patent, which is “[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 biocidal agent, and
- b) at least one quaternary thickener.” (*Id.* 11:1-7.)

The '802 Patent also states that the at least one cationic agent in the formulation is a polymeric quaternary ammonium compound for one embodiment. (*Id.* 10:49-51.)

B. Brief Overview of the Prosecution History

The '802 Patent issued on April 24, 2012, from U.S. App. No. 12/467,271 (“the '271 Application”), filed on May 16, 2009. The '271 Application claimed priority to provisional application No. 61/085,855, filed on August 3, 2008 and Provisional Application 61/078478, filed on July 7, 2008. The priority date is assumed by the Petitioner to be July 7, 2008¹ and the critical date is assumed to be July 7, 2007 (“Critical Date”) for purposes of this IPR. However, Petitioner preserves the right to contest this priority and critical date in any related litigation proceedings.

The '271 Application incorporates by reference US Application Nos. 61/085555; 60/570103; 61/078472; 60/598462 and 10/082978; and US. Patent Nos.

¹ The filing date of the '802 Patent is before the effective date of the America Invents Act (“AIA”), and therefore the applicable laws are 35 U.S.C. 102 (pre-AIA) and 35 U.S.C. 103 (pre-AIA). All citations to any sections of 35 U.S.C. in this Petition mean the pre-AIA version of those laws.

5468488; 5674481; and 6844005. The Examiner issued one Office Action during the prosecution of the '802 Patent and rejected all claims, *i.e.*, Claims 1–23, under 35 U.S.C. § 112 “because the specification...does not reasonably provide enablement for the prevention of [infections].” (Ex. 1004 55, 90.) After one response in which the claims were amended to change “preventing” to “inhibiting,” the Examiner issued a Notice of Allowance. (*Id.* 24.)

V. BRIEF OVERVIEW OF THE SCOPE AND CONTENT OF THE PRIOR ART

A. US Patent Publication No. 2005/0232895 (“Chen”)

Chen (Ex. 1005) is entitled “Anti-viral Pharmaceutical Compositions,” was filed on December 3, 2004 (claiming priority to a provisional application filed on December 10, 2003), was published on October 20, 2005 and was issued as a patent on June 28, 2011, and constitutes prior art against the '802 Patent under 35 U.S.C. § 102(b).

Chen was not considered by the PTO in the prosecution of the '802 Patent. Chen teaches “antiviral compositions and methods of ...using such compositions.” (Ex. 1005 at [0021].) The compositions comprise “a cationic polymer” such as “poly(dimethyl-aminoethylmethacrylate...EUDRAGIT®E” (*Id.* at [0022] and [0078]), poly(meth)acrylic acid-based copolymers with cationic groups (*i.e.* ... quaternary amine), and chitosan (*Id.* at [0055] and [0079]-[0081].) The compositions also comprise “a cationic surfactant” that includes those in the form of

quaternary ammonium salts, such as cetyl trimethyl ammonium chloride or alkylbenzyl dimethyl ammonium chloride (e.g., benzalkonium or benzethonium type preservative, disinfectant and fungicide). (*Id.* at [0082]-[0084].) Chen discloses poly(methyl methacrylate-b-N-methyl-4-vinyl pyridinium iodide). (*Id.* at [0078].) Additionally, a biocidal agent may be present in the composition, as seen in, e.g., Antiviral Composition 9, with benzalkonium chloride (“BAC”). (*Id.* at [0097].)

The compositions may take various forms such as “nasal ointments, gels, [or]... nasal drops” which may be administered locally, including topically and in a mucosal application on the “the nasal mucous membrane.” (*Id.* at [0111] and [0110]; see e.g., at [0110] (discussing where to apply the compositions.)) Chen teaches “a thin film of the composition is applied and sticks to the membrane or skin.” (Ex. 1002² ¶77.) Methods of applying the compositions “generally cause the formulation to coat and remain in contact with those membrane or skin surfaces for a period of time, like a chemical barrier at those sites.” (Ex. 1005 13:58-61.) For example, the formulation of Example 1 is a viscous gel, which provides excellent muco-

² Declaration of Kinam Park, Ph.D. (Ex. 1002), an expert in the field of the ‘802 Patent.

adhesiveness by forming a physical barrier over the mucous membrane. (*Id.* 15: 38-41.)

B. US Patent No. 6,559,189 (“Baker”)

Baker (Ex. 1006) is entitled “Non-Toxic Antimicrobial Compositions and Methods of Use,” was issued on May 6, 2003, and constitutes prior art against the ’802 Patent under 35 U.S.C. § 102(b).

Baker was not considered by the PTO in the prosecution of the ’802 Patent. Baker provides methods and composition for reducing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses. (Ex. 1006 at Abstract.) Baker provides a composition applied to the surface of the skin and mucosal cells and tissues (including nasal mucosa) comprising a quaternary ammonium compound, for example N,N-Dimethyl-2-hydroxypropyl ammonium chloride polymer. (*Id.* 5:66-67; 7:1-2; 13:24-26; and 36:12-14.) Additional cationic halogen contacting compounds may be present in the compositions. (*Id.* 17:5-41.) The composition also may comprise TWEEN 60 (polyoxyethylene sorbitan monostearate), and/or TRITON (a phoxypolyethoxyethanol), each of which has virucidal effects. (*Id.* 16:38-54.) The compositions may have the form of cream, foam, lotion, gel among other forms. (*Id.* 36:32-33.) “These compositions may be formulated with varying components in varying amounts, resulting in different viscosities. (Ex.1005 FIGS. 29A-29E.)” (Ex. 1002 ¶86.)

Baker also provides a method of “decontaminating a sample comprising ... treating a sample ...[with] physical contact [of the compositions described above] with bacteria, [and/or] virus...” (Ex. 1006 69:23-33.)

C. US Patent No. 6,844,005 (“Wahi ’005”)

Wahi ’005 (Ex. 1007) is entitled “Electrostatically Charged Nasal Application Product With Increased Strength,” was issued on January 18, 2005, and constitutes prior art against the ’802 Patent under 35 U.S.C. § 102(b).

Wahi ’005 is incorporated by reference into the ’802 Patent, and is cited on the face of the ’802 Patent. (Ex. 1001 Front Page.) The invention of Wahi ’005 is a “nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage” by an electrostatic field. (Ex. 1007 2:9-12) The electrostatic polymer, which creates the electrostatic field “is a poly (dimethyl diallyl ammonium chloride) (Agequat 400),” (*Id.* 2:16-18) which is “a polymeric quaternary compound” as is Celquat SC-240C (Polyquaternium-10), used in the Wahi ’005 formulation, and thus a polymeric quaternary ammonium compound was already used in Wahi ’005. This nasal product includes a cationic agent and a biocidal agent. (Ex. 1002 ¶96.)

Example #4 of Wahi ’005 teaches a composition comprising Celquat SC-240C and Agequat 400. (Ex. 1007 4:50-63.) Each of Celquat SC-400 and Agequat 400 is both a cationic agent and a biocidal agent. (Ex. 1002 ¶96.) Celquat SC-400

is a poly quaternary ammonium compound, the International Nomenclature Cosmetic Ingredient (“INCI”) name is “Polyquaternium-10”, which is listed in the ’802 Patent at Col. 5, lines 17, (Ex. 1001 5:17) and also is a quaternary thickener. (*Id.* at ¶94.)

Further, the “nasal application product ... may be selected from the group consisting of topical solutions, semisolids, ... and vaporizable solutions...ointments, pastes, creams and gels.” (Ex. 1007 2:22-26.) Wahi ’005 teaches applying these nasal application products in a thin film on the skin or tissue of nasal passages. Ex. 1002 ¶¶ 97-98). The thin film would electrostatically attract airborne contaminants with the cationic agent (such as Celquat SC-400 and Agequat 400) and hold them harmless with the biocidal agent (such as Celquat SC-400 and Agequat 400). (*Id.* at ¶¶ 93-99.)

D. US Patent Publication No. 2004/0071757 (“Rolf”)

Rolf (Ex. 1008) is entitled “Inhalation Device,” was issued on April 15, 2004, and constitutes prior art against the ’802 Patent under 35 U.S.C. § 102(b).

Rolf was not considered by the PTO in the prosecution of the ’802 Patent. Rolf teaches “a method for preventing respiratory infection” by “contacting a live respiratory pathogen at risk of entering the respiratory tract...with a therapeutically effective amount of an essential oil.” (Ex. 1008 Abstract.) “[T]he live respiratory

virus is inactivated upon contact with the essential oil[.]” (*Id.* at [0021]) Therefore, Rolf is teaching an essential oil as a biocidal agent. (Ex. 1002 ¶105.)

Further, Rolf’s compositions may also comprise cationic agents, for example quat-15. (*Id.* at [0148]) “Quat-15 thickens formulation, for example, Examples 1-16 in Rolf. (*Id.* at [0268]-[0283].) Thus, quat-15 is a quaternary thickener.” (*Id.* at ¶107.)

VI. BRIEF OVERVIEW OF THE LEVEL OF SKILL IN THE ART

The relevant art is pharmaceutical formulation. “A person having ordinary skill in the art (“POSITA”) at the time of the Critical Date 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. A POSITA would be familiar with the chemical ingredients in the 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.” (Ex. 1002 ¶¶ 38-39.)

VII. REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Grounds for Standing

Petitioner certifies that the ’802 Patent is available for IPR, and Petitioner is not barred or estopped from requesting IPR on the grounds herein.

Claims 1–3 and 8 have not been the subject of a prior IPR (other than IPR2020-01592, which was dismissed), or to our knowledge, a district court litigation concluded on the merits.

B. Claims Challenged

Petitioner requests review and cancellation of Claims 1–3 and 8 (“Challenged Claims”) of the ’802 Patent.

C. Grounds

The Challenged Claims should be canceled as unpatentable based on the following grounds:

Ground 1: Claims 1-3 and 8 are anticipated under 35 U.S.C. § 102(b) or rendered obvious under 35 U.S.C. §103 by Chen.

Ground 2: Claims 1-3 and 8 are anticipated under 35 U.S.C. § 102(b) or rendered obvious under 35 U.S.C. § 103 by Baker.

Ground 3: Claims 1-3 and 8 are anticipated under 35 U.S.C. § 102(b) or rendered obvious under 35 U.S.C. §103 by Wahi ’005.

Ground 4: Claims 1, 2 and 8 are anticipated under 35 U.S.C. 102(b) or rendered obvious under 35 U.S.C. § 103 by Rolf.

Ground 5: Claim 3 is rendered obvious under 35 U.S.C. § 103 by Rolf in view of Wahi ’005.

VIII. CLAIM CONSTRUCTION

Claims in this Petition are construed by Petitioner under Rule 42.100(b) and in accordance with the *Phillips* claim construction standard. In the Challenged Claims, only three terms require an express construction.

A. “Biocidal Agent”

For purposes of this IPR, as used in the ’802 Patent claims, the phrase “biocidal agent” 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. This is consistent with the definition offered by Trutek in its proposed claim construction (which was adopted by the court) in *Trutek Corp. v. Bluewillow Biologics, Inc.*, Case No. 2:21cv10312 (E.D. Mich. Feb. 10, 2021) (“Mich. CC. Order”) (Ex. 1010 at 22).

This meaning is consistent with the ’802 Patent specification which states:

[A]n electrostatically charged composition ... creates 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.)

B. “Adequate Impermeability”

For purposes of this IPR, as used in the ’802 Patent claims, we will adopt the claim construction for the term “adequate impermeability” proposed by Trutek and accepted as the claim construction by the court in the Mich. CC. Order. (Ex. 1010).

“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.” (Mich. CC. Order at 17.)

C. “Skin or Tissue of Nasal Passages of the Individual”

For purposes of this IPR, as used in the ’802 Patent claims, the phrase “skin or tissue of nasal passages” means skin in or near the area of the nasal passages or tissue of the nasal passages. “Skin” 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*.” (Ex. 1001 10:19-21; 10:34-36; 11:1-3. (Emphasis added.)) Therefore, the formulations must be in or near the nasal passages in order to prevent nasal inhalation.

“The object of the invention of the ’802 Patent describes that a composition can be readily applied to “the exterior region around the nostril and/or slightly inside the edge of the nostril.” (Ex. 1001 2:62-65; 3:6-7; 3:15-16.) Logically, 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. (Ex. 1002 ¶71.)

The specification of the '802 Patent includes support for placing the formulation in or near the nasal passages. (Ex. 1008 Abstract (“in close proximity of one or more nostrils”); 1:64-67 (“creating an electrostatic field in an area near about the nasal passages”); 2:63-65 (“applied to the exterior region around the nostril”); 3:47-48 (“creating an electrostatic field in an area near about the nasal passages.”))

Petitioner reserves the right to propose alternative constructions in the event that PO proposes constructions for any other terms that vary from the plain and ordinary meaning of such terms to a POSITA.

IX. DETAILED EXPLANATION OF GROUNDS

A detailed explanation showing that there is a reasonable likelihood the Challenged Claims are unpatentable follows.

A. Ground 1: Claims 1-3 and 8 Are Anticipated or Rendered Obvious by Chen

Chen anticipates claims 1-3 and 8 of the '802 Patent. In 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 to a POSITA at the Critical Date.

1. Claim 2³

a. “A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”

To the extent that the preamble of claim 2 is considered to be limiting, Chen teaches it. (Ex. 1002 ¶¶ 108-112.) *See also* Section V.A. (overview of Chen).

Chen discloses an “antiviral composition[] . . . administered locally, such as to skin . . . [or] nasal membrane.” (Ex. 1005 [0044].) Chen discloses a “cationic polymer... poly(dimethyl-aminoethylmethacrylate) (commercially available as EUDRAGIT®E by Degussa).” (*Id.* [0078].) The composition comprising the cationic polymer placed on skin near the nose or in the nasal membrane would perform the function of “electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.” (Ex. 1002 ¶112.)

b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film,”

Chen discloses this element. Chen discloses an “antiviral composition[] . . . administered locally, such as to skin . . . [or] nasal membrane. (Ex. 1005 at [0044].) Examples 1-4 describe formulations applied to the skin or mucosal tissues to prevent

³ In each of the grounds for unpatentability, claim 2 is argued before claim 1 because independent claim 2’s elements are also included in independent claim 1’s elements. Claim 3 is dependent on claim 2, and therefore discussion about claim 2 is immediately followed with claim 3, and then independent claims 1 and 8.

infection by a pathogenic virus. The formulations have muco-adhesiveness by forming a physical barrier over the mucous membrane. (*Id.* [0121], [0148].) Thus, this element is met.

Chen's compositions may be applied as a "paste, gel, ... lotion, cream, ..., lacquer, or ointment ... for local application." (*Id.* [0111].) Specifically, Chen's example formulations are applied to the skin or mucosal tissues to prevent infection by a pathogenic virus (*e.g.*, coronavirus, rhinovirus, respiratory syncytial virus), and are tested for the antiviral effect. (*Id.* [0127]-[0149], Fig 6.) The formulations have muco-adhesiveness by forming a physical barrier over the mucous membrane. (*Id.* [0121], [0148].) Accordingly, Chen teaches or suggests a formulation applied to skin or tissue of nasal passages in a thin film. In addition, a POSITA would understand that a "paste, gel, ... lotion, cream, ..., lacquer, or ointment ..." is "applied ... in a thin film." (Ex. 1002 ¶115.)

c. "said formulation comprising at least one cationic agent and"

Chen discloses this element. Chen discloses a "cationic polymer... poly(dimethyl-aminoethylmethacrylate) (commercially available as EUDRAGIT®E by Degussa)" and "poly(meth)acrylic acid) based copolymers with cationic groups (*i.e.* . . . quaternary amine)." (*Id.* [0078].) Chen discloses poly(methyl methacrylate-*b*-N-methyl-4-vinyl pyridinium iodide). (*Id.*) This is a polymeric quaternary ammonium compound. (Ex. 1002 ¶117.) Chen also discloses

various cationic surfactants at various concentrations. (Ex. 1005 [0082]-[0093].) Chen additionally discloses various cationic polymers at various concentrations. (*Id.* [0076]-[0081].) Chen additionally discloses “cationic polymers [such as] poly-(D, L or DL)-arginine salts.” (*Id.* [0078].) Thus, Chen discloses “at least one cationic agent.”

d. “at least one biocidic agent”

Chen discloses this element. Chen discloses BAC. (*Id.* [0086].) The '802 Patent claims BAC as the biocidic agent in claims 7 and 9. Thus, Chen discloses one of the same biocidic agents that the '802 Patent claims. Thus, this element is met.

e. “and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film;”

Chen discloses this element. (Ex. 1002 ¶¶ 126-130.) As discussed above, Chen discloses “cationic polymers, such as “poly(meth)acrylic acid) based copolymers with cationic groups (i.e. . . . quaternary amine),” poly(methyl methacrylate-b-N-methyl-4-vinyl pyridinium iodide), and poly-(D, L or DL)-arginine salts. (Ex. 1005 [0076]-[0078].) Cationic agents, particularly the quaternary ammonium compound, necessarily electrostatically attract “particulate matter” as they are used in the formulation of claim 2. (Ex. 1002 ¶127.) Chen discloses that its compositions can be “gel, lotion, . . . cream, ointment, or other

formulation appropriate for local application for the treatment or prevention of viral infectious diseases.” (Ex. 1005 [0038].) Thus, Chen discloses a formulation that when applied “electrostatically attracts the particulate matter to the thin film.”

In the event that it were found that this element is not expressly taught, a POSITA would understand that find it obvious that Chen’s formulations with cationic polymers would inherently electrostatically attract the particulate matter. (Ex. 1002 ¶130.)

- f. “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”**

Chen discloses this element. Chen’s composition discloses holding particulate matter to the thin film. Chen’s compositions can be a gel, lotion . . . cream, ointment . . . for local application for the treatment or prevention of viral infectious diseases.” (Ex. 1005 [0038].) Chen teaches “a thin film of the composition is applied and sticks to the membrane or skin.” (Ex. 1002 ¶77.) Chen’s thin films can include cationic agents such as cationic surfactants and cationic polymers. (Ex. 1005 [0032].) A cationic agent attracts particulate matter and holds the particulate matter in place. (Ex. 1002 ¶134.) Thus, the thin film comprising a cationic agent holds particulate matter to the thin film.

Chen discloses adjusting the adhesion and cohesion of the formulation to provide adequate impermeability to the thin film under the definition set forth in Section VIII.B. Chen discloses multiple examples showing different formulations that “vary the concentration of ingredients.” (Ex. 1005 [0097].) For instance, cationic poly(dimethyl-aminoethylmethacrylate), may be adjusted from 1.5 wt.% in Antiviral Composition 12 to 0.15 wt.% in Antiviral Composition 14. Changing the amount of cationic polymer in a composition will change the adhesion and cohesion of a formulation applied as a thin film. (Ex. 1002 ¶134.) Chen’s Antiviral Compositions 9, 12 and 14 including EUDRAGIT E100 and BAC, and Compositions 1, 2 and 11, including Chitosan hydrochloride and BAC, which are applied topically and on the nasal mucous membrane and which coat the membrane or skin surfaces, teach thin films of the compositions on the skin and nasal membranes. (*Id.* ¶139.)

In the event that this element is not taught, a POSITA would find it obvious to modify Chen’s formulations per Chen’s teachings and suggestions such that they would hold the particulate matter and that they would have adequate impermeability to prevent the viruses from reaching the skin, tissue, or mucosa of the nasal passages. A POSITA would have a reasonable expectation of success of such modifications. (*Id.* ¶140.)

g. “c) inactivates the particulate matter and renders said particulate matter harmless.”

Chen discloses this element. Chen discloses BAC. (Ex. 1005 [0086].) This is the same biocidic agent recited in claims 7 and 9 of the '802 Patent. (Ex. 1001 10:64-65, 11:8-9.) “Chen’s Antiviral Compositions 9, 12 and 14 including EUDRAGIT E100 and BAC, would each inactivate and render harmless the virus (particulate matter).” (Ex. 1002 ¶143.)

In the event that it were found that this element is not expressly taught, a POSITA would understand that Chen’s formulations with a biocidic agent inherently inactivate the particulate matter and render the particulate matter harmless.

Chen teaches each element of claim 2 of the '802 Patent and therefore anticipates claim 2 of the '802 Patent under 35 USC 102(b). In the event that claim 2 is not found anticipated by Chen, Chen renders claim 2 obvious because all of the claim elements are taught or suggested by Chen and the claimed combination of the elements is obvious over Chen for the reasons discussed above.

2. Claim 3

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

Chen discloses this element. Claim 3 depends from claim 2, and the discussion of claim 2 is incorporated herein by reference.

Chen discloses “cationic polymers ... [such as] poly(dimethyl-aminoethylmethacrylate) (commercially available as EUDRAGIT®E by Degussa)” and “poly(meth)acrylic acid) based copolymers with cationic groups (i.e., . . . quaternary amine).” (Ex. 1005 at [0078].) Chen discloses poly(methyl methacrylate-b-N-methyl-4-vinyl pyridinium iodide). (*Id.*) This is a polymeric quaternary ammonium compound. (Ex. 1002 ¶149.)

Thus, Chen discloses a polymeric quaternary ammonium compound, and this claim is anticipated. (*Id.* ¶150.)

In the event that claim 3 is not found anticipated by Chen, Chen renders claim 3 obvious because all of the claim elements are taught or suggested by Chen and the claimed combination of the elements is obvious over Chen.

3. Claim 1

a. **A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”**

The discussion of claim 2 is incorporated herein. Claim 1 is identical to claim 2 except that 1) it claims a method rather than a formulation, 2) it does not include the following element: “said formulation comprising at least one cationic agent and at least one biocidal agent,” and 3) parts a, b and c are method steps, rather than descriptions of the formulation. Chen discloses each and every element of claim 1.

To the extent that the preamble of claim 1 is considered to be limiting, Chen teaches the claimed method's preamble. (Ex. 1002 ¶¶ 155-157; *see also* Section V.A. (overview of Chen).) Chen discloses an “antiviral composition[] . . . administered locally, such as to skin . . . [or] nasal membrane. (Ex. 1005 [0044].) Chen discloses a “a method for ameliorating viral infection comprising administering to a subject in need thereof the composition described herein in an amount effective to ameliorate viral infection.” (*Id.* [0109].) Chen discloses that “ameliorating viral infection” includes “reducing or eliminating the likelihood that a person or an animal exposed to potentially infective viral particles will be infected with the viral particles” (*Id.*) According to Section IX.A.1.a, the composition used in Chen's method “electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.”

b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:”

According to Section IX.A.1.b, Chen discloses this element. Chen discloses an antiviral composition[] . . . administered locally, such as to skin . . . [or] nasal membrane (*Id.* [0044]), specified in Examples 1-4, which formulations are applied to the skin or mucosal tissues to inhibit infection by a pathogenic virus and have muco-adhesiveness by forming a physical barrier over the mucous membrane.

c. “a) electrostatically attracting the particulate matter to the thin film”

According to Section IX.A.1.e, Chen discloses this element. Chen discloses “cationic polymers such as “poly(meth)acrylic acid) based copolymers with cationic groups (i.e. . . . quaternary amine),” poly(methyl methacrylate-b-N-methyl-4-vinyl pyridinium iodide), and poly-(D, L or DL)-arginine salts.” (*Id.* [0078].) Cationic polymers are cationic agents which attract particulate matter. (Ex. 1002 ¶164.)

In the event that it were found that this element is not expressly taught, a POSITA would understand that Chen’s formulations with cationic polymers inherently electrostatically attract the particulate matter.

d. “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”

According to Section IX.A.1.f, Chen discloses this element. (Ex. 1002 ¶¶ 165-169.) The formulation holds particulate matter in place once it is applied, and the adhesion and cohesion of the thin film can be adjusted via varying the concentration of ingredients. (*Id.* ¶168.)

A POSITA would understand that, if Chen’s thin films were not adequately impermeable, Chen would not achieve the desired antiviral activity. Therefore, thin films of Chen’s compositions must be adequately impermeable to viruses. Thus, in the event that this element is not taught, a POSITA would find it obvious to modify

Chen's formulations per Chen's teachings and suggestions such that they would hold the particulate matter and that they would have adequate impermeability to prevent the viruses from reaching the skin, tissue, or mucosa of the nasal passages. (Ex. 1002 ¶169.)

- e. **“c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.”**

According to Section IX.A.1.g, Chen discloses this element. (Ex. 1002 ¶¶ 170-176.) The “at least one ingredient that would render said particulate matter harmless” is the biocidic agent in Section IX.A.1.d. Chen discloses BAC. (Ex. 1005 [0086].) The '802 Patent lists BAC as a biocidic agent. (Ex. 1001 10:64-65, 11:8-9.)

In the event that this element is not expressly taught, a POSITA would understand that Chen's formulations with a biocidic agent inherently inactivate the particulate matter and render the particulate matter harmless. (Ex. 1002 ¶176.)

Chen teaches each element of claim 1 of the '802 Patent and therefore anticipates claim 1 of the '802 Patent. In the event that claim 1 is not found anticipated by Chen, Chen renders claim 1 obvious because all of the claim elements are taught or suggested by Chen and the claimed combination of the elements is obvious over Chen. (*Id.* ¶177.)

4. Claim 8

- a. **“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 biocidal agent, and**
- b) at least one quaternary thickener.”**

Chen discloses claim 8. According to Section IX.A.1.a, Chen discloses a formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. According to Section IX.A.1.b, Chen discloses “wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film.” According to Section IX.A.1.d, Chen discloses “at least one biocidal agent.”

Chen discloses cationic polymers for “antiviral compositions” such as “poly(meth)acrylic acid) based copolymers with cationic groups (i.e. . . . quaternary amine).” (*Id.* [0078].) Chen discloses poly(methyl methacrylate-*b*-N-methyl-4-vinyl pyridinium iodide). (*Id.*) This is a polymeric quaternary ammonium compound. (Ex. 1002 ¶183.)

Inclusion of this polymer in compositions would increase the thickness of the compositions. (*Id.* ¶184.) Thus, they are quaternary thickeners.

Therefore, this claim is anticipated by Chen. In the event that claim 8 is not found anticipated by Chen, a POSITA would find it obvious to modify Chen’s

formulations per Chen’s teaching and suggestions to arrive at the formulation of claim 8 and would have a reasonable expectation of success in doing. (*Id.* ¶186.)

B. Ground 2: Claims 1-3 and 8 Are Anticipated or Rendered Obvious by Baker

Baker anticipates claims 1-3 and 8 of the ’802 Patent. In the event that one or more claims 1-3 or 8 are not found to be anticipated by Baker, claims 1-3 and 8 would nevertheless have been obvious over Baker to a POSITA at the Critical Date.

1. Claim 2

a. “A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”

To the extent that the preamble of claim 2 is considered to be limiting, Baker teaches it. (*Id.* ¶¶ 187-197.) *See also* Section V.B. (overview of Baker).

The ’802 Patent teaches electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation by an electrostatic field that is oppositely charged from airborne particles, which are negatively charged. (Ex. 1001 3:32-40.) Cationic agents are positively charged, and are attracted to negatively-charged harmful particulate matter, including bacterial cell surfaces. (Ex. 1002 ¶44.) Baker discloses cationic agents, including numerous cationic halogen containing compounds, including cetylpyridinium chloride (CPC) and benzalkonium chloride (BAC). (Ex. 1006 17:5-41, 17:24-27, 25:28-29, 63.)

Additionally, Baker discloses formulations that comprise quaternary ammonium compounds. (*Id.* 5:64-7:12). In particular, Baker discloses N,N-dimethyl-2-hydroxypropylammonium chloride polymer, which is a polymeric quaternary ammonium compound. (*Id.* 7:1-2.) According to the '802 Patent, a polymeric quaternary ammonium compound is a cationic agent. (*E.g.*, Ex. 1001 10:49-51 (claim 3.)) Indeed, Baker claims “an antimicrobial oil-in-water nanoemulsion comprising . . . a quaternary ammonium compound” and explicitly claims an embodiment where “said quaternary ammonium compound is . . . “N,N-Dimethyl-2-hydroxypropylammonium chloride polymer.” (Ex. 1006 69:23-33, 69:59-70:53.)

A POSITA would understand that cationic agents are positively charged, and are attracted to negatively-charged harmful particulate matter, including bacterial cell surfaces. (Ex. 1002 ¶44.) Further, a POSITA would understand that cationic agents, such as those in Baker, placed in or near the nasal passages would “electrostatically inhibit harmful particulate matter from infecting an individual through nasal inhalation.” (See Ex. 1002 ¶197.)

Regarding “harmful particulate matter from infecting an individual,” Baker discloses that its composition is intended to be used for “decreasing the infectivity . . . associated with a variety of pathogens.” (Ex. 1006 2:66-67; *see also*

3:7-16.) Thus, Baker's formulation has the same use as the '802 Patent's formulation: inhibiting infection.

Regarding "through nasal inhalation," Baker's composition can be in a nasal form. (*Id.* 36:12-16.) This will inhibit harmful particulate matter from infecting an individual through inhalation. (Ex. 1002 ¶197.)

Therefore, Baker teaches "a formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhibition."

b. "wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film"

Baker discloses this element. (*Id.* ¶¶ 198-203; Ex. 1006 36:12-16.) Further, Baker discloses that the compositions are applied to the nasal passages of mice. (Ex. 1006 51:15-18.) A POSITA would understand that Baker's composition could be applied to the skin or tissue of nasal passages of an individual. (Ex. 1002 ¶200.)

Baker's composition can be applied as a topical cream, lotion, or gel. (Ex. 1006 36:31-33.) A POSITA would understand that a cream, lotion, and gel can be applied to nasal passages. (Ex. 1002 ¶200.) In the event that it were found that this element was not expressly taught, a POSITA would be motivated per Baker's teachings and suggestions to apply Baker's creams, foams, lotions, and gels in a thin film in or near nasal passages and would have a reasonable expectation of success in doing so.

c. said formulation comprising at least one cationic agent and”

Baker discloses cationic agents, such as cationic halogen containing compounds. (Ex. 1006 17:5-41.) In particular, Baker discloses cetylpyridinium chloride (CPC). (*Id.* 17:24-27.) Additionally, Baker discloses that the composition may comprise quaternary ammonium compounds. (*Id.* 5:64-7:12.) In particular, Baker discloses N,N-dimethyl-2-hydroxypropylammonium chloride polymer. (*Id.* 7:1-2).

e. “at least one biocidic agent”

Baker discloses multiple compounds that meet this element. (Ex. 1002 ¶¶ 207-214.) Baker discloses multiple formulation embodiments that use BAC. (Ex. 1006 25:28-29, 25:63, 30:39). BAC is the same biocidic agent recited in claims 7 and 9 of the '802 Patent. (Ex. 1001 10:64-65, 11:8-9.)

Baker further discloses a composition comprising “TWEEN 60 (polyoxyethylenesorbitan monostearate).” (Ex. 1006 16:38.) Baker states that “TWEEN surfactants [] appear to have virucidal effects on lipid-enveloped viruses.” (Ex. 1006 16:43-46.) Virucidal effects are encompassed in the definition of the capacity of a biocidic agent (having the capacity to neutralize, inactivate, render harmless or kill airborne particles such as viruses). Section VIII.A. (“biocidic agent.”) Thus, TWEEN 60 is at least one biocidic agent.

Baker also discloses other compounds that are biocidal agents such as phenoxypolyethoxyethanols such as TRITON X-100 (Ex. 1006 16:47-49) and phosphonate-based solvents such as tri-n-butyl phosphate (Ex. 1006 15:55).

f. “and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film;”

Baker discloses this element. (Ex. 1002 ¶¶ 215-222.) As discussed above, Baker discloses applying a composition with at least one cationic agent, such as cationic halogen containing compounds, which electrostatically attracts the particulate matter. (Ex. 1006 17:5-41; see Section IX.B.1.d. (discussing cationic agents.)) Baker discloses that its compositions may be creams, foams, lotion, or gels. (Ex. 1006 36:31-33.) “A POSITA would understand that these compositions are applied as a thin film.” (Ex. 1002 ¶220.) Thus, Baker discloses a formulation that when applied “electrostatically attracts the particulate matter to the thin film.” In the event that it were found that this element is not expressly taught, a POSITA would understand that cationic agents inherently attract negatively charged particulate matter. Alternatively, a POSITA would be motivated per Baker’s teachings and suggestions to use cationic agents in this manner given Baker’s purpose of “decreasing the infectivity ... associated with a variety of pathogenic organisms and viruses” and would have a reasonable expectation of success in doing so. (Ex. 1006 Abstract; Ex. 1002 ¶222.)

- g. “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”**

Baker meets these elements. The composition in Baker can take the form of a topical, cream, lotion, or gel and can include emulsifiers, gelling agents. (Ex. 1006 36:31-34.) A POSITA would understand that these compositions are applied as a thin film. (Ex. 1002 ¶224.) Baker’s thin films can include cationic agents such as cationic halogen containing compounds (Ex. 1006 17:5-41) and quaternary ammonium compounds (*Id.* 5:64-7:12) including N,N-Dimethyl-2-hydroxypropylammonium chloride polymer. (*Id.* 7:1-2.) Cationic agents electrostatically attract particulate matter and therefore hold the particulate matter. (Ex. 1002 ¶226.) Thus, the thin film comprising a cationic agent holds the particulate matter.

Baker discloses adjusting the adhesion and cohesion of the formulation to provide adequate impermeability to the thin film under the definition set forth in Section VIII.B. Baker shows multiple formulations that “vary[] the concentration of ingredients.” FIGS. 29A to 29E show 20 different formulations with varying concentrations of ingredients. (Ex. 1006 FIGS. 29A-29E.) For example, formulation ATB_Tween 20 E has 22% DiH₂O with 8% alcohol (FIG. 29E), and formula ATB-X has 49% DiH₂O (FIG. 29A). Changing the amount of water with

adding an alcohol in a composition is described by Baker as a way to adjust the viscosity and therefore adhesion and cohesion of his composition. (Ex. 1002 ¶228.) In the event that it were found that this element is not expressly taught, a POSITA would understand that that cationic agents inherently attract negatively charged particulate matter. The cationic agents inherently hold particulate matter after initially attracting it. Alternatively, a POSITA would be motivated to use cationic agents in this manner given Baker's purpose of "decreasing the infectivity ... associated with a variety of pathogenic organisms and viruses" and would have a reasonable expectation of success in doing so. (Ex. 1006 Abstract; Ex. 1002 ¶232.)

h. "c) inactivates the particulate matter and renders said particulate matter harmless."

Baker discloses this element. Baker discloses compositions with at least one biocidal agent, for example TWEEN 60, which is noted as having virucidal effects. (Ex. 1006 16: 38-54.) Further, Baker's specification shows evidence that its compositions with these concentrations have "virucidal effectiveness." (*E.g.*, Ex. 1006 67:9-10; *see generally id.* 47:60-69:8 (discussing biocidal activity of various formulations of compositions disclosed in Baker.) In the event that it were found that this element is not expressly taught, a POSITA would understand that Baker's formulations with virucidal effectiveness and the ability to disrupt the membranes of target pathogens (*e.g.*, bacteria) inherently inactivate and render the particulate

matter harmless. (Ex. 1002 ¶236.) Thus, claim 2 of the '802 Patent is anticipated by Baker.

In the event that claim 2 is not found anticipated by Baker, Baker renders claim 2 obvious because all of the claim elements are taught or suggested by Baker, and the combination of the elements as taught or suggested by Baker would result in the formulation of claim 2 with a reasonable expectation of success in reaching the formulation as recited in the claim. (*Id.* ¶237.)

2. Claim 3

a. “the at least one cationic agent is a polymeric quaternary ammonium.”

Baker discloses this element. Claim 3 depends on claim 2. The discussion of claim 2 is incorporated herein. Baker discloses that its composition contains as a first component a quaternary ammonium compound and describes a limited number of the compounds including N,N-dimethyl-2-hydroxypropylammonium chloride polymer. (Ex. 1006 7:1-2, claims 1-9.) This is a polymeric quaternary ammonium. (Ex. 1002 ¶183.) A POSITA reading Baker would envisage the claimed arrangement or combination. Thus, claim 3 of the '802 Patent is anticipated by Baker under 35 U.S.C. 102(b). To the extent that one or more of the claim elements is deemed to be not found in Baker, Baker renders claim 3 obvious, as Baker teaches a limited number of the quaternary ammonium compounds and selecting N,N-dimethyl-2-hydroxypropylammonium chloride polymer would be obvious. Indeed,

Baker explicitly claims an embodiment where “said quaternary ammonium compound is . . . N,N-Dimethyl-2-hydroxypropylammonium chloride polymer.” (Ex. 1006 69:23-33, 69:59-70:53.)

3. Claim 1

a. **“A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”**

The discussion of claim 2 is incorporated herein. Claim 1 is identical to claim 2 except for the differences discussed in Section IX.A.3.a. Baker discloses each and every element of claim 1. (See Section IX.A.1.)

To the extent that the preamble is considered limiting, Baker teaches it. (Ex. 1002 ¶¶ 242-247.) *See also* Section V.B. (overview of Baker). Baker discloses that its composition is intended to be used in a method for “decreasing the infectivity . . . associated with a variety of pathogens.” (Ex. 1006 2:66-67; *see also* 3:7-16.) Thus, Baker’s method has the same use as the ’802 Patent’s method: inhibiting infection.

b. **“wherein a formulation is applied to skin or tissue of nasal passages of the individual, said method comprising in a thin film”**

According to Section IX.B.1.b, Baker discloses this element. Baker’s composition can be applied as a topical cream, lotion, or gel. (Ex. 1006 36:31-33.) A POSITA would understand that a cream, lotion, and gel can be applied to nasal passages. (Ex. 1002 ¶250.) In the event that it were found that this element is not

taught, a POSITA would be motivated per Baker's teachings and suggestions to apply Baker's creams, foams, lotions, and gels in a thin film in or near nasal passages and would have a reasonable expectation of success in doing so. (Ex. 1002 ¶254.)

c. "a) electrostatically attracting the particulate matter to the thin film"

According to Section IX.B.1.f, Baker discloses this element. The formulation as applied to the skin or nasal passages of the individual electrostatically attracts the particulate matter to the thin film. (Ex. 1002 ¶257.) In the event that it were found that this element is not expressly taught, a POSITA would understand that cationic agents inherently attract negatively charged particulate matter. Alternatively, a POSITA would be motivated per Baker's teachings and suggestions to use cationic agents in a formulation in a method for "electrostatically attracting" particulate matter to the thin film given Baker's purpose of "decreasing the infectivity ... associated with a variety of pathogenic organisms and viruses" and would have a reasonable expectation of success in doing so. (Ex. 1006 Abstract; Ex. 1002 ¶258.)

d. "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"

According to Section IX.B.1.g, Baker discloses this element. The formulation holds particulate matter in place once it is applied, and the adhesion and cohesion of the thin film can be adjusted via varying the concentration of ingredients. (Ex. 1002

¶260.) In the event that it were found that this element is not taught, a POSITA would understand that cationic agents inherently attract negatively charged particulate matter. The cationic agents inherently hold particulate matter after initially attracting it. Alternatively, a POSITA would be motivated to use cationic agents in a method to “hold[] ... particulate matter” given Baker’s purpose of “decreasing the infectivity ... associated with a variety of pathogenic organisms and viruses” (Ex. 1006 Abstract) (holding particulate matter would prevent inhalation and thus infectivity), and would have a reasonable expectation of success in doing so. (Ex. 1002 ¶261.)

e. “c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.”

According to Section IX.B.1.e, Baker discloses this element. (Ex. 1002 ¶¶ 262-265.) Baker discloses compositions with at least one biocidic agent, which is noted as having virucidal effects. (Ex. 1006 16: 38-54.)

Thus, claim 1 of the ’802 Patent is anticipated by Baker under 35 U.S.C. 102(b). In the event that claim 1 is not found anticipated by Baker, Baker renders claim 1 obvious because all of the claim elements are taught or suggested by Baker and the claimed combination of the elements is obvious over Baker. (Ex. 1002 ¶266.)

4. Claim 8

- a. **“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 biocidal agent, and**
- b) at least one quaternary thickener.”**

Baker discloses claim 8. According to Section IX.B.1.a, Baker discloses “[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.” Baker discloses “wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film.” (Sections IX.B.1.b and c.) Baker discloses “at least one biocidal agent.” (Section IX.B.1.e.)

Regarding the quaternary thickener, Baker discloses that its composition can comprise N,N-dimethyl-2-hydroxypropylammonium chloride polymer. (Ex. 1006 7:1-2.) This is a polymeric quaternary ammonium compound. (Ex. 1002 ¶191). N,N-dimethyl-2-hydroxypropylammonium chloride polymer can have varying viscosities based on its molecular weight. (*Id.* ¶270.) It would be obvious for a POSITA to use a high molecular weight N,N-dimethyl-2-hydroxypropylammonium chloride polymer in the composition to thicken the composition. (*Id.* ¶271.) Thus, claim 8 of the '802 Patent is anticipated by Baker. In the event that claim 8 is not found anticipated by Baker, Baker renders claim 8 obvious because all of the claim

elements are taught or suggested by Baker and the claimed combination of the elements is obvious over Baker. (*Id.* ¶273.)

C. Ground 3: Claims 1-3 and 8 Are Anticipated or Rendered Obvious by Wahi '005.

Wahi '005 anticipates claims 1-3 and 8 of the '802 Patent. In the event that one or more of claims 1-3 or 8 are not found to be anticipated by Wahi '005, claims 1-3 and 8 would nevertheless have been obvious over Wahi '005 to a POSITA at the Critical Date.

1. Claim 2

a. “A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”

To the extent that the preamble of claim 2 is considered to be limiting, Wahi '005 teaches it. (Ex. 1002 ¶¶ 274-277.) *See also* Section V.C (overview of Wahi '005).

Wahi '005 discloses “products for restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage. This prevents or reduces the inflow of airborne contaminants to the nasal passage.” (Ex. 1007 1:21-26.)

b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film,”

Wahi '005 discloses this element. Wahi '005 discloses that the “nasal application product” may be an ointment, paste, cream, or gel. (Ex. 1007 2:22-26.)

These formulations may be applied to the skin or tissue of nasal passages in a thin film. (Ex. 1002 ¶¶ 278-282.) Wahi '005 describes (specifically in U.S. Pat. No. 5,674,481 (“Wahi ’481”), which is incorporated by reference in its entirety in Wahi ’005) that its gel formulation is applied in a thin film with the finger on the outside of the nostril and above the upper lip and to repeat the application four times a day. (Ex. 1009 6:52-55.) In the event that this element is not taught, the element is obvious as of the Critical Date because Wahi ’005 discloses a “product for restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage. This prevents or reduces the inflow of airborne contaminants to the nasal passage.” (Ex. 1007 1:21-26.) It would be obvious to a POSITA to apply a formulation near the nasal passage to create an electrostatic field with a reasonable expectation of success. (Ex. 1002 ¶282.)

c. “said formulation comprising at least one cationic agent and”

Wahi ’005 discloses this element. Wahi ’005 discloses Celquat SC 240C, which “is a polyquaternary [sic] animonium [sic] cellulose. (*Id.* 4:32-33.) In addition, Wahi ’005 discloses Agequat 400 which is poly (dimethyl diallyl ammonium chloride). (*Id.* 3:34-35.) Each of these are in Example 4 of Wahi ’005. Each of Celquat SC 240C and Agequat 400 is a cationic agent. (Ex. 1002 ¶287.)

d. “at least one biocidic agent”

Wahi '005 discloses this element. Wahi '005 discloses numerous biocidic agents, including Celquat SC-240C, Agequat 400 and TWEEN 60. (Ex. 1007 4:47-62.) Baker evidences that TWEEN 60 can have “virucidal effects.” (Ex. 1002 ¶85.) Each of these is a biocidic agent. (*Id.* ¶291.)

e. “and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film;”

Wahi '005 discloses this element. (Ex. 1002 ¶¶ 293-298.) Wahi '005 discloses compositions with a cationic agent, such as Example 4 with Celquat SC-240C, and Agequat 400. (Ex. 1007 4:32-35.) Each of Celquat SC-240C and Agequat 400 is a cationic agent. (Ex. 1002 ¶294.) Further, Wahi '005 discloses an “artificial electrostatic field near the human nose” and “a topical carrier.” (Ex. 1007 5:39-53.) Wahi '005 incorporates Wahi '481 by reference in its entirety. “Wahi '481 describes that its gel formulation is applied in a thin film with the finger on the outside of the nostril and above the upper lip and to repeat the application four times a day. (Ex. 1009 6:23-26.)” (Ex. 1002 ¶97). The cationic agents in the thin film would “electrostatically attract[] the particulate matter to the thin film.” (Ex. 1002 ¶¶ 298-298.)

In the event that it were found that this element is not expressly taught, a POSITA would understand that Wahi '005's thin film with the cationic agent(s) for

restricting the flow of airborne negatively charged contaminants into a nasal passage inherently creates an electrostatic field of increased charge in an area about the nasal passage. Alternatively, a POSITA would be motivated to use Wahi '005's thin film to electrostatically attract the particulate matter per Wahi's '005's teachings and suggestions and would have a reasonable expectation of success in doing so. (Ex. 1002 ¶299.)

- f. **“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”**

Wahi '005 discloses this element. Wahi '005's formulation discloses holding particulate matter to the thin film. Wahi '005 discloses “a nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of an artificial electrostatic field near the human nose.” (Ex. 1007 2:9-12.) The topical application may be in the form of ointments, pastes, creams and gels.” (*Id.* 2:25-26.) Wahi '005's films include cationic polymers such as poly (dimethyl diallyl ammonium chloride) polymer. (*Id.* 2:17-18.) The cationic polymer will continually attract the particulate matter and thus hold the particulate matter in place. (Ex. 1002 ¶301.) Thus, the thin film “holds particulate matter in place.”

Wahi '005 discloses adjusting the adhesion and cohesion of the formulation to provide adequate impermeability to the thin film under the definition set forth in

Section VIII.B. Wahi '005 discloses multiple examples showing different formulations that “vary the concentration of ingredients.” (Ex. 1007 3:45-4:63.) For instance, Example 1 has 5 wt. % of Agequat 400 and Example 4 has 11 wt.%. Agequat is a polymer. (Ex. 1002 ¶304.) Changing the amount of cationic polymer in a formulation will change the adhesion and cohesion of a formulation applied as a thin film. (*Id.* ¶305.)

In the event that it were found that this element is not expressly taught, a POSITA would understand that Wahi '005 teaches formulations with a cationic agent and that cationic agents inherently attract and hold negatively-charged particulate matter. Alternatively, a POSITA would be motivated to use Wahi '005's formulations in this manner per Wahi '005's teachings and suggestions and would have a reasonable expectation of success in doing so because Wahi's purpose is restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage, which prevents or reduces the inflow of airborne contaminants to the nasal passage. (Ex. 1002 ¶308.)

g. “c) inactivates the particulate matter and renders said particulate matter harmless.”

Wahi '005 discloses this element. As discussed in Section IX.C.1.d, Wahi '005 discloses biocidal agents such as TWEEN 60, Celquat SC 240C, and Agequat

400. TWEEN 60 is virucidal. (Ex. 1007 16:43-46.). Each of Celquat SC 240C and Agequat 400 is a biocidic agent. (Ex. 1002 ¶289.)

Wahi '005 teaches each element of claim 2 of the '802 Patent and therefore anticipates claim 2 of the '802 Patent. In the event that claim 2 is not found anticipated by Wahi '005, Wahi '005 renders claim 2 obvious because all of the claim elements are taught or suggested by Wahi '005 and the claimed combination of the elements would be obvious to a POSITA at the Critical Date. (*Id.* ¶313.)

2. Claim 3

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

Wahi '005 discloses this element. Claim 3 depends from claim 2, and the discussion of claim 2 is incorporated herein by reference.

Wahi '005 discloses Celquat SC-240C and Agequat 400. (Ex. 1007 4:32-35.) Each of these is a polymeric quaternary ammonium compound. (Ex. 1002 ¶315.) Thus, this claim is anticipated. To the extent that one or more elements is deemed to be not found in Wahi '005, claim 1 would be obvious over Wahi '005 to a POSITA at the Critical Date. (*Id.* ¶317.)

3. Claim 1

a. **“A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”**

The discussion of claim 2 is incorporated herein. Claim 1 is identical to claim 2 except for the differences discussed in Section IX.A.3.a. Wahi '005 discloses each and every element of claim 1. (See Section IX.C.1.)

To the extent that the preamble of claim 1 is considered to be limiting, Wahi '005 teaches it. (Ex. 1002 ¶¶ 318-322) and *see also* Section V.C (overview of Wahi '005). Wahi '005 discloses “products for restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage. This prevents or reduces the inflow of airborne contaminants to the nasal passage.” (Ex. 1007 1:22-26.) It would be obvious to a POSITA to use the “product” of Wahi '005 in a method for “[a] method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.” In other words, a POSITA would use a product for its intended use.

b. **“wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:”**

According to Section IX.C.1.b, Wahi '005 discloses this element. (Ex. 1002 ¶¶ 323-327). Wahi '005 discloses that the “nasal application product” may be an ointment, paste, cream, or gel. (Ex. 1007 2:22-26.) These formulations are applied

to the skin or tissue of nasal passages in a thin film. (Ex. 1002 ¶325.) In the event that it were found that this element is not expressly taught, a POSITA would understand that Wahi '005 discloses formulations with a cationic agent for restricting the flow of airborne negatively-charged contaminants into a nasal passage inherently creates an electrostatic field of increased charge in an area about the nasal passage, which prevents or reduces the inflow of airborne contaminants to the nasal passage. Alternatively, a POSITA would understand that Wahi '005 teaches or suggests that the formulations are applied in a thin film in or near nasal passages and would have a reasonable expectation of success in doing so. (Ex. 1002 ¶327.)

c. “a) electrostatically attracting the particulate matter to the thin film”

According to Section IX.C.1.e, Wahi '005 discloses this element. (Ex. 1002 ¶¶ 328-333.) Wahi '005 discloses “a nasal topical application product for creating an “artificial electrostatic field near the human nose.” (Ex. 1007 5:39-53.) (Ex. 1002 ¶329.) The cationic agents in the thin film would electrostatically attract the particulate matter to the thin film. (*Id.* ¶332.)

d. “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”

According to Section IX.C.1.f, Wahi '005 discloses this element. (Ex. 1002 ¶¶ 334-342.) The formulation holds particulate matter in place once applied, and the

adhesion and cohesion of the thin film can be adjusted via varying the concentration of ingredients. For instance, Example 1 has 5 wt. % of Agequat 400 and Example 4 has 11 wt.%. Agequat is a polymer. (*Id.* ¶338.) Changing the amount of cationic polymer in a formulation, for example, will change the adhesion and cohesion of a formulation applied in a thin film. (*Id.* ¶339.)

In the event that it were found that this element is not expressly taught, a POSITA would understand that Wahi '005 teaches formulations with a cationic agent and cationic agents inherently attract and hold negatively charged particulate matter. Alternatively, a POSITA would be motivated to use Wahi '005's formulations in this manner per Wahi's '005's teachings and suggestions because Wahi's purpose is restricting the flow of airborne negatively charged contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage, which prevents or reduces the inflow of airborne contaminants to the nasal passage and would have a reasonable expectation of success in doing so. (*Id.* ¶342.)

- e. “c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.”**

According to Section IX.C.1.d and g, Wahi '005 discloses this element. (Ex. 1002 ¶¶ 343-345.) Wahi '005 discloses biocidal agents such as TWEEN 60, Celquat SC 240C, and Agequat 400. (Ex. 1002 ¶344.)

Wahi '005 teaches each element of claim 1 of the '802 Patent and therefore anticipates claim 1 of the '802 Patent. In the event that claim 1 is not found anticipated by Wahi '005, Wahi '005 renders claim 1 obvious because all of the claim elements are taught or suggested by Wahi '005 and the claimed combination of the elements would be obvious over to a POSITA at the Critical Date. (*Id.* ¶347.)

4. Claim 8

- a. **“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 biocidal agent, and

b) at least one quaternary thickener.”**

Wahi '005 discloses claim 8. According to Section IX.C.1.a, Wahi '005 discloses “[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. Wahi '005 discloses “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film.” (Section IX.C.1.b.) Wahi '005 discloses “at least one biocidal agent.” (Section IX.C.1.d.)

Wahi '005 discloses Celquat SC-240C, which “is a polyquaternary [sic] animonium [sic] cellulose.” (Ex. 1007 4:32-33.) Wahi '005 states that the formulations “thickens” after the addition of Celquat SC-240C. (*Id.* 5:1-7.) Thus,

Celquat SC-240C is a thickener. (Ex. 1002 ¶353.) Thus, claim 8 of the '802 Patent is anticipated by Wahi '005.

In the event that claim 8 is not found anticipated by Wahi '005, a POSITA would find it obvious to modify Wahi '005's formulations per Wahi '005's teaching and suggestions to arrive at the formulation of claim 8 and would have a reasonable expectation of success in doing so. (Ex. 1002 ¶355.)

D. Ground 4: Claims 1, 2 and 8 Are Anticipated or Rendered Obvious by Rolf.

Rolf anticipates claims 1, 2 and 8 of the '802 Patent. In the event that one or more of claims 1, 2 and 8 are not found to be anticipated by Rolf, claims 1, 2 and 8 would nevertheless have been obvious over Rolf to a POSITA at the Critical Date.

1. Claim 2

a. “A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”

To the extent that the preamble of claim 2 is considered to be limiting, Rolf teaches it. The '802 Patent teaches electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation by an electrostatic field that is oppositely charged from airborne particles, which are negatively charged. (Ex. 1001 3:32-40.) “[C]ationic agents electrostatically attract particulate matter, electrostatically inhibiting particulate matter from nasal inhalation, when placed in or near nasal passages.” (Ex. 1002 ¶360.) Rolf discloses a formulation comprising

cationic agents—including quat-15. (Ex. 1008 [0148].) A POSITA would understand that cationic agents “electrostatically inhibit.” (Ex. 1002 ¶360.)

Rolf discloses that its gel is used in “a method for inhibiting a respiratory pathogen.” (Ex. 1008 [0024].) Rolf further states that its gel that includes an essential oil may be used in a method of “contacting a live respiratory pathogen with a therapeutically effective amount of an essential oil, such that the live respiratory pathogen is inactivated upon contact with the essential oil.” (*Id.*) Because Rolf’s gel inactivates the respiratory pathogen upon contact with the essential oil in the gel, the gel inhibits “harmful particulate matter from infecting an individual.” Thus, the composition of Rolf has the same use as the ’802 Patent’s formulation: inhibiting infection.

Rolf discloses that the formulation may be “located in the vicinity of the nasal passages” so that the “respiratory pathogen is inactivated upon contact with the essential oil.” (Ex. 1008 [0020].) This will inhibit harmful particulate matter from entering into the body through inhalation. (Ex. 1002 ¶362.)

b. “wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film”

Rolf discloses this element. Rolf discloses that “[t]he adhesive patch 1 includes a formulation 5 located on . . . the front side 3 of the backing 2” (Ex. 1008 [0045].) Rolf further states that “[t]he backing 2 is define[d] by a front side 3 (the side exposed to the skin during use) (*Id.* [0047].) Rolf discloses that

adhesive skin patch 1, which includes formulation 5, “can be applied to the region between the upper lip and the nose of a patient.” (*Id.* [0147]). Therefore, the formulation 5 is applied to front side 3, and front side 3 is exposed to the skin during use. Therefore, the formulation is applied to the skin or tissue.

Rolf discloses that “formulation 5 [is] located on at least a portion of the front side 3 of the backing 2.” (*Id.* [0045].) The front side 3 is applied to the skin during use. (*Id.* [0047].) As such, a POSITA would understand that formulation 5 located on backing 2 on the skin of an individual would be applied in a thin film. (Ex. 1002 ¶368.)

In the event that this element is not taught, the element is obvious as of the Critical Date because Rolf discloses a thin film applied to the skin or tissue of the nasal passages for the purpose of “contacting a live respiratory pathogen [which] ... is inactivated upon contact.” (Ex. 1008 [0024]; Ex. 1002 ¶369.)

c. “said formulation comprising at least one cationic agent and”

Rolf discloses a formulation comprising a cationic agent such as quat-15. (Ex. 1008 [0024]; Ex. 1002 ¶371.)

d. “at least one biocidic agent”

Rolf discloses this element. Formulation 5 can comprise essential oil 15. (*Id.* at [0065].) Rolf discloses, essential oils that can deactivate “live respiratory pathogens.” (*Id.* at [0020].) Rolf discloses eucalyptus oil, which a POSITA would

understand is a biocidal agent because it can deactivate viruses. (Ex. 1008 [0070]-[0073]; Ex. 1002 ¶375.) Virucidal effects are encompassed in the definition of the capacity of a biocidal agent (having the capacity to neutralize, inactivate, render harmless or kill airborne particles such as viruses). Section VIII.A. (“biocidal agent.”)

e. “and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film;”

Rolf discloses this element. As discussed above, Rolf discloses applying a composition with at least one cationic agent, such as quat-15, which electrostatically attracts the particulate matter. (Ex. 1008 [0024], [0148]) (Quat-15 is a cationic agent, and the formulation contacts the live respiratory agent by attracting the live respiratory agent to it via the cationic agent.) As discussed in Section IX.D.1.c., Rolf’s formulation 5 is applied in a thin film. Thus, Rolf discloses a formulation that when applied “electrostatically attracts the particulate matter to the thin film.” (Ex. 1002 ¶380.) In the event that it were found that this element is not expressly taught, a POSITA would understand that Rolf’s thin film with the cationic agent(s) “contact[s] a live respiratory pathogen [which] ... is inactivated upon contact” and inherently electrostatically attracts the particulate matter (Ex. 1008 [0024].) Alternatively, a POSITA would be motivated per Rolf’s teachings and suggestions

to use Rolf's thin film to electrostatically attract the particulate matter and would have a reasonable expectation of success in doing so. (Ex. 1002 ¶381.)

- f. **“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”**

Rolf discloses this element. Rolf's formulation discloses holding particulate matter to the thin film. Rolf's formulation can be an ointment or a gel. (Ex. 1008 [0041].) A POSITA would understand that an ointment or gel can be applied as a thin film. (Ex. 1002 ¶¶ 384-385.) Rolf's thin films can comprise cationic agents such as quat-15. (Ex. 1008 [0148].) Cationic agents will attract particulate matter to them. (Ex. 1002 ¶387.) The cationic agents will then attract the particulate matter and thus hold the particulate matter in place. (Ex. 1002 ¶387.) Thus, the thin film holds particulate matter.

Rolf discloses adjusting the adhesion and cohesion of the formulation to provide adequate impermeability to the thin film under the definition set forth in Section VIII.B. Rolf discloses 16 examples that “vary[] the concentration of ingredients,” and “thereby adjust[] the adhesion and cohesion of the thin film.” (Ex. 1008 [0268]-[0283].) Each of the Examples states that the formulation may comprise a percentage range of an ingredient and then lists a “typical” (i.e., preferred) percentage. For instance, in Example 6 in paragraph [0273] has a range

percentage of 10% to 50% polyvinyl alcohol; Example 8 in paragraph [0275] has a range percentage of 10% to 40%. “Varying the concentration” of polyvinyl alcohol in a formulation by up to 40% will “adjust[] the adhesion and cohesion of the thin film.” (Ex. 1002 ¶392.)

In the event that it were found that this element is not expressly taught, a POSITA would understand that Rolf’s formulations with a cationic agent inherently attract and hold negatively charged particulate matter. Alternatively, a POSITA would be motivated to use Rolf’s formulations in this manner because Rolf’s purpose is “contacting a live respiratory pathogen [which] ... is inactivated upon contact” And would have a reasonable expectation of success in doing so. (Ex. 1008 [0024]; Ex. 1002 ¶394.)

g. “c) inactivates the particulate matter and renders said particulate matter harmless.”

Rolf discloses compounds to deactivate virus cells by membrane disruption, such as essential oils. Rolf discloses that the formulations comprise essential oil in any suitable amount, and specifically, an amount of essential oil to “effectively kill[] or inactivate[] an airborne pathogen, respiratory tract pathogen, or a combination thereof.” (Ex. 1008 [0076]-[0077].) Rolf’s examples describe various amounts of essential oils. (*Id.* at [0268]-[0283].)

Rolf teaches each element of claim 2 of the ’802 Patent and therefore anticipates claim 2 of the ’802 Patent. In the event that claim 2 is not found

anticipated by Rolf, Rolf renders claim 2 obvious because all of the claim elements are taught or suggested by Rolf and the claimed combination of the elements would be obvious to a POSITA at the Critical Date. (Ex. 1002 ¶400.)

2. Claim 1

a. “A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”

The discussion of claim 2 is incorporated herein. Claim 1 is identical to claim 2 except for the differences discussed in Section IX.A.3.a.

Rolf discloses a formulation that performs all the steps required by claim 2. (Section IX.D.1.)

To the extent that the preamble of claim 1 is considered to be limiting, Rolf teaches it. (Ex. 1002 ¶¶ 401-406.) *See also* Section V.D. Rolf discloses a gel or ointment. (Ex. 1008 [0042].) Rolf discloses that the composition is used in “a method for inhibiting a respiratory pathogen.” (*Id.* [0024].) *See also* Section IX.D.1.a.

b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:”

As discussed above in Sections IX.D.1.b and c, Rolf discloses this element. Rolf discloses that the formulation 5 is applied to front side 3, and front side 3 is “exposed to the skin during use.” (Ex. 1008 [0045]-[0047].) As such, a POSITA would understand that formulation 5 located on backing 2 on the skin of an

individual would be applied in a thin film. (Ex. 1002 ¶368.) In the event that it were found that this element is not taught, a POSITA would be motivated to use a thin film of Rolf's formulations for application to the skin or tissue of the nasal passages for the purpose of "contacting a live respiratory pathogen [which]... is inactivated upon contact" per Rolf's teachings and suggestions and would have a reasonable expectation of success in doing so. (Ex. 1008 [0024]; Ex. 1002 ¶411.)

c. "a) electrostatically attracting the particulate matter to the thin film"

As discussed above in Section IX.D.1.f, Rolf discloses this element. Rolf discloses a thin film that can have at least one cationic agent. (Ex. 1008 [0148].) The cationic agent would attract particulate matter. (Ex. 1002 ¶414.) In the event that it were found that this element is not expressly taught, a POSITA would understand that Rolf's thin film with the cationic agent(s) for the purpose of "contacting a live respiratory pathogen [which]... is inactivated upon contact" would inherently electrostatically attract the particulate matter. (Ex. 1008 [0024].) Alternatively, a POSITA would be motivated to use Rolf's thin film to electrostatically attract the particulate matter per Rolf's teachings and suggestions and would have a reasonable expectation of success in doing so. (Ex. 1002 ¶415.)

d. "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”

As discussed above in Section IX.D.1.g, Rolf discloses this element. The formulation holds particulate matter in place once it is applied, and the adhesion and cohesion of the thin film can be adjusted via varying the concentration of ingredients. (Ex. 1002 ¶417.) In the event that it were found that this element is not expressly taught, because a POSITA would understand that Rolf’s formulations with a cationic agents inherently attract and hold negatively charged particulate matter. Alternatively, a POSITA would be motivated to use Rolf’s formulations in this manner because Rolf’s purpose is “contacting a live respiratory pathogen [which]... is inactivated upon contact” and would have a reasonable expectation of success in doing so. (Ex. 1008 [0024]; Ex. 1002 ¶418.)

e. “c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.”

According to Section IX.D.1.h, Rolf discloses this element. The “at least one ingredient that would render said particulate matter harmless” is the essential oil, which is a biocidic agent in Section IX.D.1.e.

Rolf teaches each element of claim 1 of the ’802 Patent and therefore anticipates claim 1 of the ’802 Patent. In the event that claim 1 is not found anticipated by Rolf, Rolf renders claim 1 obvious because all of the claim elements

are taught or suggested by Rolf and the claimed combination of the elements would be obvious to a POSITA at the Critical Date. (Ex. 1002 ¶¶ 422-23.)

3. Claim 8

a. **“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 biocidal agent, and

b) at least one quaternary thickener.”

Rolf anticipates or renders claim 8 obvious. According to Section IX.D.1.a, Rolf discloses “[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.” According to Section IX.D.1.b and c, Rolf discloses “wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film.” According to Section IX.D.1.e, Rolf discloses “at least one biocidal agent.”

Regarding the quaternary thickener, as discussed in Section IX.D.1.d., Rolf discloses quat-15. (Ex. 1008 [0148].) Quat-15 thickens formulations, for example, Examples 1-16 in Rolf. (*Id.* [0268]-[0283]; Ex. 1002 ¶107.) Thus, Rolf discloses a quaternary thickener. (Ex. 1002 ¶428.)

Rolf teaches each element of claim 8 of the '802 Patent and therefore anticipates claim 8 of the '802 Patent. In the event that claim 8 is not found anticipated by Rolf, a POSITA would find it obvious to modify Rolf's formulations

per Rolf's teaching and suggestions to arrive at the formulation of claim 8 and would have a reasonable expectation of success in doing so. (*Id.* ¶¶ 429-30.)

E. Ground 5: Claim 3 Is Rendered Obvious by Rolf in View of Wahi '005.

1. Claim 3

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

Rolf in view of Wahi '005 discloses this claim. Rolf renders claim 2 anticipated or obvious. (Section IX.D.1.) The grounds set forth for claim 2 are reasserted here. Claim 3 depends on claim 2. Rolf discloses quaternary ammonium compounds such as quat-15. (Ex. 1008 [0253].) Wahi '005 discloses Celquat SC-240C, which is a polymeric quaternary ammonium compound. (Ex. 1007 4:46-63.) Wahi '005 states that "Celquat SC 240C is a polyquaternary [sic] ammonium [sic] cellulose." (*Id.* 6:31.) Celquat SC 240C is also known as polyquaternium-10.

A POSITA would have been motivated to combine Rolf with Wahi '005 because they are both directed to methods of preventing respiratory infection via the function of the compositions. (Ex. 1008 [0020]; Ex. 1007 Abstract.) Further, Rolf discloses quaternary ammonium compounds, and a POSITA would find it obvious to modify Rolf with a different quaternary ammonium compound: Celquat SC-400 as taught in Wahi '005. Thus, claim 3 of the '802 Patent is rendered obvious by Rolf in view of Wahi '005 to a POSITA at the Critical Date. (Ex. 1002 ¶¶ 437-40.)

X. SECONDARY CONSIDERATIONS

Petitioner is not required to predict which arguments PO might make, if any, about secondary considerations. *Cf. Petroleum Geo-Services Inc. v. Western Geco LLC*, IPR2014-01477, Paper 18 at 32 (P.T.A.B. Mar. 17, 2015) (finding “at the time of filing of the present Petition, no evidence of secondary indicia of non-obviousness in the record of this proceeding” and “evidence of secondary indicia of non-obviousness must be first developed in this proceeding by patent owner”).

Petitioner is unaware of secondary considerations, including commercial success and industry praise, relating to the products embodied by the '802 Patent, and thus are attributable to the claimed invention.

Petitioner reserves the right to supplement its positions regarding secondary considerations to respond to PO's potential allegations of non-obviousness.

XI. TRIAL SHOULD BE INSTITUTED

A. *Fintiv* Factors Weigh Against Discretionary Denial

The *Fintiv* factors as a whole favor institution. *See Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020). This Petition presents compelling evidence of unpatentability. With respect to the concurrent proceeding, Petitioner agrees to a *Sotera*-like stipulation and presents evidence of a median time-to-trial after the Board's projected statutory deadline for a Final Written Decision. *See* Interim Procedure Memorandum issued by Director Vidal on June 21, 2022 (Ex. 1016).

The first *Fintiv* factor favors institution. A motion for stay has already been filed **by *Patent Owner*** in the *Cho* litigation (see Ex. 1014, ECF 70), to which Defendants, including Petitioner, have stipulated (see Ex. 1028 at ¶8). The district court has granted stays in similar circumstances; that is, where litigation has just begun, discovery is in its infancy, issues for trial may be streamlined, and the plaintiff is not unduly prejudiced. See, e.g., *Gesture Tech. Partners, LLC v. LG Elecs., Inc.*, No. 21-19234, 2022 U.S. Dist. LEXIS 62248, at *6-17 (D.N.J. Apr. 4, 2022); *Batinkoff v. Church & Dwight Co.*, No. 3:18-cv-16388, 2020 U.S. Dist. LEXIS 172262, at *5-15 (D.N.J. Sept. 21, 2020).

The second *Fintiv* factor favors institution. The court has not set a trial date as yet. (See Ex. 1015.) However, the median time-to-trial in the District of New Jersey in civil cases is currently 50.8 months. (Ex. 1017 (time-to-trial for the time period of 12/31/22 to 12/31/23).) Thus, any trial in the related litigation likely will not occur until in or after October 2027, which is well after the Board's likely final written decision.

The third *Fintiv* factor weighs in favor of institution. The related litigation is at an early stage, and an answer by only one defendant has been filed. (See Ex. 1014 at ECF 68.) Only limited fact discovery has taken place, no depositions have been taken, and expert discovery has not yet begun. The deadline to propose a date for a *Markman* hearing is not scheduled to occur until September 30, 2024. (See Ex.

1015.) Because the parties' investment in the litigation is limited, discretionary denial is not warranted. *See Vudu, Inc. v. Ideahub, Inc.*, No. IPR2020-01688, Paper 16, at 12-13 (P.T.A.B. Apr. 19, 2021) (recognizing that this factor weighs against using discretion to deny institution when the parties in the related litigation have not engaged in significant discovery or begun claim construction briefing).

The fourth *Fintiv* factor strongly weighs against denial. This Petition challenges claims 1-3 and 8 in the '802 Patent, even though not all those claims are currently asserted in the related litigation. Institution here promotes efficiency, because this IPR petition is the only venue in which certain invalidity challenges will be adjudicated.

Moreover, if trial is instituted, Petitioner stipulates that it will not argue the invalidity of asserted claims in the case before the district court on the same grounds as in the Petition or on any grounds that could have been reasonably raised in the Petition. As the Board found in *Sotera*, this stipulation strongly weighs in favor of not exercising discretion under 35 U.S.C. § 314(a). *See Sotera Wireless, Inc. v. Masimo Corp.*, No. IPR2020-01019, Paper No. 12, at 18-19 (P.T.A.B. Dec. 1, 2020) (precedential as to § II.A).

Because Petitioner and PO are the same parties in the district court, the fifth *Fintiv* factor is neutral and should therefore be given no weight. *See, e.g., Kranos*

Corp. d/b/a Schutt Sports v. Apalone, Inc., No. IPR2020-00501, Paper No. 13, at 13-14 (P.T.A.B. July 16, 2020).

In the event that the Board were inclined to exercise discretion to deny institution in its evaluation of the first five factors, the sixth *Fintiv* factor would nonetheless favor institution because the merits of the Petition are compelling. Prior art references anticipate or render obvious independent claims 1, 2, and 8, and dependent claim 3.

Taken together, the *Fintiv* factors strongly weigh in favor of institution and against denial.

B. The Circumstances Weigh Against Discretionary Denial

This IPR petition is not a serial petition under any of the factors in *General Plastics. General Plastic Indus. Co., Ltd. v. Canon Kabushiki*, No. IPR2016-01357, Paper 19 (P.T.A.B. Sept. 6, 2017). Petitioner's grounds rely on prior art not previously considered or applied by the Examiner and do not present the same or substantially the same arguments presented earlier to the Office, either during prosecution or in an earlier petition submitted by a third party, which was dismissed prior to a Decision on Institution being entered. *See Matrixx Initiatives, Inc. v. Trutek Corp.*, IPR2020-01592, Paper 1 (Sept. 3, 2020), Paper 11 (Dec. 3, 2020). The Board should decline to exercise its discretion to deny review under 35 U.S.C. §§ 314(a) and 325(d).

XII. CONCLUSION

For the above reasons, Claims 1-3, and 8 of the '802 Patent should be found unpatentable, and Petitioner requests review of these claims.

Respectfully submitted,

Dated: May 29, 2024

/s/William H. Oldach III

Reg. No. 42,048

Lead Counsel for Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I hereby certify that the foregoing “Petition for *Inter Partes* Review of U.S. Patent No. 8,163,802” contains 13,924 words as measured by the word processing software used to prepare the document, excluding the parts of the document exempted by 37 C.F.R. § 42.24(a)(1).

/s/William H. Oldach III
Reg. No. 42,048
Lead Counsel for Petitioner

CERTIFICATION OF SERVICE

The undersigned hereby certifies that the above-captioned “Petition for *Inter Partes* Review of U.S. Patent No. 8,163,802” including its supporting evidence (Exhibits 1001-1029), was served on May 29, 2024, upon the following via FedEx:

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As well as a courtesy copy to the patent owner’s litigation counsel, by email:

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