

*SALVACION USA, INC., v.
TRUTEK CORP.*

Petitioner's Demonstratives

IPR2024-00711
Patent No. 8,163,802

Salvacion

September 8, 2025

Petitioner Salvacion USA, Inc. Ex. 1030

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

1

Overview

IPR2024-00711 ('802 Patent)

- A. Claim Construction
- B. Ground 1: Chen, Anticipation
- C. Ground 2: Baker, Anticipation
- D. Ground 3: Wahi '005, Anticipation
- E. Ground 4: Rolf, Anticipation
- F. Motion to Strike/Exclude
- G. Ground 5: Rolf in view of Wahi '005, Obviousness
- H. Ground 1: Chen, Obviousness
- I. Ground 2: Baker, Obviousness
- J. Ground 3: Wahi '005, Obviousness
- K. Ground 4: Rolf, Obviousness



Claim Construction

“Patent Owner does not challenge Petitioner’s claim constructions.”

Sur Reply (Paper 13), 2.

In the introduction to its reply, Petitioner argued that, "Patent Owner has refused to accept Petitioner's claim construction, but instead has offered a claim construction that is incorrect and unsupported by any evidence of record." Patent Owner does not challenge Petitioner's claim constructions. Further, Patent Owner

Sur Reply (Paper 13), 2.

Patent Owner then challenges Petitioner's claim construction.

Response (Paper 9), 9.

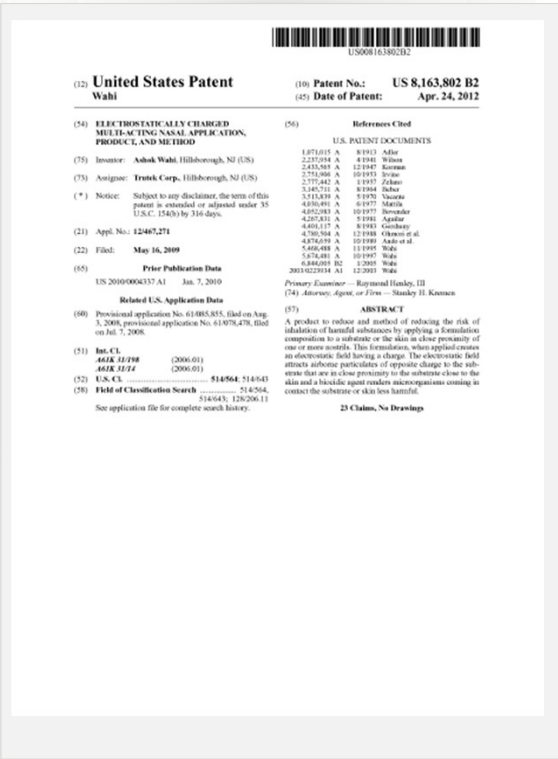
deactivate various viruses which they contact. While there is some attraction of these negatively charged particles to the positively charged composition, there is no indication that there is a purposeful adjustment of the positive charge so as to effectively create an electrostatic field surrounding the user's nose and face that would attract airborne particles that float in the vicinity of the nostrils. In the '802 Patent's specification, the meaning of "electrostatic attraction" being of airborne particles is stated repeatedly.⁶ However, Wahi's earlier patents clearly recite this feature, and the examiner of the '271 Application was aware of these patents. This feature is the CATCH element of the '802 Patent.

Response (Paper 9), 9.

The '802 Patent

- Claims “[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.”

'802 Patent (Ex. 1001) 10:34-38; Petition (Paper 2), 4.



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:

'802 Patent (Ex. 1001) 10:34-39; Petition (Paper 2), 4.

The '802 Patent

- “electrostatically attracts” and “holds the particulate matter.”

'802 Patent (Ex. 1001) 10:40-46.

- 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,

'802 Patent (Ex. 1001) 10:40-46.

Patent Owner's arguments concerning limitation a) of Claims 1 and 2 and a “purposeful adjustment of the positive charge”

Sur Reply (Paper 13), 2 and 7.

individual. From the claim language and specification, it is obvious that there must be a purposeful adjustment of the electrostatic field to attract these particles to prevent them from entering the respiratory tract. An electrostatic field that is too weak defeats the intended

Sur Reply (Paper 13), 7.

unsupported by any evidence of record." Patent Owner does not challenge Petitioner's claim constructions. Further, Patent Owner

Sur Reply (Paper 13), 2.

Patent Owner's arguments concerning limitation b) of Claims 1 and 2

Sur Reply (Paper 13), 2 and 10.

adjusted to that the film sticks to the nasal skin or tissue. The HOLD element requires the thin film to hold the particles in place and to not be inhaled into the respiratory system. However, the cohesion of the formulation is adjusted to have adequate impermeability so that the harmful particles will have no contact with the skin or tissue of the nasal passages. The HOLD function is essential, because it inhibits inhalation of the particles. The HOLD function is not implied by Chen,

Sur Reply (Paper 13), 10.

unsupported by any evidence of record." Patent Owner does not challenge Petitioner's claim constructions. Further, Patent Owner

Sur Reply (Paper 13), 2.

Petitioner's claim construction for "adequate impermeability"

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

Mich. CC. Order (Ex. 1010) at 17 and 18; Petition (Paper 2), 15;
Reply (Paper 12), 3; Sur Reply (Paper 13), 2.

Id. (emphasis added). Plaintiff argued that "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." *Id.* at 562 (emphasis omitted). Defendant

Mich. CC. Order (Ex. 1010) at 17.

long enough to be rendered harmless. It is an expression of the qualities inherent in the thin film that allow the technology to work according to its specification. Put

Mich. CC. Order (Ex. 1010) at 18.

unsupported by any evidence of record." Patent Owner does not challenge Petitioner's claim constructions. Further, Patent Owner

Sur Reply (Paper 13), 2.

Petitioner's claim construction for "skin or tissue of nasal passages of the individual"

Wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film,

'802 Patent (Ex. 1001) 2:60-67; Petition (Paper 2), 15-16; Sur Reply (Paper 13), 2.

OBJECTS OF THE INVENTION

It is therefore an object of the invention to provide a composition that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release with method and compositions capable of capturing particulates and microorganisms.

'802 Patent (Ex. 1001) 2:60-67

unsupported by any evidence of record." Patent Owner does not challenge Petitioner's claim constructions. Further, Patent Owner

Sur Reply (Paper 13), 2.



Ground 1: Claims 2, 3, 1, and 8 are anticipated by Chen

Breakdown of elements for claim 2

'802 Patent (Ex. 1001) 10:34-48.

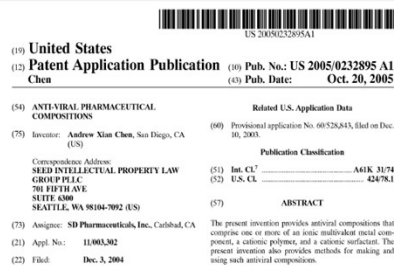
- 2[a] A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation
- 2[b] wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film,
- 2[c] said formulation comprising at least one cationic agent and
- 2[d] at least one biocidal agent,
- 2[e] and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film;
- 2[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; and,
- 2[g] c) inactivates the particulate matter and renders said particulate matter harmless.

'802 Patent (Ex. 1001) 10:34-48.

Petitioner has established Chen discloses Claim 2[a]

2[a] A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation

Chen (Ex. 1005) at front page, [0044], and [0078]; Petition (Paper 2), 17; Dr. Park Dec. (Ex. 1002) ¶¶ 108-112.



Chen (Ex. 1005), front page.

[0044] In certain embodiments, the antiviral compositions of the present invention are administered locally, such as to skin, oral membrane, nasal membrane or genital membrane.

[0078] The cationic polymers used for the antiviral compositions as disclosed herein, include, but are not limited to:

• • •

secondary, tertiary or quaternary amine) on the repeating monomer unit, such as poly(dimethyl-aminoethylmethacrylate) (commercially available as EUDRAGIT®E by Degussa), poly(acrylic acid-b-methyl methacrylate), poly(methyl methacrylate-b-sodium acrylate), poly(methacrylic acid-b-neopentyl methacrylate), poly(t-butyl methacrylate-b-ethylene oxide), poly(methyl methacrylate-b-sodium methacrylate), poly(methyl methacrylate-b-N-methyl-4-vinyl pyridinium iodide), and poly(methyl methacrylate-b-N,

Petitioner has established Chen discloses Claim 2[b]

2[b] Wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film,

Chen (Ex. 1005) at [0044] and [0111]; Petition (Paper 2), 17-18; Dr. Park Dec. (Ex. 1002) ¶¶ 113-115.

[0044] In certain embodiments, the antiviral compositions of the present invention are administered locally, such as to skin, oral membrane, nasal membrane or genital membrane.

[0111] The compositions of the present invention may be in any form suitable for local administration. For example, the composition may be in a form of a solution, paste, gel, suspension, lotion, cream, aerosol, dressing, bandage, lacquer, or ointment formulation for local application. In certain embodiments, the compositions of the present invention are formulated (or adapted) for preventing or treating virus infection through nasal passages, such as in a form of nasal ointments, nasal drops, nasal washes, nasal packings, or nasal sprays.

Petitioner has established Chen discloses Claim 2[c]; Patent Owner admits this

2[c] Said formulation comprising at least one cationic agent and

Chen (Ex. 1005) at [0078]; Petition (Paper 2), 19; Sur Reply (Paper 13), 16; Dr. Park Dec. (Ex. 1002) ¶¶116-121.

It is true that Chen's composition contains at least one cationic agent which would create a positively charged electrostatic field that would inherently attract some negatively charged airborne particles. It is also true that Chen's composition contains at least one biocidal agent. However, Chen does not teach the HOLD function of claims

Sur Reply (Paper 13), 16.

[0078] The cationic polymers used for the antiviral compositions as disclosed herein, include, but are not limited to:

• • •

secondary, tertiary or quaternary amine) on the repeating monomer unit, such as poly(dimethyl-aminoethylmethacrylate) (commercially available as EUDRAGIT®E by Degussa), poly(acrylic acid-b-methyl methacrylate), poly(methyl methacrylate-b-sodium acrylate), poly(methacrylic acid-b-neopentyl methacrylate), poly(t-butyl methacrylate-b-ethylene oxide), poly(methyl methacrylate-b-sodium methacrylate), poly(methyl methacrylate-b-N-methyl-4-vinyl pyridinium iodide), and poly(methyl methacrylate-b-N,

Petitioner has established Chen discloses Claim 2[d]; Patent Owner admits this

2[d] At least one biocidal agent

Chen (Ex. 1005) at [0086]; Petition (Paper 2), 19; Sur Reply (Paper 13), 16; Dr. Park Dec. (Ex. 1002) ¶¶122-125.

It is true that Chen's composition contains at least one cationic agent which would create a positively charged electrostatic field that would inherently attract some negatively charged airborne particles. It is also true that Chen's composition contains at least one biocidal agent. However, Chen does not teach the HOLD function of claims

Sur Reply (Paper 13), 16.

[0086] Benzalkonium chloride (i.e., alkyldimethyl (phenylmethyl) ammonium chloride [CAS 8001-54-5]), or its closely relative compound benzethonium, is a surface-active germicide for many pathogenic nonsporulating bacteria and fungi. Aqueous solutions of this agent have a low surface tension, and possess detergent, keratolytic, and emulsifying properties that aid the penetration and wetting of tissue surfaces. Commercially, benzalkonium chloride has been widely used in ophthalmic, otic, nasal and injectable formulations, as well as in cosmetic products as preservatives. In addition, benzalkonium chloride has been used as spermicides, which are a type of contraceptive for birth control. Furthermore, benzalkonium chloride has been formulated into topical antiseptics (ZEPHIRAN®, Sanofi) for skin and mucous membranes and as a disinfectant in surgery, obstetrics and gynecology, urology, ophthalmology, otorhinolaryngology and general practice.

Petitioner has established Chen discloses Claim 2[e]; Patent Owner admits this

2[e] And wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film

Chen (Ex. 1005) at [0111]; Petition (Paper 2), 20; Sur Reply (Paper 13), 16; Dr. Park Dec. (Ex. 1002) ¶¶126-130.

It is true that Chen's composition contains at least one cationic agent which would create a positively charged electrostatic field that would inherently attract some negatively charged airborne particles. It is also true that Chen's composition contains at least one biocidal agent. However, Chen does not teach the HOLD function of claims

[0111] The compositions of the present invention may be in any form suitable for local administration. For example, the composition may be in a form of a solution, paste, gel, suspension, lotion, cream, aerosol, dressing, bandage, lacquer, or ointment formulation for local application. In certain embodiments, the compositions of the present invention are formulated (or adapted) for preventing or treating virus infection through nasal passages, such as in a form of nasal ointments, nasal drops, nasal washes, nasal packings, or nasal sprays.

Thin films

Sur Reply (Paper 13), 16.

Petitioner has established Chen discloses Claim 2[f]

2[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

Chen (Ex. 1005) at [0097], [0111], and [0078]; Petition (Paper 2), 20-22; Sur Reply (Paper 13), 16; Dr. Park Dec. (Ex. 1002) ¶¶131-140.

[0111] The compositions of the present invention may be in any form suitable for local administration. For example, the composition may be in a form of a solution, paste, gel, suspension, lotion, cream, aerosol, dressing, bandage, lacquer, or ointment formulation for local application. In certain embodiments, the compositions of the present invention are formulated (or adapted) for preventing or treating virus infection through nasal passages, such as in a form of nasal ointments, nasal drops, nasal washes, nasal packings, or nasal sprays.

It is true that Chen's composition contains at least one cationic agent which would create a positively charged electrostatic field that would inherently attract some negatively charged airborne particles. It is also true that Chen's composition contains at least one biocidal agent. However, Chen does not teach the HOLD function of claims

[0078] The cationic polymers used for the antiviral compositions as disclosed herein, include, but are not limited to:

...

secondary, tertiary or quaternary amine) on the repeating monomer unit, such as poly(dimethyl-aminoethylmethacrylate) (commercially available as EUDRAGIT®E by Degussa), poly(acrylic acid-b-methyl methacrylate), poly(methyl methacrylate-b-sodium acrylate), poly(methacrylic acid-b-neopentyl methacrylate), poly(t-butyl methacrylate-b-ethylene oxide), poly(methyl methacrylate-b-sodium methacrylate), poly(methyl methacrylate-b-N-methyl-4-vinyl pyridinium iodide), and poly(methyl methacrylate-b-N,

Sur Reply (Paper 13), 16.

Petitioner has established Chen discloses Claim 2[f] (cont'd)

2[f] ... and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film

Chen (Ex. 1005) at [0112] and [0148]; Decision to Institute, (Paper 7), 9, Petition (Paper 2), 20-22; Dr. Park Dec. (Ex. 1002) ¶¶131-140.

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

Decision to Institute, (Paper 7), 9.

Antiviral Composition 1 (Same as the composition used in Example 1)

...

Antiviral Composition 16

Chen (Ex. 1005) at [0097]

[0112] Any methods appropriate for local administering a pharmaceutical composition to a subject known in the art may be used in the present invention. Such methods 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.

[0148] The cell protection assay was designed to mimic the situation when a formulation is applied onto human tissue such as a nasal mucosa, other skin or mucous tissues to prevent the tissue from being infected by a pathogenic virus. Since all three test articles (two antiviral formulations and the zinc-only preparation) are of mucoadhesive and can be expected to form an adhesive layer covering mucous membrane or skin surface, they would form a physical barrier to the invading virus.

Petitioner has established Chen discloses Claim 2[g]; Patent Owner admits this

2[g] c) inactivates the particulate matter and renders said particulate matter harmless

Chen (Ex. 1005) at [0086]; Petition (Paper 2), 22-23; Sur Reply (Paper 13), 16; Dr. Park Dec. (Ex. 1002) ¶¶141-144.

It is true that Chen's composition contains at least one cationic agent which would create a positively charged electrostatic field that would inherently attract some negatively charged airborne particles. It is also true that Chen's composition contains at least one biocidal agent. However, Chen does not teach the HOLD function of claims

Sur Reply (Paper 13), 16.

[0086] Benzalkonium chloride (i.e., alkyldimethyl (phenylmethyl) ammonium chloride [CAS 8001-54-5]), or its closely relative compound benzethonium, is a surface-active germicide for many pathogenic nonsporulating bacteria and fungi. Aqueous solutions of this agent have a low surface tension, and possess detergent, keratolytic, and emulsifying properties that aid the penetration and wetting of tissue surfaces. Commercially, benzalkonium chloride has been widely used in ophthalmic, otic, nasal and injectable formulations, as well as in cosmetic products as preservatives. In addition, benzalkonium chloride has been used as spermicides, which are a type of contraceptive for birth control. Furthermore, benzalkonium chloride has been formulated into topical antisepsis (ZEPHIRAN®, Sanofi) for skin and mucous membranes and as a disinfectant in surgery, obstetrics and gynecology, urology, ophthalmology, otorhinolaryngology and general practice.

Petitioner has established Chen anticipates Claim 2

Petitioner has established Chen anticipates Claim 3

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

Chen (Ex. 1005) at [0078]; Petition (Paper 2), 22-23; Dr. Park Dec. (Ex. 1002) ¶¶147-150.

[0078] The cationic polymers used for the antiviral compositions as disclosed herein, include, but are not limited to:

...

secondary, tertiary or quaternary amine) on the repeating monomer unit, such as poly(dimethyl-aminoethylmethacrylate) (commercially available as EUDRAGIT®E by Degussa), poly(acrylic acid-b-methyl methacrylate), poly(methyl methacrylate-b-sodium acrylate), poly(methacrylic acid-b-neopentyl methacrylate), poly(t-butyl methacrylate-b-ethylene oxide), poly(methyl methacrylate-b-sodium methacrylate), poly(methyl methacrylate-b-N-methyl-4-vinyl pyridinium iodide), and poly(methyl methacrylate-b-N,

Petitioner has established Chen anticipates Claim 1

'802 Patent (Ex. 1001) 10:19-48; Petition (Paper 2), 23-26.

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.

'802 Patent (Ex. 1001) 10:19-33.

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.

'802 Patent (Ex. 1001) 10:34-48.

Petitioner has established Chen anticipates Claim 8

'802 Patent (Ex. 1001) 11:1-7; Chen (Ex. 1005) at [0078]; Petition (Paper 2), 27-28; Dr. Park Dec. (Ex. 1002) ¶¶178-185.

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

'802 Patent (Ex. 1001) 11:1-7.

[0078] The cationic polymers used for the antiviral compositions as disclosed herein, include, but are not limited to:

...

secondary, tertiary or quaternary amine) on the repeating monomer unit, such as poly(dimethyl-aminoethylmethacrylate) (commercially available as EUDRAGIT®E by Degussa), poly(acrylic acid-b-methyl methacrylate), poly(methyl methacrylate-b-sodium acrylate), poly(methacrylic acid-b-neopentyl methacrylate), poly(t-butyl methacrylate-b-ethylene oxide), poly(methyl methacrylate-b-sodium methacrylate), poly(methyl methacrylate-b-N-methyl-4-vinyl pyridinium iodide), and poly(methyl methacrylate-b-N,



Ground 2: Claims 2, 3, 1, and 8 are anticipated by Baker

Petitioner has established Baker discloses Claim 2[a]

2[a] A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation

Baker (Ex. 1006) front page, 36:12-13, and 69:59-70:53; Petition (Paper 2), 28-30; Dr. Park Dec. (Ex. 1002) ¶¶187-197.

Particular examples of pharmaceutically acceptable forms include but are not limited to oral, nasal, buccal, rectal,

Baker (Ex. 1006) 36:12-13

9. The method of claim 1, wherein said quaternary ammonium compound is selected from the group consisting of N-alkyldimethyl benzyl ammonium saccharinate; 1,3,5-s-triazine; myristalkonium chloride (and) Quat RNIUM 14; N,N-Dimethyl-2-hydroxypropylammonium chloride polymer; n-alkyl dimethyl benzyl ammonium chloride; n-alkyl

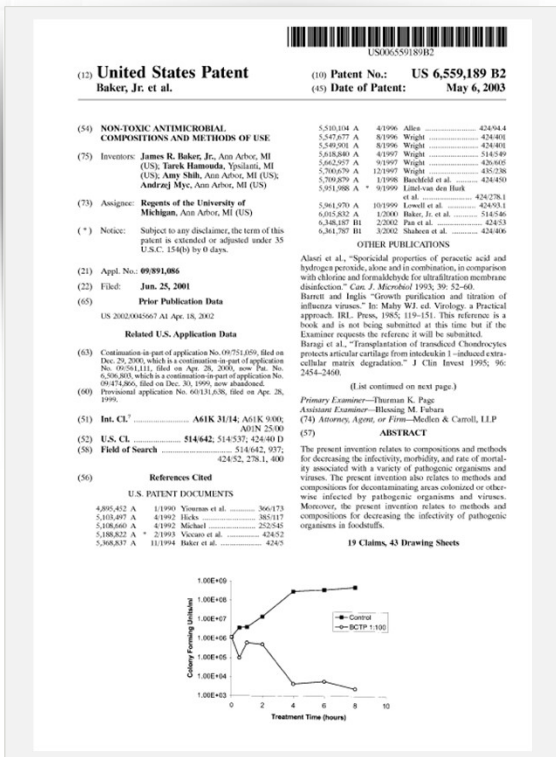
Baker (Ex. 1006) 69:59-70:53.

Baker (Ex. 1006), front page.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

27

SALVACION: IPR2024-00711
EXHIBIT 1030 PAGE 000027



Petitioner has established Baker discloses Claim 2[b]

2[b] Wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film,

Baker (Ex. 1006) 36:31-33, 51:15-19;
Petition (Paper 2), 30-31; Dr. Park
Dec. (Ex. 1002) ¶¶198-203.

For topical applications, the pharmaceutically acceptable carrier may take the form of a liquid, cream, foam, lotion, or gel, and may additionally comprise organic solvents, emulsifiers, gelling agents, moisturizers, stabilizers, surfactants, wetting agents, preservatives, time release agents, and minor amounts of humectants, sequestering agents, dyes, perfumes, and other components commonly employed in pharmaceutical compositions for topical administration.

Baker (Ex. 1006) 36: 31-33

Mucous Membrane

Intranasal toxicity was preformed in mice by installation of 25 μ L of 4% of the nanoemulsion per nare. No clinical or histopathological changes were observed in these mice.

Baker (Ex. 1006) 51:15-19

Petitioner has established Baker discloses Claim 2[c]

2[c] Said formulation comprising at least one cationic agent and

Baker (Ex. 1006) 6:64-66, 7:1-2, 17:5, and 17:24-27; Petition (Paper 2), 31-32; Dr. Park Dec. (Ex. 1002) ¶¶204-206.

D. Cationic Halogen Containing Compounds

In some embodiments, the compositions of the present invention further comprise a cationic halogen containing compound (e.g., from about 0.5 to 1.0 wt. % or more, based

...

trimethylammonium halides. In some particular embodiments, suitable cationic halogen containing compounds comprise, but are not limited to, cetylpyridinium chloride (CPC), cetyltrimethylammonium chloride, cetyl-

Baker (Ex. 1006) 17:5 and 17:24-27.

The present invention also provides non-toxic, non-irritant, a composition comprising an oil-in-water emulsion, said oil-in-water emulsion comprising a quaternary ammonium compound, wherein said oil-in-water emulsion is

...

N,N-Dimethyl-2-hydroxypropylammonium chloride polymer; n-alkyl dimethyl benzyl ammonium chloride; n-alkyl

Baker (Ex. 1006) 6:64-66 and 7:1-2.

Petitioner has established Baker discloses Claim 2[d]

2[d] At least one biocidal agent

Baker (Ex. 1006) 25:28-29, 15:55, 16:38-45, and 16:50-54; Petition (Paper 2), 31-32; Dr. Park Dec. (Ex. 1002) ¶¶207-214.

In some embodiments of the present invention, the inventive formulations comprise from about 4 to 8 vol. % of TRITON X-100, from about 5 to 8 vol. % of TBP, about 30 to 70 vol. % of oil (e.g., soybean or olive oil), and about 0 to 30 vol. % of aqueous phase (e.g., DiH_2O or PBS). Additionally, certain of these embodiments further comprise about 1 vol. % of CPC, about 1 vol. % of benzalkonium chloride, about 1 vol. % cetylridinium bromide, about 1

Baker (Ex. 1006) 25:28-29.

organic phosphate based solvents or alcohols. In preferred embodiments, the organic phosphate based solvents include, but are not limited to, dialkyl- and trialkyl phosphates (e.g., tri-n-butyl phosphate [TBP]) in any combination. A particu-

Baker (Ex. 1006) 15:55.

TWEEN 60 (polyoxyethylenesorbitan monostearate), together with TWEEN 20, TWEEN 40 and TWEEN 80, comprise polysorbates that are used as emulsifiers in a number of pharmaceutical compositions. In some embodiments of the present invention, these compounds are also used as co-components with adjuvants. TWEEN surfactants also appear to have virucidal effects on lipid-enveloped viruses (See e.g., Eriksson et al., Blood Coagulation and

Baker (Ex. 1006) 16:38-45.

X-200), and TYLOXAPOL. TRITON X-100 is a strong non-ionic detergent and dispersing agent widely used to extract lipids and proteins from biological structures. It also has virucidal effect against broad spectrum of enveloped viruses (See e.g., Maha and Igarashi, Southeast Asian J.

Baker (Ex. 1006) 16:50-54.

Petitioner has established Baker discloses Claim 2[e]

2[e] And wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film

Baker (Ex. 1006) 7:1-2, 17:5-41, and 36:31-33; Petition (Paper 2), 32; Dr. Park Dec. (Ex. 1002) ¶¶220 and 222.

D. Cationic Halogen Containing Compounds

In some embodiments, the compositions of the present invention further comprise a cationic halogen containing compound (e.g., from about 0.5 to 1.0 wt. % or more, based

...

trimethylammonium halides. In some particular embodiments, suitable cationic halogen containing compounds comprise, but are not limited to, cetylpyridinium chloride (CPC), cetyltrimethylammonium chloride, cetyl-

Baker (Ex. 1006) 17:5 and 17:24-27.

7

N,N-Dimethyl-2-hydroxypropylammonium chloride polymer; n-alkyl dimethyl benzyl ammonium chloride; n-alkyl

Baker (Ex. 1006) 7:1-2.

For topical applications, the pharmaceutically acceptable carrier may take the form of a liquid, cream, foam, lotion, or gel, and may additionally comprise organic solvents, emulsifiers, gelling agents, moisturizers, stabilizers, surfactants, wetting agents, preservatives, time release agents, and minor amounts of humectants, sequestering agents, dyes, perfumes, and other components commonly employed in pharmaceutical compositions for topical administration.

Baker (Ex. 1006) 36:31-33

220. 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.

...

a POSITA would understand that cationic agents inherently attract negatively-charged particulate matter. Alternatively, a POSITA would be motivated per

Dr. Park Dec. (Ex. 1002) ¶¶220 and 222.

Petitioner has established Baker discloses Claim 2[f];

2[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

Baker (Ex. 1006) 36:31-33 and 17:5; 17:24-27; Petition (Paper 2), 33-34; Dr. Park Dec. (Ex. 1002) ¶¶223-232.

For topical applications, the pharmaceutically acceptable carrier may take the form of a liquid, cream, foam, lotion, or gel, and may additionally comprise organic solvents, emulsifiers, gelling agents, moisturizers, stabilizers, 5 surfactants, wetting agents, preservatives, time release agents, and minor amounts of humectants, sequestering agents, dyes, perfumes, and other components commonly employed in pharmaceutical compositions for topical administration.

Baker (Ex. 1006) 36:31-33.

D. Cationic Halogen Containing Compounds

In some embodiments, the compositions of the present invention further comprise a cationic halogen containing compound (e.g., from about 0.5 to 1.0 wt. % or more, based

...

trimethylammonium halides. In some particular embodiments, suitable cationic halogen containing compounds comprise, but are not limited to, cetylpyridinium chloride (CPC), cetyltrimethylammonium chloride, cetyl-

Baker (Ex. 1006) 17:5; 17:24-27.

Petitioner has established Baker discloses Claim 2[f] (cont'd)

2[f] ... and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film

Baker (Ex. 1006) 36:31-33; Petition (Paper 2), 33-34; Dr. Park Dec. (Ex. 1002) ¶¶223-232.

For topical applications, the pharmaceutically acceptable carrier may take the form of a liquid, cream, foam, lotion, or gel, and may additionally comprise organic solvents, emulsifiers, gelling agents, moisturizers, stabilizers, surfactants, wetting agents, preservatives, time release agents, and minor amounts of humectants, sequestering agents, dyes, perfumes, and other components commonly employed in pharmaceutical compositions for topical administration.

Baker (Ex. 1006) 36:31-33

ATB-T60		Slightly less effective than ATB-X100;
5%	Tween 60	
8%	Tributyl Phosphate	
64%	Soybean Oil	Effective against enveloped viruses, all Gram positive bacteria, all Gram negative bacteria and fungi
1%	CPC	
22%	DiH2O	

Baker (Ex. 1006) FIG. 29A

Baker (Ex. 1006) FIG. 29E

Emulsion Formulas		Result
90% ATB-T22E/GE		Effective against enveloped viruses, all Gram positive bacteria, all Gram negative bacteria and fungi; Increased safety for oral uptake
1.8%	Triton X-100	
1.8%	Tyloxapol	
7.2%	Ethanol (200 Proof)	
57.6%	Soybean Oil	
0.9%	CPC	
0.09%	Peppermint Oil	
5 mM	Inosine	
5 mM	L-Alanine	
10 mM	Ammonium Chloride	
1 mM	Sodium Phosphate	
13 mM	Sodium Chloride	
30.61%	DiH2O	

ATB-X		Effective against enveloped viruses, all Gram positive bacteria, all Gram negative bacteria and fungi;
5%	Triton X-100	
5%	Tributyl Phosphate	
40%	Soybean Oil	
1%	CPC	
49%	DiH2O	

Baker (Ex. 1006) FIG. 29A

ATB Tween 20 E		Effective against all Gram negative bacteria.
5%	Tween 20	
1%	CPC	
64%	Soybean Oil	
8%	Ethanol	
22%	DiH2O	

Baker (Ex. 1006) FIG. 29E

Petitioner has established Baker discloses Claim 2[g]

2[g] c) inactivates the particulate matter and renders said particulate matter harmless.

Baker (Ex. 1006) 16:38-54; Petition (Paper 2), 34-35 ; Dr. Park Dec. (Ex. 1002) ¶¶233-236.

TWEEN 60 (polyoxyethylenesorbitan monostearate), together with TWEEN 20, TWEEN 40 and TWEEN 80, comprise polysorbates that are used as emulsifiers in a number of pharmaceutical compositions. In some embodiments of the present invention, these compounds are also used as co-components with adjuvants. TWEEN surfactants also appear to have virucidal effects on lipid-enveloped viruses (See e.g., Eriksson et al., Blood Coagulation and Fibrinolysis 5 (Suppl. 3):S37-S44 [1994]).

Baker (Ex. 1006) 16:38-54.

Petitioner has established Baker anticipates Claim 2

Petitioner has established Baker anticipates Claim 3

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

Baker (Ex. 1006) 6:64-66 and 7:1-2; Petition (Paper 2), 35-36; Dr. Park Dec. (Ex. 1002) ¶¶238-240.

The present invention also provides non-toxic, non-irritant, a composition comprising an oil-in-water emulsion, said oil-in-water emulsion comprising a quaternary ammonium compound, wherein said oil-in-water emulsion is

...

N,N-Dimethyl-2-hydroxypropylammonium chloride polymer; n-alkyl dimethyl benzyl ammonium chloride; n-alkyl

Baker (Ex. 1006) 6:64-66; 7:1-2

Petitioner has established Baker anticipates Claim 1

'802 Patent (Ex. 1001) 10:19-48; Petition (Paper 2), 36-39.

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.

'802 Patent (Ex. 1001) 10:19-33.

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.

'802 Patent (Ex. 1001) 10:34-48.

Petitioner has established Baker anticipates Claim 8

'802 Patent 11:1-7; Baker (Ex. 1006) 6:64-66 and 7:1-2; Petition (Paper 2), 39-40; Dr. Park Dec. (Ex. 1002) ¶¶267-272.

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

'802 Patent 11:1-7.

The present invention also provides non-toxic, non-irritant, a composition comprising an oil-in-water emulsion, said oil-in-water emulsion comprising a quaternary ammonium compound, wherein said oil-in-water emulsion is

...

N,N-Dimethyl-2-hydroxypropylammonium chloride polymer; n-alkyl dimethyl benzyl ammonium chloride; n-alkyl

Baker (Ex. 1006) 6:64-66 and 7:1-2.

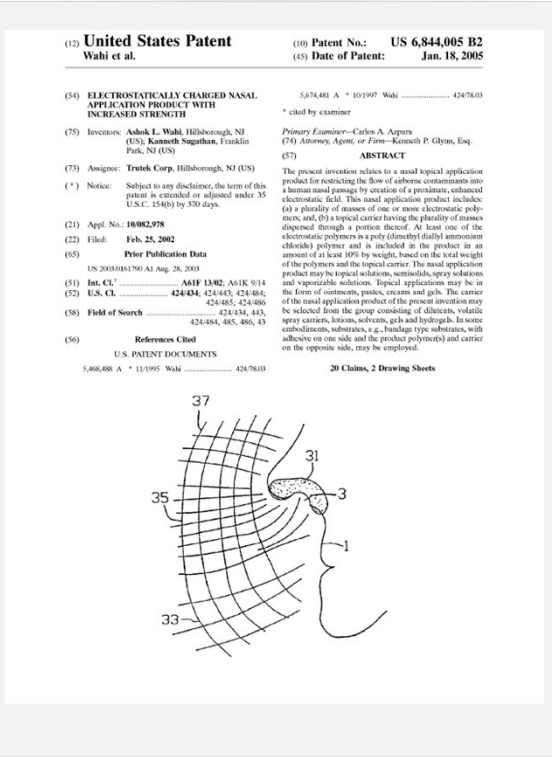


Ground 3: Claims 2, 3, 1, and 8 are anticipated by Wahi '005

Petitioner has established Wahi '005 discloses Claim 2[a]

2[a] A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation

Wahi '005 (Ex. 1007) front page and 1:21-26; Petition (Paper 2), 41; Dr. Park Dec. (Ex. 1002) ¶¶274-277.



1. Field of the Invention

The present invention relates to 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.

Wahi '005 (Ex. 1007) 1:21-26.

Wahi '005 (Ex. 1007) front page.

Petitioner has established Wahi '005 discloses Claim 2[b]

2[b] Wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film,

Wahi '005 (Ex. 1007) 2:22-26; Petition (Paper 2), 41; Dr. Park Dec. (Ex. 1002) ¶¶278-281.

The nasal application product of the present invention may be selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels.

Wahi '005 (Ex. 1007) 2:22-26.

The present invention relates to electrostatically charged topical nasal application products which have been developed and improved since their original development as set forth in two previously issued United States patents. For this reason, the entire specification and claims are incorporated herein in their entirety by reference, as to U.S. Pat. No. 5,468,488, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT AND METHOD" issued to Ashok L. Wahi, inventor, on Nov. 21, 1995, and U.S. Pat. No. 5,674,481, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT" ISSUED TO Ashok L. Wahi on Oct. 7, 1997.

Wahi '005 (Ex. 1007) 1:6-18.

EXAMPLE #3

1. Deionized water	89.9
2. Celquat SC 240 C	4.0
3. Agestat 400	6.0
4. Potassium Sorbate	0.1
	100.0

Generic/Chemical name of the above ingredients are:
Celquat SC 240 C; Quarternary Cellulosic Derivative
Polawax; Fatty Alcohol. Polysorbate Blend
Agequat 400; Poly(Dimethyl Diallyl Ammonium Chloride)

Wahi '481 (Ex. 1009) 6:13-26.

Each patient was provided with the gel along with directions for use which included that a very thin film should be applied with the finger on the outside of the nostril and above the upper lip and to repeat the application four times a day. In the case of a runny nose, the patient was supposed

Wahi '481 (Ex. 1009) 6:52-55.

Petitioner has established Wahi '005 discloses Claim 2[c]

2[c] Said formulation comprising at least one cationic agent and

Wahi '005 (Ex. 1007) 4:25-33; Petition (Paper 2), 42; Dr. Park Dec. (Ex. 1002) ¶¶283-287.

Agequat 400; Poly(Dimethyl Diallyl Ammonium Chloride)
Arlacel 165; Glycerol Monostearate and Polyethylene Stear-
ate
Necon LO; A surfactant
Tween 60; Polysorbate
Propylene Glycol; 1,2-Propane Diol
Celquat SC 240C is a polyquaternary ammonium cellulose
manufactured by National Starch and Chemical Company

Wahi '005 (Ex. 1007) 4:25-33.

Petitioner has established Wahi '005 discloses Claim 2[d]

2[d] At least one biocidic agent

Wahi '005 (Ex. 1007) 4:47-62; Petition (Paper 2), 42; Dr. Park Dec. (Ex. 1002) ¶¶288-292.

EXAMPLE #4		
Ingredient	Weight (Kg/15 Kg)	% w/w
1. Polawax (5% dispersion)	0.7500	5.00
2. Propylene Glycol	0.3000	2.00
3. Celquat SC-240C	0.6000	4.00
4. Agequat 400	1.6500	11.00
5. Methylparaben	0.0300	0.20
6. Propylparaben	0.0150	0.10
7. Tetrasodium Edetate	0.0075	0.05
8. Arlacel 165	0.1500	1.00
9. Tween 60	0.0150	0.10
10. Gerinall-II	0.0450	0.30
11. Water	11.4375	76.25
TOTAL	15.0000	100.00

Wahi '005 (Ex. 1007) 4:47-62.

Petitioner has established Wahi '005 discloses Claim 2[e]

2[e] And wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film

Wahi '005 (Ex. 1007) 4:47-62 and 2:22-26; Petition (Paper 2), 43; Dr. Park Dec. (Ex. 1002) ¶¶293-299.

1. 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, wherein the nasal application product consists essentially of:

- (a) a plurality of masses of one or more electrostatic polymers; and,
- (b) a topical carrier having said plurality of masses dispersed through a portion thereof;

Wahi '005 (Ex. 1007) 5:39-53.

Each patient was provided with the gel along with directions for use which included that a very thin film should be applied with the finger on the outside of the nostril and above the upper lip and to repeat the application four times a day. In the case of a runny nose, the patient was supposed

Wahi '481 (Ex. 1009) 6:52-55.

The nasal application product of the present invention may be selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels.

Wahi '005 (Ex. 1007) 2:22-26.

Petitioner has established Wahi '005 discloses Claim 2[f];

2[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

Wahi '005 (Ex. 1007) 2:9-18, 2:25-26; Petition (Paper 2), 44-45; Dr. Park Dec. (Ex. 1002) ¶¶300-308.

SUMMARY OF THE INVENTION

The present invention relates to 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. This nasal application product includes: (a) a plurality of masses of one or more electrostatic polymers; and, (b) a topical carrier having the plurality of masses dispersed through a portion thereof. In the present invention, at least one of the electrostatic polymers is a poly (dimethyl diallyl ammonium chloride) polymer and is included in the product in an amount of at least 10% by weight, based on the total weight of the plurality of

Wahi '005 (Ex. 1007) 2:9-18.

The nasal application product of the present invention may be selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels.

Wahi '005 (Ex. 1007) 2:25-26.

Petitioner has established Wahi '005 discloses Claim 2[f] (cont'd)

2[f] ... and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film

Wahi '005 (Ex. 1007) 2:25-26.; Petition (Paper 2), 44-45; Dr. Park Dec. (Ex. 1002) ¶¶300-308.

EXAMPLE #1		
Ingredient	% age composition by weight	
1. Deionized Water	75.9	
2. Potassium Sorbate	0.1	
3. Celquat SC 240 C	3.9	
4. Polawax 5% in water	4.9	
5. Agequat 400	12.9	
6. Arlacel 165	1.0	
7. Tween 60	0.1	
8. Propylene Glycol	1.2	
	100.0	

The nasal application product of the present invention may be selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels.

Wahi '005 (Ex. 1007) 2:25-26.

Wahi '005 (Ex. 1007) 3:44-58.

EXAMPLE #2		
Ingredient	% age composition	
1. Deionized water	73.5	
2. Celquat SC 240 C	3.8	
-continued		
Ingredient	% age composition	
3. Agequat 400	12.6	
4. Polawax 5% in water	9.5	
5. Potassium Sorbate	0.1	
6. Necon LO	0.5	
	100.0	

EXAMPLE #3		
1. Deionized water	84.9	
2. Celquat SC 240 C	4.0	
3. Agequat 400	11.0	
4. Potassium Sorbate	0.1	
	100.0	

Wahi '005 (Ex. 1007) 4:12-20.

EXAMPLE #4		
Ingredient	Weight (Kg/15 Kg)	% w/w
1. Polawax (5% dispersion)	0.7500	5.00
2. Propylene Glycol	0.3000	2.00
3. Celquat SC-240C	0.6000	4.00
4. Agequat 400	1.6500	11.00
5. Methylparaben	0.0300	0.20
6. Propylparaben	0.0150	0.10
7. Tetrasodium Edetate	0.0075	0.05
8. Arlacel 165	0.1500	1.00
9. Tween 60	0.0150	0.10
10. Gerinall-II	0.0450	0.30
11. Water	11.4375	76.25
TOTAL	15.0000	100.00

Wahi '005 (Ex. 1007) 4:47-62.

Wahi '005 (Ex. 1007) 3:60-4:9.

Petitioner has established Wahi '005 discloses Claim 2[g]

2[g] c) inactivates the particulate matter and renders said particulate matter harmless

Wahi '005 (Ex. 1007) 4:46-63;
Petition (Paper 2), 45; Dr. Park Dec. (Ex. 1002) ¶¶309-312.

EXAMPLE #4		
Ingredient	Weight (Kg/15 Kg)	% w/w
1. Polawax (5% dispersion)	0.7500	5.00
2. Propylene Glycol	0.3000	2.00
3. Celquat SC-240C	0.6000	4.00
4. Agequat 400	1.6500	11.00
5. Methylparaben	0.0300	0.20
6. Propylparaben	0.0150	0.10
7. Tetrasodium Edetate	0.0075	0.05
8. Arlacel 165	0.1500	1.00
9. Tween 60	0.0150	0.10
10. Gerinall-II	0.0450	0.30
11. Water	11.4375	76.25
TOTAL	15.0000	100.00

Wahi '005 (Ex. 1007) 4:46-63.

Petitioner has established Wahi '005 anticipates Claim 2

Petitioner has established Wahi '005 anticipates Claim 3

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

Wahi '005 (Ex. 1007) 4:46-63;
Petition (Paper 2), 46; Dr. Park
Dec. (Ex. 1002) ¶¶314-316.

EXAMPLE #4		
Ingredient	Weight (Kg/15 Kg)	% w/w
1. Polawax (5% dispersion)	0.7500	5.00
2. Propylene Glycol	0.3000	2.00
3. Celquat SC-240C	0.6000	4.00
4. Agequat 400	1.6500	11.00
5. Methylparaben	0.0300	0.20
6. Propylparaben	0.0150	0.10
7. Tetrasodium Edetate	0.0075	0.05
8. Arlacel 165	0.1500	1.00
9. Tween 60	0.0150	0.10
10. Gerinall-II	0.0450	0.30
11. Water	11.4375	76.25
TOTAL	15.0000	100.00

Wahi '005 (Ex. 1007) 4:46-63.

Petitioner has established Wahi '005 anticipates Claim 1

'802 Patent (Ex. 1001) 10:19-48; Petition (Paper 2), 46-49.

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.

'802 Patent (Ex. 1001) 10:19-33.

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.

'802 Patent (Ex. 1001) 10:34-48.

Petitioner has established Wahi '005 anticipates Claim 8

Wahi '005 (Ex. 1007) 4:46-63; Petition (Paper 2), 50; Dr. Park Dec. (Ex. 1002) ¶¶348-354.

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.

EXAMPLE #4		
Ingredient	Weight (Kg/15 Kg)	% w/w
1. Polawax (5% dispersion)	0.7500	5.00
2. Propylene Glycol	0.3000	2.00
3. Celquat SC-240C	0.6000	4.00
4. Agequat 400	1.6500	11.00
5. Methylparaben	0.0300	0.20
6. Propylparaben	0.0150	0.10
7. Tetrasodium Edetate	0.0075	0.05
8. Arlacel 165	0.1500	1.00
9. Tween 60	0.0150	0.10
10. Gerinall-II	0.0450	0.30
11. Water	11.4375	76.25
TOTAL	15.0000	100.00

Wahi '005 (Ex. 1007) 4:46-63.

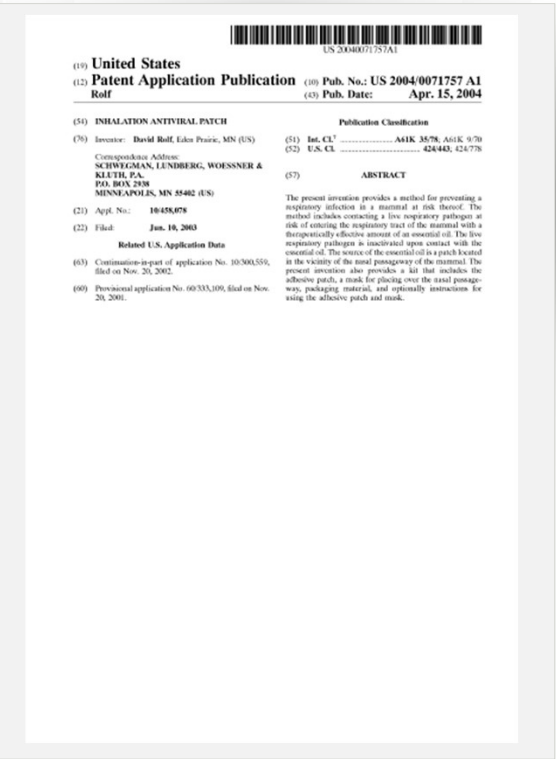


Ground 4: Claims 2, 1, and 8 are anticipated by Rolf

Petitioner has established Rolf discloses Claim 2[a]

2[a] A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation

Rolf (Ex. 1008) at front page, [0148], and [0020]; Petition (Paper 2), 51-52; Dr. Park Dec. (Ex. 1002) ¶¶356-362.



Rolf (Ex. 1008), front page

[0148] Suitable preservatives 7 include, e.g., quat-15, parabens, dichlorobenzyl alcohol, ethylene diamine

[0020] The present invention provides a method for preventing a respiratory infection in a mammal at risk thereof. The method includes contacting a live respiratory pathogen at risk of entering the respiratory tract of the mammal with a therapeutically effective amount of an essential oil, such that the live respiratory pathogen is inactivated upon contact with the essential oil, wherein the source of the essential oil is a patch located in the vicinity of the nasal passageway of the mammal.

Petitioner has established Rolf discloses Claim 2[b]

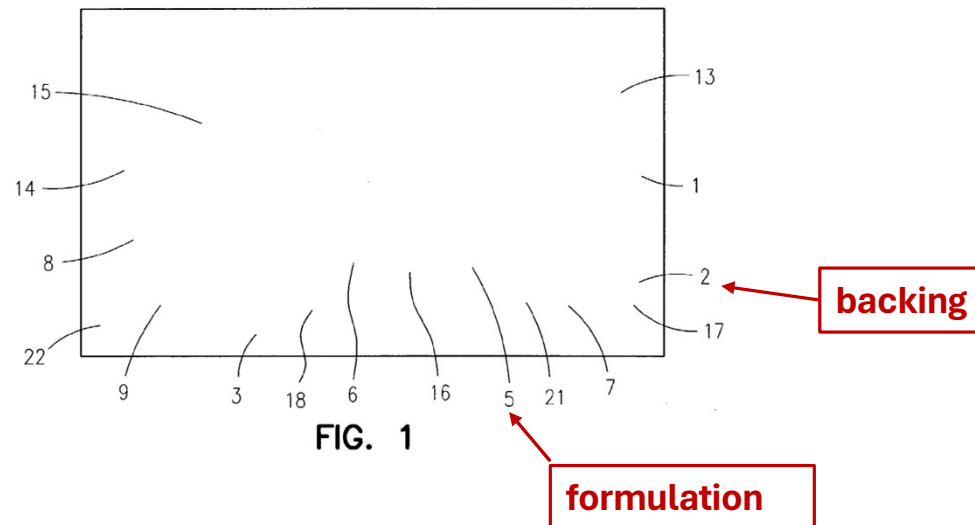
2[b] Wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film,

Rolf (Ex. 1008) at [0174], [0041], and FIG. 1; Petition (Paper 2), 52-53; Dr. Park Dec. (Ex. 1002) ¶¶364-368.

[0174] The adhesive skin patch **1** can be applied to the region between the upper lip and the nose of a patient. Such

greater incidence of skin irritation. The relatively low occlusiveness of the present invention can be envisioned to be a special adhesive ointment or gel which is water-breathable, such as a water washable or water soluble ointment or gel.

Rolf (Ex. 1008) at [0041].



Petitioner has established Rolf discloses Claim 2[c]

2[c] Said formulation comprising at least one cationic agent and

Rolf (Ex. 1008) at [0148]; Petition (Paper 2), 53; Dr. Park Dec. (Ex. 1002) ¶¶370-371.

[0148] Suitable preservatives 7 include, e.g., quat-15, parabens, dichlorobenzyl alcohol, ethylene diamine

Petitioner has established Rolf discloses Claim 2[d]

2[d]	at least one biocidal agent
------	-----------------------------

Rolf (Ex. 1008) at [0065] and [0020]; Petition (Paper 2), 53; Dr. Park Dec. (Ex. 1002) ¶¶372-376.

[0065] In one specific embodiment of the present invention, the essential oil 15 is not: methyl salicylate, menthol, camphor, eucalyptus oil, spearmint oil, or a combination thereof. In another specific embodiment of the present invention, the formulation 5 of the present invention can include any one or more of methyl salicylate, menthol, camphor, eucalyptus oil, or spearmint oil; provided another essential oil 15 is included in the formulation 5.

[0020] The present invention provides a method for preventing a respiratory infection in a mammal at risk thereof. The method includes contacting a live respiratory pathogen at risk of entering the respiratory tract of the mammal with a therapeutically effective amount of an essential oil, such that the live respiratory pathogen is inactivated upon contact with the essential oil, wherein the source of the essential oil is a patch located in the vicinity of the nasal passageway of the mammal.

Petitioner has established Rolf discloses Claim 2[e]

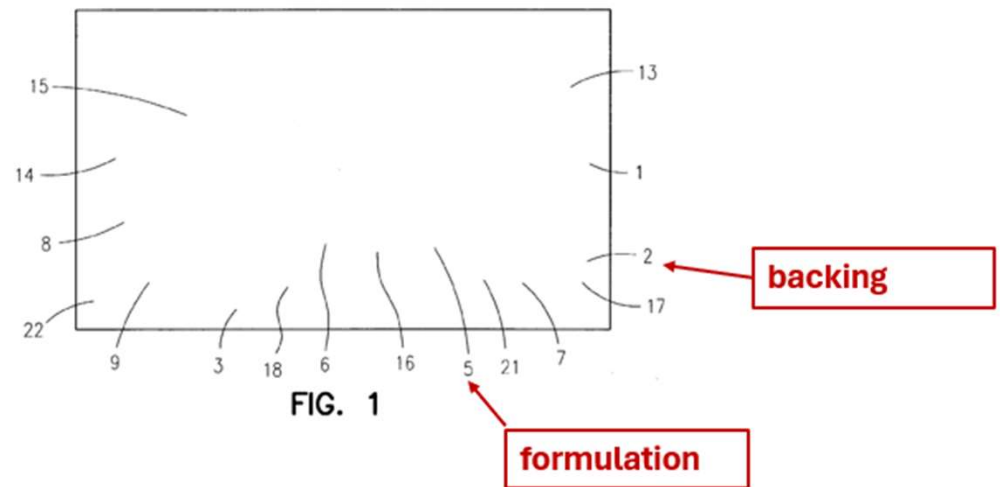
2[e] and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film

Rolf (Ex. 1008) at [0148], [0041], and FIG. 1; Petition (Paper 2), 54; Dr. Park Dec. (Ex. 1002) ¶¶377-381.

[0148] Suitable preservatives 7 include, e.g., quat-15, parabens, dichlorobenzyl alcohol, ethylene diamine

greater incidence of skin irritation. The relatively low occlusiveness of the present invention can be envisioned to be a special adhesive ointment or gel which is water-breathable, such as a water washable or water soluble ointment or gel.

Rolf (Ex. 1008) at [0041].



Petitioner has established Rolf discloses Claim 2[f]

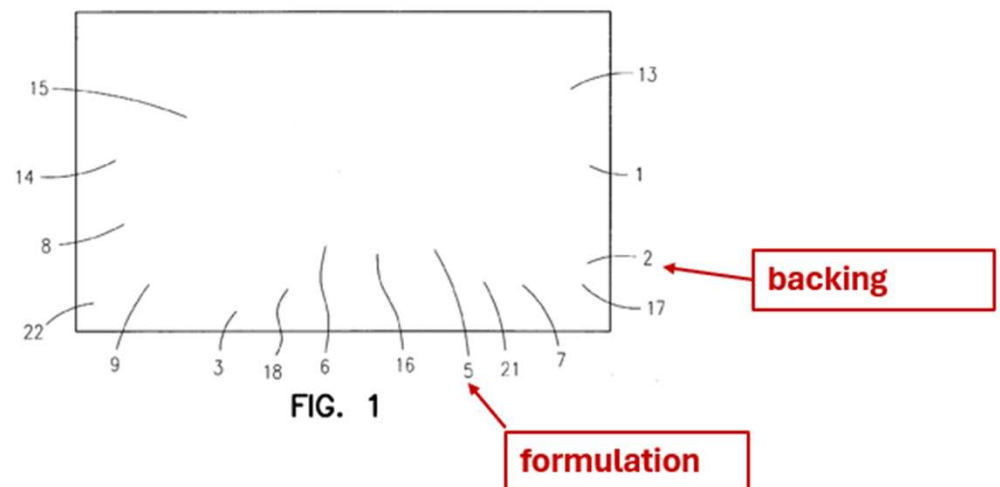
2[f] b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue

Rolf (Ex. 1008) at [0024], [0148], and FIG. 1; Petition (Paper 2), 54-56; Dr. Park Dec. (Ex. 1002) ¶¶382-394.

[0148] Suitable preservatives 7 include, e.g., quat-15, parabens, dichlorobenzyl alcohol, ethylene diamine

greater incidence of skin irritation. The relatively low occlusiveness of the present invention can be envisioned to be a special adhesive ointment or gel which is water-breathable, such as a water washable or water soluble ointment or gel.

Rolf (Ex. 1008) at [0041].



Petitioner has established Rolf discloses Claim 2[f] (cont'd)

2[f] ... and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film

Rolf (Ex. 1008) at [0041], [0273], and [0275]; Petition (Paper 2), 54-56; Dr. Park Dec. (Ex. 1002) ¶¶382-394.

greater incidence of skin irritation. The relatively low occlusiveness of the present invention can be envisioned to be a special adhesive ointment or gel which is water-breathable, such as a water washable or water soluble ointment or gel.

Rolf (Ex. 1008) at [0041].

EXAMPLES

Example 1

[0268]

	Range %	Typical %
Glycerin	20-70	50
Karaya	15-50	27
aloe vera	0.1-10	0.97
-continued		
	Range %	Typical %
acrylic emulsion adhesive	2-30	14
water	1-20	2
natural peppermint oil	1-5	1
eucalyptus oil	1-5	1
Spanish rosemary	1-5	2
sweet basil	1-5	2
Q-15	0.01-0.5	0.03

Example 6

[0273]

	Range %	Typical %
Glycerin	20-70	50
Polyvinyl alcohol	10-50	17
Gelatin	1-20	4
aloe vera	0.1-10	0.97
acrylic emulsion adhesive	2-30	14
water	1-20	8
bergamot	1-5	1
lavender	1-5	1
clary sage	1-5	2
sweet marjoram	1-5	2
Q-15	0.01-0.5	0.03

Example 8

[0275]

	Range %	Typical %
Glycerin	20-70	50
Polyvinyl alcohol	10-40	10
-continued		
	Range %	Typical %
Gamma Cyclodextrin	1-10	5
Polyacrylamide	5-30	12
aloe vera	0.1-10	0.97
acrylic emulsion adhesive	2-30	14
water	1-20	2
natural peppermint oil	1-5	1
bergamot	1-5	1
Spanish rosemary	1-5	2
basil	1-5	2
Q-15	0.01-0.5	0.03

Example 16

[0283]

	Range %	Typical %
Glycerin	20-70	50
polyacrylamide	15-50	17
malto dextrin	5-25	10
aloe vera	0.1-10	0.97
gelatin	1-20	4
water	1-20	12
camphor	1-5	1
menthol	1-5	1
myrrh	1-5	2
pine needle	1-5	2
Q-15	0.01-0.5	0.03

Petitioner has established Rolf discloses Claim 2[g]

2[g] c) inactivates the particulate matter and renders said particulate matter harmless

Rolf (Ex. 1008) at [0076] and [0077]; Petition (Paper 2), 56; Dr. Park Dec. (Ex. 1002) ¶¶395-399.

[0076] The essential oil **15** can be present in any appropriate and suitable amount, provided:

[0077] (1) the amount of essential oil **15** has the desired therapeutic and/or prophylactic properties (e.g., the essential oil **15** effectively kills or inactivates an airborne pathogen, respiratory tract pathogen, or a combination thereof); and

Petitioner has established Rolf anticipates Claim 2

Petitioner has established Rolf anticipates Claim 1

'802 Patent (Ex. 1001) 10:19-48; Petition (Paper 2), 57-59.

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.

'802 Patent (Ex. 1001) 10:19-33.

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.

'802 Patent (Ex. 1001) 10:34-48.

Petitioner has established Rolf anticipates Claim 8

Rolf (Ex. 1008) at [0020], [0148], and [0065]; Petition (Paper 2), 60; Dr. Park Dec. (Ex. 1002) ¶¶424-429.

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

'802 Patent (Ex. 1001) 11:1-7.

[0020] The present invention provides a method for preventing a respiratory infection in a mammal at risk thereof. The method includes contacting a live respiratory pathogen at risk of entering the respiratory tract of the mammal with a therapeutically effective amount of an essential oil, such that the live respiratory pathogen is inactivated upon contact with the essential oil, wherein the source of the essential oil is a patch located in the vicinity of the nasal passageway of the mammal.

Rolf (Ex. 1008) at [0020].

[0148] Suitable preservatives 7 include, e.g., quat-15, parabens, dichlorobenzyl alcohol, ethylene diamine

Rolf (Ex. 1008) at [0148].

[0065] In one specific embodiment of the present invention, the essential oil 15 is not: methyl salicylate, menthol, camphor, eucalyptus oil, spearmint oil, or a combination thereof. In another specific embodiment of the present invention, the formulation 5 of the present invention can include any one or more of methyl salicylate, menthol, camphor, eucalyptus oil, or spearmint oil; provided another essential oil 15 is included in the formulation 5.

Rolf (Ex. 1008) at [0148].



Motion to Strike and Motion to Exclude Evidence

Patent Owner’s evidence should be struck and excluded from the record

Declaration of Ashok Wahi (Ex. 2003), cover page; Motion to Exclude (Paper 22), 1; Motion to Strike (Paper 22), 2.

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. IPR-2024-00711

DECLARATION OF ASHOK WAHI

I. STATEMENT OF FACTS

As summarized in Petitioner’s Motion to Strike (Paper 19), Patent Owner submitted new Exhibits 2003-2007 with its Sur-Reply (Paper 13) to support its contentions of commercial success, in violation of 37 C.F.R. § 42.23(b). These exhibits are as follows:

- Exhibit 2003, which is presented as a Declaration of Ashok Wahi.
- Exhibit 2004, which is presented as Representative NasalGuard Products.
- Exhibit 2005, which is presented as How to Use NasalGuard.
- Exhibit 2006, which is presented as a Clinical Study.
- Exhibit 2007, which is presented as a listing of website where products allegedly embodying U.S. Patent No. 8,163,802 (“the ‘802 Patent”) can be bought.

Under the current rules governing PTAB trials, evidence is not to be submitted with a sur-reply: “A sur-reply ... **may not be accompanied by new evidence** other than deposition transcripts of the cross-examination of any reply witness.” 37 C.F.R. 42.23(b) (emphasis added). One reason for the rule prohibiting new arguments or evidence with a sur-reply is simple: that “**Petitioner lacks an opportunity to respond to new evidence submitted with a sur-reply.**” *Intel Corp. v. ParkerVision, Inc.*, IPR2020-01265, Paper 44, at 74 (Jan. 21, 2022) (granting motion to exclude evidence submitted with sur-reply), *aff’d by ParkerVision v. Vidal*, 88 F.4th 969 (Fed. Cir. 2023).

Motion to Strike (Paper 19), 2.

Declaration of Ashok Wahi (Ex. 2003), cover page.

Motion to Exclude (Paper 22), 1.

LATE, VIOLATES FED. RULES OF EVIDENCE

Patent Owner offered Mr. Wahi for deposition after the Scheduling Order's deadline

Scheduling Order (Paper 8), 4.

5. Cross-Examination

Except as the parties might otherwise agree, for each due date:
Cross-examination ordinarily takes place after any supplemental evidence is due. 37 C.F.R. § 42.53(d)(2).

Cross-examination ordinarily ends no later than a week before the filing date for any paper in which the cross-examination testimony is expected to be used. *Id.*

Scheduling Order (Paper 8), 4.

Patent Owner's late production of evidence was avoidable; Patent Owner admitted this

Patent Owner's Response to Petitioner's Motion to Strike, 4.

The exhibits which are the subject of Petitioner's motion could have been presented in Patent Owner's response to the petition. Instead, they were submitted in the sur-reply to rebut the erroneous allegation by Petitioner that "Patent Owner has failed to establish the required nexus between the alleged success and the alleged invention in the '802 Patent." The exhibits were not previously submitted because Patent Owner's Attorney believed that the statements of fact sufficiently established commercial success of the patented product.

Patent Owner's Response to Petitioner's Motion to Strike, 4.



Ground 5: Claim 3 is rendered obvious by Rolf in view of Wahi '005

Claim 3 depends from Claim 2

Petitioner has established Rolf anticipates Claim 2

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.

'802 Patent (Ex. 1001) 10:34-48.

Petitioner has established Claim 3 is obvious by Rolf in view of Wahi '005

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

Rolf (Ex. 1008) at [0253]; Wahi '005 (Ex. 1007) 4:46-63; Petition (Paper 2), 61; Dr. Park Dec. (Ex. 1002) ¶¶431-440.

[0253] [74] Another embodiment of the present invention provides the method of embodiment [72], wherein the antimicrobial agent is quat-15.

Rolf (Ex. 1008) at [0253].

EXAMPLE #4		
Ingredient	Weight (Kg/15 Kg)	% w/w
1. Polawax (5% dispersion)	0.7500	5.00
2. Propylene Glycol	0.3000	2.00
3. Celquat SC-240C	0.6000	4.00
4. Agequat 400	1.6500	11.00
5. Methylparaben	0.0300	0.20
6. Propylparaben	0.0150	0.10
7. Tetrasodium Edetate	0.0075	0.05
8. Arlacel 165	0.1500	1.00
9. Tween 60	0.0150	0.10
10. Gerinall-II	0.0450	0.30
11. Water	11.4375	76.25
TOTAL	15.0000	100.00

Wahi '005 (Ex. 1007) 4:46-63.

Celquat SC 240C is a polyquaternary ammonium cellulose manufactured by National Starch and Chemical Company (New Jersey). Necon LO is dimethyl lauramine oleate manu-

Wahi '005 (Ex. 1007) 4:31-32.

Petitioner has established a reasonable expectation of success combining Rolf and Wahi '005

Rolf (Ex. 1008) at [0020]; Wahi '005 (Ex. 1007) Abstract; Petition (Paper 2), 61; Dr. Park Dec. (Ex. 1002) ¶437.

[0020] The present invention provides a method for preventing a respiratory infection in a mammal at risk thereof. The method includes contacting a live respiratory pathogen at risk of entering the respiratory tract of the mammal with a therapeutically effective amount of an essential oil, such that the live respiratory pathogen is inactivated upon contact with the essential oil, wherein the source of the essential oil is a patch located in the vicinity of the nasal passageway of the mammal.

Rolf (Ex. 1008) at [0020].

(57)

ABSTRACT

The present invention relates to a nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of a proximate, enhanced electrostatic field. This nasal application product includes:

Wahi '005 (Ex. 1007) Abstract.

437. 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 and would have a reasonable expectation of success in doing so. (Ex. 1008 at [0020] and Ex. 1007 at Abstract.)

Dr. Park Dec. (Ex. 1002) ¶437.

Petitioner has established Claim 3 is obvious by Rolf in view of Wahi '005



Secondary Considerations of Nonobviousness

Patent Owner has not established that there is a nexus between the Patent Owner's "evidence of commercial success" and the patented invention.

Declaration of Ashok Wahi (Ex. 2003), 2.

8. Since April 24, 2012, the '802 Patent number is marked on every tube of product sold in the United States.
9. Among other online stores and venues, NasalGuard[®] is sold on the Amazon, Shopify, and Walmart website marketplaces in many countries, including the United States.
10. Since 2012, Trutek sold more than fifteen-million tubes of gel worldwide with brand names Crystal Veil, Chloraseptic, and NasalGuard[®], among others.

Declaration of Ashok Wahi (Ex. 2003), 2.

Patent Owner has not established that its evidence overcomes the *prima facie* case of obviousness

Representative NasalGuard™ Products (Ex. 2004), 2-3.



Representative NasalGuard™ Products (Ex. 2004), 2.

Representative NasalGuard™ Products (Ex. 2004), 2.

Representative NasalGuard™ Products (Ex. 2004), 3.

Representative NasalGuard™ Products (Ex. 2004), 3.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Patent Owner has not established that its evidence overcomes the *prima facie* case of obviousness

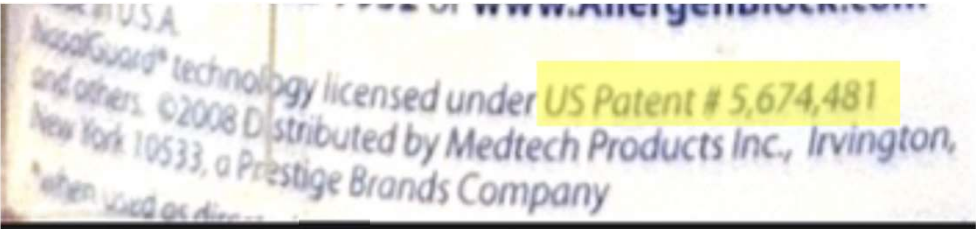
Representative NasalGuard™ Products (Ex. 2004), 2 and 4.



Representative NasalGuard™ Products (Ex. 2004), 2.



Representative NasalGuard™ Products (Ex. 2004), 4.



Representative NasalGuard™ Products (Ex. 2004), 2.



MADE IN USA

Manufactured for and Distributed by:
Trutek Europe LTD.
Northolt, UK UB5 5AR

US Patent #

- US 5, 674, 481, US 5, 468, 488
- US 6, 844, 005, US 8, 163, 802

www.NasalGuard.co.uk



CE 5 060304 630018 >

Representative NasalGuard™ Products (Ex. 2004), 4.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE



Grounds 1-4: Obviousness contentions for Claim 2, 1, 3, and 8

Petitioner has established that Chen teaches each and every element of claims 1-3 and 8.

Petitioner has established Chen renders Claim 2[e] obvious

2[e] And wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film

Petition (Paper 2), 20; Sur Reply (Paper 13), 16; Dr. Park Dec. (Ex. 1002) ¶¶44 and 130; Dr. Park Dec. (Ex. 1002) ¶¶126-130.

It is true that Chen's composition contains at least one cationic agent which would create a positively charged electrostatic field that would inherently attract some negatively charged airborne particles. It is also true that Chen's composition contains at least one biocidal agent. However, Chen does not teach the HOLD function of claims

Sur Reply (Paper 13), 16.

44. Bacteria and viruses are often negatively charged. (Ex. 1023 at 251.) Cationic agents, including QUATS, are positively charged, and therefore are electrostatically attracted to negatively-charged bacteria and viruses. (*See id.* at 250-51.)

Dr. Park Dec. (Ex. 1002) ¶44.

130. 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.

Dr. Park Dec. (Ex. 1002) ¶130.

Petitioner has established Chen renders Claim 2[f] obvious

2[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

Petition (Paper 2), 20-22; Sur Reply (Paper 13), 16; Dr. Park Dec. (Ex. 1002) ¶¶ 134 and 140.

It is true that Chen's composition contains at least one cationic agent which would create a positively charged electrostatic field that would inherently attract some negatively charged airborne particles. It is also true that Chen's composition contains at least one biocidal agent. However, Chen does not teach the HOLD function of claims

Sur Reply (Paper 13), 16.

134. Chen discloses multiple examples showing different formulations that “vary the concentration of ingredients.” (*Id.* at [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. (*Id.*) Changing the amount of cationic polymer in a composition will change the adhesion and cohesion of a formulation applied as a thin film. Cationic agents attract particulate matter and hold particulate matter in place.

140. 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. A POSITA would have a reasonable expectation of success of such modifications.

Petitioner has established that Baker teaches each and every element of claims 1-3, and 8.

Petitioner has established Baker renders Claim 2[e] obvious

2[e] And wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film

Baker (Ex. 1006) 17:5-41, 36:31-33; Petition (Paper 2), 32; Dr. Park Dec. (Ex. 1002) ¶222.

D. Cationic Halogen Containing Compounds

In some embodiments, the compositions of the present invention further comprise a cationic halogen containing compound (e.g., from about 0.5 to 1.0 wt. % or more, based

...

trimethylammonium halides. In some particular embodiments, suitable cationic halogen containing compounds comprise, but are not limited to, cetylpyridinium chloride (CPC), cetyltrimethylammonium chloride, cetyl-

Baker (Ex. 1006) 17:5; 17:24-27.

222. 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.)

Dr. Park Dec. (Ex. 1002) ¶222.

Petitioner has established Baker renders Claim 2[f] obvious

2[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

Baker (Ex. 1006) 17:5; 17:24-27; Petition (Paper 2), 33-34; Dr. Park Dec. (Ex. 1002) ¶232.

D. Cationic Halogen Containing Compounds

In some embodiments, the compositions of the present invention further comprise a cationic halogen containing compound (e.g., from about 0.5 to 1.0 wt. % or more, based

...

trimethylammonium halides. In some particular embodiments, suitable cationic halogen containing compounds comprise, but are not limited to, cetylpyridinium chloride (CPC), cetyltrimethylammonium chloride, cetyl-

Baker (Ex. 1006) 17:5; 17:24-27.

232. 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. 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.)

Dr. Park Dec. (Ex. 1002) ¶232.

Petitioner has established that Wahi '005 teaches each and every element of claims 1-3, and 8.

Petitioner has established Wahi '005 renders Claim 2[b] obvious

2[b] Wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film,

Wahi '005 (Ex. 1007) 2:22-26; Wahi '481 (Ex. 1009) 6:13-26 and 6:52-55; Petition (Paper 2), 41-2; Dr. Park Dec. (Ex. 1002) ¶282.

282. 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.

Dr. Park Dec. (Ex. 1002) ¶282.

EXAMPLE #3	
1. Deionized water	89.9
2. Celquat SC 240 C	4.0
3. Agestat 400	6.0
4. Potassium Sorbate	0.1
	100.0
Generic/Chemical name of the above ingredients are: Celquat SC 240 C; Quarternary Cellulosic Derivative Polawax; Fatty Alcohol, Polysorbate Blend Agequat 400; Poly(Dimethyl Diallyl Ammonium Chloride)	

Wahi '481 (Ex. 1009)
6:13-26.

The nasal application product of the present invention may be selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels.

Wahi '005 (Ex. 1007) 2:22-26.

Each patient was provided with the gel along with directions for use which included that a very thin film should be applied with the finger on the outside of the nostril and above the upper lip and to repeat the application four times a day. In the case of a runny nose, the patient was supposed

Wahi '481 (Ex. 1009) 6:52-55.

Petitioner has established Wahi '005 renders Claim 2[e] obvious

2[e] And wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film

Wahi '005 (Ex. 1007) 4:47-62 and 2:22-26; Wahi '481 (Ex. 1009) 6:52-55; Petition (Paper 2), 43; Dr. Park Dec. (Ex. 1002) ¶299.

1. 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, wherein the nasal application product consists essentially of:

- (a) a plurality of masses of one or more electrostatic polymers; and,
- (b) a topical carrier having said plurality of masses dispersed through a portion thereof;

Wahi '005 (Ex. 1007) 5:39-53.

Each patient was provided with the gel along with directions for use which included that a very thin film should be applied with the finger on the outside of the nostril and above the upper lip and to repeat the application four times a day. In the case of a runny nose, the patient was supposed

Wahi '481 (Ex. 1009) 6:52-55.

The nasal application product of the present invention may be selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels.

Wahi '005 (Ex. 1007) 2:22-26.

299. 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.

Dr. Park Dec. (Ex. 1002) ¶299.

Petitioner has established Wahi '005 renders Claim 2[f] obvious;

2[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 (Ex. 1007) 2:9-18, 2:25-26; Petition (Paper 2), 44-45; Dr. Park Dec. (Ex. 1002) ¶308.

SUMMARY OF THE INVENTION

The present invention relates to 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. This nasal application product includes: (a) a plurality of masses of one or more electrostatic polymers; and, (b) a topical carrier having the plurality of masses dispersed through a portion thereof. In the present invention, at least one of the electrostatic polymers is a poly (dimethyl diallyl ammonium chloride) polymer and is included in the product in an amount of at least 10% by weight, based on the total weight of the plurality of

Wahi '005 (Ex. 1007) 2:9-18.

The nasal application product of the present invention may be selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels.

Wahi '005 (Ex. 1007) 2:25-26.

308. 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's '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.

Dr. Park Dec.
(Ex. 1002) ¶308.

Petitioner has established that Rolf teaches each and every element of claims 1, 2 and 8.

Petitioner has established Rolf renders Claim 2[b] obvious

2[b] Wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film,

Rolf (Ex. 1008) at [0174], [0041], and [0024]; Petition (Paper 2), 52-53;
Dr. Park Dec. (Ex. 1002) ¶369.

[0174] The adhesive skin patch 1 can be applied to the region between the upper lip and the nose of a patient. Such

Rolf (Ex. 1008) at [0174].

greater incidence of skin irritation. The relatively low occlusiveness of the present invention can be envisioned to be a special adhesive ointment or gel which is water-breathable, such as a water washable or water soluble ointment or gel.

Rolf (Ex. 1008) at [0041].

[0024] The present invention also provides a method for inhibiting a respiratory pathogen. The method includes 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, wherein the source of the essential oil is a patch located in the vicinity of the respiratory pathogen.

Rolf (Ex. 1008) at [0024].

369. 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 at [0024].)

Dr. Park Dec. (Ex. 1002) ¶369.

Petitioner has established Rolf renders Claim 2[e] obvious

2[e] and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film

Rolf (Ex. 1008) at [0024], [0148], and [0041]; Petition (Paper 2), 54; Dr. Park Dec. (Ex. 1002) ¶381.

[0148] Suitable preservatives 7 include, e.g., quat-15, parabens, dichlorobenzyl alcohol, ethylene diamine

Rolf (Ex. 1008) at [0148].

greater incidence of skin irritation. The relatively low occlusiveness of the present invention can be envisioned to be a special adhesive ointment or gel which is water-breathable, such as a water washable or water soluble ointment or gel.

Rolf (Ex. 1008) at [0041].

[0024] The present invention also provides a method for inhibiting a respiratory pathogen. The method includes 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, wherein the source of the essential oil is a patch located in the vicinity of the respiratory pathogen.

Rolf (Ex. 1008) at [0024].

381. 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 at [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.

Dr. Park Dec. (Ex. 1002) ¶381.

Petitioner has established Rolf renders Claim 2[f] obvious

2[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 (Ex. 1008) at [0024], [0041], and [0148]; Petition (Paper 2), 54-56;
Dr. Park Dec. (Ex. 1002) ¶394.

[0148] Suitable preservatives 7 include, e.g., quat-15, parabens, dichlorobenzyl alcohol, ethylene diamine

Rolf (Ex. 1008) at [0148].

greater incidence of skin irritation. The relatively low occlusiveness of the present invention can be envisioned to be a special adhesive ointment or gel which is water-breathable, such as a water washable or water soluble ointment or gel.

Rolf (Ex. 1008) at [0041].

Dr. Park Dec. (Ex. 1002) ¶394.

[0024] The present invention also provides a method for inhibiting a respiratory pathogen. The method includes 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, wherein the source of the essential oil is a patch located in the vicinity of the respiratory pathogen.

Rolf (Ex. 1008) at [0024].

394. 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 at [0024].)

Claims Appendix

Claim 1 of the '802 Patent

'802 Patent (Ex. 1001) 10:19-33.

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.

'802 Patent (Ex. 1001) 10:19-33.

Claim 2 of the '802 Patent

'802 Patent (Ex. 1001) 10:33-48.

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.

'802 Patent (Ex. 1001) 10:34-48.

Claims 1 and 2 of the '802 Patent

'802 Patent (Ex. 1001) 10:19-33, 10:34-48.

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.

'802 Patent (Ex. 1001) 10:19-33.

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.

'802 Patent (Ex. 1001) 10:34-48.

Claim 3 of the '802 Patent

'802 Patent (Ex. 1001) 10:49-51.

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

'802 Patent (Ex. 1001) 10:49-51.

Claim 8 of the '802 Patent

'802 Patent (Ex. 1001) 11:1-7.

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

'802 Patent (Ex. 1001) 11:1-7.

THANK YOU