

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 26, 2012

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

Inter Partes Review No. IPR2024-00711

**RESPONDENT/PATENT OWNER'S PRELIMINARY RESPONSE
TO PETITION FOR INTER PARTES REVIEW
OF U.S. PATENT NO. 8,163,802**

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I. INTRODUCTION

On May 29, 2024, Petitioner Salvacion USA, Inc. filed the instant IPR Petition challenging the validity of claims 1-3 and 8 of Respondent/Patent Owner, Trutek Corp.'s US Patent No. 8,163,802 issued on April 24, 2012. Respondent/Patent Owner Trutek Corp will be hereinafter referred to as "Trutek." U.S. Patent No. 8,163,802 will be hereinafter referred to as "the '802 Patent."

On June 13, 2024, the USPTO PTAB issued a "Notice of Filing Date Accorded to Petition and Time For Filing Patent Owner Preliminary Response." In that notice, Trutek was afforded three months from the date of the notice to file a preliminary response to the petition. The end date of that period is September 13, 2024.

Trutek hereby submits its preliminary response to the instant IPR petition for the express purpose of setting forth the reasons why the requested review should not be instituted.

A. ALLEGED PRIOR ART

Petitioner challenged claims of the '802 Patent citing the following prior art documents:

1. USPTO Patent Application Publication No. US 2005/0232895 A1 published on October 20, 2005 of a patent application by Andrew Xian Chen. This reference will be hereinafter referred to as "Chen."
2. U.S. Patent No. 6,559,189 issued to James R. Baker, Jr. on May 6, 2003. This reference will be hereinafter referred to as "Baker."
3. U.S. Patent No. 6,844,005 issued to Ashok Wahi on January 18, 2005. This reference will be hereinafter referred to as "Wahi '005."
4. U.S. Patent Application Publication No. US 2004/0071757 A1, published on April 15, 2004 of a patent application by David Rolf. This reference will be hereinafter referred to as "Rolf."

B. ISSUES PRESENTED IN THE PETITION

Ground 1: Whether claims 1-3 and 8 are anticipated under 35 U.S.C. § 102(a) by Chen or rendered obvious under 35 U.S.C. § 103 by Chen alone?

Ground 2: Whether claims 1-3 and 8 are anticipated under 35 U.S.C. § 102(a) by Baker or rendered obvious under 35 U.S.C. § 103 by Baker alone?

Ground 3: Whether claims 1-3 and 8 are anticipated under 35 U.S.C. § 102(a) by Wahi '005 or rendered obvious under 35 U.S.C. § 103 by Wahi '005 alone?

Ground 4: Whether claims 1, 2 and 8 are anticipated under 35 U.S.C. § 102(a) by Rolf or rendered obvious under 35 U.S.C § 103 by Rolf alone?

Ground 5: Whether claim 3 is rendered obvious under 35 U.S.C. § 103 over Rolf in view of Wahi '005?

II. THE '802 PATENT

A. THE CHALLENGED CLAIMS

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
 - a) electrostatically attracting the particulate matter to the thin film;
 - b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
 - c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.
2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidal agent, and wherein said formulation, once applied:
 - a) electrostatically attracts the particulate matter to the thin film;
 - b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

- c) inactivates the particulate matter and renders said particulate matter harmless.
- 3. The formulation of claim 2 wherein the at least one cationic agent is a polymeric quaternary ammonium compound.
- 8. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:
 - a) at least one biocidal agent, and
 - b) at least one quaternary thickener.

B. GENERAL CONSIDERATIONS

Independent claim 1 of the '802 Patent recites a method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. Independent claim 2 recites formulations for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. Dependent claim 3 depends from claim 2 and it further limits the cationic agent recited in claim 2. Independent claim 8 recites formulations for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.

The '802 Patent discloses a method and several formulations. Those formulations are applied into and/or around a person's nasal passages. Once applied, the formulations create an electrostatically

charged thin film. Oppositely charged airborne particles (including microorganisms) in the vicinity of the skin or tissue of the person's nasal passages are attracted to the thin film. The thin film traps and holds them. The formulations contain a biocidal agent that renders the trapped microorganisms harmless.

Claim 1 recites a method wherein a formulation is applied to a person's nasal passages forming a thin film, which adheres to the skin or tissue of his nasal passages. The applied formulation creates an electrostatically charged field in and around the nasal passages, thereby attracting airborne particles, including those that are harmful. The electrostatically charged film holds these particles in place. The formulation contains at least one ingredient that renders the particles harmless.

Claim 2 recites a formulation that is applied to a person's nasal passages, forming a thin film that adheres to the skin or tissue of his nasal passages. The formulation contains at least one cationic agent. Cationic agents create a positive electrostatic charge. The formulation also contains at least one biocidal agent (a biocide). Once applied to the skin or tissue, the thin film attracts oppositely

charged particles, and holds them in place. The formulation then inactivates the harmful particles and renders them harmless.

Claim 3 depends from claim 2, and it incorporates all of the limitations and features of claim 2 by reference. Claim 3 recites that the at least one cationic agent of claim 2 is a polymeric quaternary ammonium compound.

Claim 8 recites a formulation that is applied to a person's nasal passages, forming a thin film that adheres to the skin or tissue of his nasal passages. The formulation contains at least one quaternary thickener which acts both as a cationic agent and as an ingredient that adjusts the cohesion of the formulation. Cationic agents create a positive electrostatic charge. The formulation also contains at least one biocidal agent (a biocide). Once applied to the skin or tissue, the thin film attracts oppositely charged particles, and holds them in place. The formulation then inactivates the harmful particles and renders them harmless.

C. CLAIM CONSTRUCTION

Trutek's proposed constructions are in each case based upon the claims, the specification, and the prosecution history of the '802

Patent. Construction of any claim must be based upon consideration of the claim as a whole, rather than of the claim elements individually.

1. CLAIM COMPONENTS:

a. The Preamble

The preamble limits the claim in that it recites specific steps in the process that are not recited in the body of the claim or are recited in a way that is enhanced in the body.

The crucial terms in the preamble are

- electrostatically inhibiting;
- harmful particulate matter;
- infecting an individual through nasal inhalation;
- formulation is applied to the skin or tissue of nasal passages;
- and
- a thin film.

b. Claim Term Construction

(1) Electrostatically

The word "electrostatically," refers to "static electricity" and utilizing electrically charged particles. *Merriam-Webster Dictionary*.

The Summary of the Invention section of the '802 Patent Specification (at 3:32-3:40) refers to "an electrostatically charged composition ... when applied to a surface creates an electrostatic field." It is well known that in an electrostatic field, oppositely charged

particles attract each other, and similarly charged particles repel each other.

(2) Harmful Particulate Matter

Harmful particulate matter refers to particles that are capable of infecting human beings. Those include viruses, microorganisms, dust, mold, and pollen.

(3) Electrostatically Attracting

In claim 2, the element is "electrostatically attracts." As discussed *supra*, opposite charged particles attract each other. Here, once applied, the formulation exhibits a static charge, while the "harmful particles" exhibit an opposite charge. Thus, the applied formulation attracts the harmful particles. The Summary of the Invention section of the specification discloses (at 3:35-3:38) that the "formulation, which when applied to a surface creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped ..."

(4) Electrostatically Inhibiting

As originally submitted, these claims recited "electrostatically preventing harmful particulate matter from infecting an individual by

nasal inhalation" At the suggestion of the examiner during prosecution, the word "preventing" was changed to "inhibiting" throughout the claims. This change allowed for at least a few active harmful particles to be inhaled by the individual. The term, "electrostatically inhibiting," as used in the claims means using an electrostatic field to attract or repel harmful particles. The recited formulation then prohibits the harmful particles from infecting the individual. The Abstract of the specification states that microorganisms coming in contact with the substrate or skin are rendered less harmful. The Summary of the Invention section discloses (at 3:35-3:40) that the "formulation, which when applied to a surface, 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."

As used in the claims, once an oppositely charged harmful particle is attracted to the charged thin film, that harmful particle will stick to the thin film. It becomes "electrostatically trapped and held

thereto." (at 3:38.) Further, the adhesion is adjusted "to permit said thin film to stick to the skin or tissue. (at 10:27 and 10:38.)

(5) Adhesion and Cohesion

Cohesion appears in claims 1 and 2. There are two relevant dictionary definitions of **cohesion**:

- (a) the act of sticking together tightly; and
- (b) molecular attraction by which the particles of a body are united throughout the mass.

(Merriam-Webster Dictionary)

Adhesion is the tendency of dissimilar particles or surfaces to cling to one-another. **Cohesion** refers to the tendency of similar or identical particles or surfaces to cling to one-another.

As used in the claims, cohesion of the formulation is adjusted so that its molecular ingredients fit so tightly together so as to restrict harmful particles from penetrating into the skin or tissue of the individual.

It is important to note that Petitioner and its expert, Kinam Park, Ph.D., appear to misunderstand the term cohesion and equates it with viscosity. **Viscosity** is the resistance to flow in any material with fluid properties. *(Merriam-Webster Dictionary.)* While more

cohesive materials could be more viscous, that is not always true. For example, pouring sand into crude oil would increase its viscosity but not its cohesion. Similarly, introduction an aqueous suspension of guar gum¹ into crude oil decreases its viscosity but not its cohesion.

(6) Adequate Impermeability

The dictionary definition of **impermeability** is "not permitting passage (as of a fluid) through its substance." (*Merriam-Webster Dictionary*.) The dictionary definition of **adequate** is "sufficient for a specific need or requirement." (*Id.*) Claims 1 and 2 state specific "needs and requirements."

The preamble of method claim 1 states in part, "... *inhibiting harmful particulate mater from infecting an individual through nasal inhalation wherein a formulation is applied to the nasal passages of the individual in a thin film ...*" Element (b) of claim 1 states in part, "... *holding the particulate matter in place ... by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film*

¹ Guar gum is a long chain polymer commonly used to decrease viscosity. It is an aqueous extract from the plant *Cyamopsis tetragonoloba*.

..." Finally, Element (c) states the purpose of the claim as, "... *render said particulate matter harmless.*"

Thus, **adequate impermeability**, as used in the claims, refers to the thin film inhibiting harmful particles from penetrating the thin film and contacting the sin or tissue of an individual's nasal passages.

(7) **Cationic Agent**

A **cationic agent** is a chemical substance that creates a positive electrostatic charge.

(8) **Biocidic Agent**

Also known as a **biocide**. A **biocidic agent** is a chemical substance that destroys or inhibits the growth or activity of living organisms. (*Merriam-Webster Dictionary.*)

(9) **Inactivates** or **Inactivating**

The relevant dictionary definition of **inactive** is "*biologically inert especially because of the loss of some quality (such as infectivity or antigenicity).*" (*Merriam-Webster Dictionary.*)

The dictionary definition of **inactivates** and **inactivating** is to make inactive. (*Id.*) The definition specifically relates to "chemicals to inactivate viruses."

c. Effect of the Preamble

The preamble of independent method claim 1 recites, "electrostatically inhibiting harmful particulate matter from infecting an individual through inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film." Here in the preamble, a formulation is first mentioned. However, application of the formulation is implied in Element (b) therein because it is referenced as an antecedent basis in the preamble. ('802 Patent at 10:26-30.) Similarly, the aforementioned thin film in Element (b) is referenced as an antecedent basis in the preamble. *Id.* Further, Element (b) recites that the thin film adheres to the skin or tissue. Once again, the skin or tissue references "nasal passages of the individual" In addition, the reference to inhalation of "harmful particles" translates into Element (b) as "particulate matter," and into Element (c) as rendering "said particulate matter harmless." Without reference to the claim's preamble, the entire claim becomes indefinite under 35 U.S.C. § 112(b). Thus, the preamble of claim 1, adds "life, meaning, and vitality" to the claim and said preamble must be considered as a claim limitation during construction.

Similarly, in independent formulation claims 2 and 8, the limitation is recited, "inhibiting harmful particulate matter from infecting an individual through inhalation wherein the formulation is applied to the skin or tissue of nasal passages of the individual in a thin film." As in claim 1, the preamble recites **harmful particulate matter, the formulation, skin or tissue of nasal passages, and thin film.** As argued for claim 1 *supra*, these terms form an antecedent basis for their corresponding terms in Elements (a) through (c) of the claim body of claim 2. Without reference to the claim's preamble, the entire claim becomes indefinite under 35 U.S.C. § 112(b). Thus, the preamble of claims 2 and 8 adds "life, meaning, and vitality" to the claims, and said preamble must be considered as a claim limitation during claim construction.

d. Body of the Claim

(1) Element (a)

In independent method claim 1, Element (a) recites, "electrostatically **attracting** the particulate matter to the thin film." Here, the formulation's electrostatically charged thin film attracts oppositely charged harmful particles. In composition claim 2, Element (a) recites, "electrostatically **attracts** the particulate matter to

the thin film." Here, the positively charged formulation attracts negatively charged airborne particulates.

Here, claims 1 and 2 recite CATCHING or capturing harmful particulate matter by electrostatic attraction.

(2) Element (b)

Element (b) of claim 1 reads:

- 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 of and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

Element (b) of claim 2 is virtually identical except for utilization of the term "**holds**" instead of the term "**holding**."

Here, the thin film formulation is designed to adhere to the skin or tissue of the nostrils and to be impermeable. The thin film captures and HOLDS the harmful particles (that were attracted to it) in place.

Here, claims 1 and 2 recite the critical HOLD function of these claims.

As is recited in the claim, one component of the HOLD function is adjusting the cohesion of the formulation. As argued *supra*, cohesion and viscosity are not the same thing. In claim 8, addition of

the quaternary thickener increases cohesion by bonding to the other ingredients in the formulation. It is not merely a viscosity modifier.

(3) Element (c)

Element (c) of claim 1 recites:

- c) **inactivating** the particulate matter and renders said particulate matter harmless.

Element (c) of claim 2 is virtually identical except for utilization of the term "**inactivates**" instead of the term "**inactivating**."

The formulation contains at least one ingredient that inactivates the captured harmful particles and renders them harmless.

Here, claims 1 and 2 recite the critical KILL function of these claims.

(4) The Claims as a Whole

Claim 1 is a method claim reciting a method **electrostatically inhibiting** harmful particles from infecting a person through nasal inhalation by applying a formulation to the nasal region, and

- a) CATCHING,
- b) HOLDING, and
- c) KILLING the harmful particulate matter.

Claim 2 is similar to claim 1, but being a formulation claim, it:

- a) CATCHES,
- b) HOLDS, and
- c) KILLS the harmful particulate matter.

Claim 3 depends from claim 2, and if claim 2 is allowable, then claim 3 must also be allowable because it incorporates all of the limitations of claim 2 in their entirety thereto.

Claim 8 reads:

- 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.

Claim 8 is a composition claim that recites **electrostatic inhibition** of infection from harmful particulates due to nasal inhalation. It comprises "at least one quaternary thickener," which is both a cationic agent (that implements the CATCH function) and a thickening agent, which adjusts the formulation's cohesion (that implements the HOLD function). The at least one biocidic agent implements the KILL function.

e. The HOLD function

The '802 patent expresses the term “hold” in the claim statements related to the multi-action mechanism of the invention. While the product attracts particulate matter from the airflow before entering the nasal passageway utilizing electrostatic forces, this alone is insufficient to protect the individual from harmful particulate matter entering the body's respiratory system. Holding is a protective concept based on adhesive and cohesive properties. Adhesion of the formulation can be viewed in two ways: first adhesion to the skin of the individual applying the formulation in and around the nasal passageway; and second, adhesion of the particles in the airflow to the formulation itself. Cohesion provides a tackiness that incorporates the concept of adhesion. Adhesion concerns the forces bonding dissimilar molecules together. Cohesion concerns the forces bonding similar molecules together. Adhesion considers particles of opposite charge, and cohesion goes beyond this concept to include particles of like charge. This sets up a barrier of impermeability trapping a significant number of these particles outside the nasal passageway. If the formulation is applied to the skin or tissue inside a person's nostrils, the holding function prevents these particles from

either being inhaled into the respiratory system or from contacting the skin or tissue directly. Therefore, holding is a critical aspect of the patent claims since the power of the electrostatic forces to attract airborne particles must be enhanced using the principles of adhesion and cohesion. This interaction of the formulation with foreign particles found in the air, by electrostatically attracting and capturing them and then holding them in place, sets up the opportunity for the formulation's ingredients to inactivate them prior to entry into the respiratory system. The formulation contains a cationic agent to attract bioactive particles such as bacteria, viruses and other biologically harmful particulates found in the air. It also contains a biocidic agent that acts to destroy or neutralize the captured bioactive particles.

Essentially, the mechanism of the formulation to carry out the protection it claims to afford the user would be incomplete if the formulation did not have the adhesive and cohesive properties required to hold the particles in place. Attraction by electrostatic forces is enhanced by the holding properties of adhesion and cohesion, and the holding properties set up the formulation's biocidic

ingredients to inactivate and kill bioactive particles that are held in place by the formulation.

Most harmful airborne particles have a negative electrostatic charge. The formulation is applied to the skin or tissue of the nasal cavities as a thin film. The presence of a cationic agent in the formulation produces a positive electrostatic charge, which attracts and captures the negatively charged particles. A biocide in the formulation would ordinarily be expected to inactivate and kill the captured bioactive particles. But, to be effective, biocidal action requires contact with bioactive particles for a certain time period. If the captured particles happen to dislodge from the formulation's thin film, they would remain active and be inhaled. Even if they were in contact with the biocide for a sufficient time to be inactivated, the dislodged inactivated particles would still be able to be inhaled. Thus the "hold" function is critical to usefulness of the invention.

An analogy would be a mouse trap. If the trap merely attracts a mouse which mounts the trap to eat the cheese, unless the trap can hold and bind the mouse to the trap, the trap would be useless. If the formulation of the '802 Patent merely has a cationic agent to attract airborne bioactive particles and a biocidal agent to inactivate and kill

the particles, it would be useless unless it can hold the particles in place long enough to inactivate them and to prevent them from entering the respiratory system. The hold function is a critical part of the claimed invention.

III. ALLEGATIONS OF ANTICIPATION AND OBVIOUSNESS OF THE CLAIMS

A. ANTICIPATION

For a claim of an issued patent to become invalid upon prior art, the prior art must teach or suggest each and every element of that claim. When such a condition arises from reference to a single prior art reference, invalidity is based upon anticipation under 35 U.S.C. § 102(a). "A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 614 F.2d 628, 631 (Fed. Cir. 1987). For each of the first four grounds set forth by Petitioner, Respondent will show that the cited art does not anticipate the claims of the '802 Patent because they do not recite all of the elements of the challenged claims. Thus, Respondent will show that Petitioner failed to present a *prima facie* case of anticipation under 35 U.S.C. § 102(a) by any of the cited references.

B. OBVIOUSNESS

Petitioner's arguments consists of five grounds of invalidity of the '802 Patent based on prior patent art. In the first four grounds, Petitioners challenge claims 1, 2, 3, and 8 as being anticipated under 35 U.S.C. § 102(a) by four different patents. For each of the four allegedly prior art patent, Petitioners allege in the alternative that these claims are obvious under 35 U.S.C. § 103 over each patent reference alone. Respondents will show that Petitioners failed to present a *prima facie* case of obviousness in these grounds. Ground 5 alleges obviousness of claim 3 by combining two of the references. It will also be shown that Petitioners did not present a *prima facie* case of obviousness under 35 U.S.C. § 103.

COMMERCIAL SUCCESS

Commercial success of a patented product tends to show that the patented claims are not obvious provided that the commercial success is due solely to the patented claims. Since the time the '802 patent was issued in 2012, more than seven million units of the product based on this patent, have been sold in the United States and internationally. This clearly is a measure of commercial success. When evaluating commercial success, a key factor is repeat sales of

a product and the length of time the product remains on the market.

Patent protection offers additional support for a product to be considered as a success. Since the Trutek products have patent protection and have been marketed successfully for ten years, this product line stands tall among products in this category. The product has a domestic and international presence which demonstrates that it has been reviewed for human use without prescription for the claimed properties established in the patent. When marketing in foreign countries, usually the ministry of health of these countries reviews the merits of the product claims before it gets approval for marketing the product to the population.

The commercial success of this product stands on the sales number and the lack of adverse events reported by the user. The '802 Patent claims a product that electrostatically inhibits harmful airborne particles from infecting an individual. The particles might be microbes, pollen, allergens, or mites that float in the air and are usually inhaled. This product effectively prevents that from happening by creating a positive electrostatic charge that attracts the particles and holds the particles in place until a biocide can inactivate them and render them harmless. Trutek does little or no advertising.

The products are either sold online or in retail outlets. The patent number of the '802 Patent is clearly marked for every unit sold in the United States. Based on what the '802 Patent claims and what the products actually do, I conclude that the commercial success of the products is due solely to the performance and features of the claimed invention of the '802 Patent.

IV. INDIVIDUAL REBUTTAL ARGUMENTS AGAINST PETITIONER'S PRIOR ART ALLEGATIONS OF INVALIDITY

A. GROUND 1: CLAIMS 1-3 AND 8 ARE NOT ANTICIPATED BY CHEN, AND ALTERNATIVELY ARE NOT RENDERED OBVIOUS BY CHEN ALONE.

Petitioners challenge claims 1-3 and 8 of the '802 Patent alleging that they are anticipated under 35 U.S.C. § 102(a) by USPTO Patent Application No. US 2005/0232895 A1 (hereinafter, "Chen").

For a prior art reference to anticipate a claim under § 102, the prior art must recite every element of that claim.

CLAIM 1

Preamble:

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.

The preamble limits the claim in that it recites specific steps in the process that are not recited in the body of the claim or are recited in a way that is enhanced in the body.

Element (a):

a) electrostatically attracting the particulate matter to the thin film;

Harmful particulate matter, once inhaled by the individual, can cause infection in the individual's respiratory system, which can spread to the entire body. Electrostatic attraction is key to the methodology. The formulations recited in the tables of the '802 Patent have been designed so as to create an electrostatic field of sufficient charge strength in the vicinity of the individual's nose and face. The electrostatic field must have sufficient charge to cause airborne particulate matter to be attracted to the thin film coating the skin or tissue of the nasal passages.

Chen did not anticipate electrostatic attraction of airborne harmful particulate mater. At [0115], Chen states:

SARS is spread when someone with SARS coughs or sneezes droplets into the air and Someone else inhales them. By forming a Viscous membrane over nasal mucous and by deactivating viruses on contact, the

formulation of the present invention could provide an effective means to prevent the virus from Spreading. This formulation is particularly useful among people who are in close contact with SARS patients, healthcare workers or air travelers.

From the above paragraph, it is clear that Chen intended his formulation to act on viruses that may be in the vicinity and randomly enter the nasal passages and comes in direct contact the viscous membrane. Other viruses may enter the nasal passages and not make contact with the thin film, and those viruses will be inhaled. Clearly, Chen did not envision employment of an electrostatic field to attract the viruses.

Now, the petitioner points to Chen's inclusion of EUDRAGIT® (poly(dimethyl-aminoethylmethacrylate)) in an embodiment of his formulation. Further, the petitioner points to inclusion of a cationic surfactant in the formulation. These ingredients exhibit cationic properties, creating a positive surface electrostatic charge. Petitioners' expert, Kinam Park, Ph.D. (hereinafter, "Park"), states in ¶ 111 of his report, "cationic agents electrostatically attract negatively charged microorganisms, such as the viruses in Chen." Park implies that cationic agents inherently have a positive charge that would have

some attraction to negatively charged microorganisms. Park further states:

112. Thus, in my opinion, 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. The cationic agent in Chen's composition would attract and hold the virus, inhibiting the virus from entering the body via inhalation, and therefore would prevent infection.

While it is true that inclusion of a cationic agent might attract some negatively charged viruses, no effort was made by Chen to perform this function effectively. Nor did Chen claim it. The specification of the '802 Patent provides ten examples of products, the concentrations of which were adjusted to electrostatically attract negatively charged particles to a thin film. However, these particles are mobile. Most of them would dislodge from the film, and would be inhaled by the individual. Respectfully, Park is wrong in his opinion in ¶ 112. The cationic agent in Chen's composition would NOT attract and HOLD the virus.

Trutek began selling electrostatic nasal products during the 1990's. Trutek's U.S. Patent No. 5,468,488 issued November 21, 1995 disclosed and claimed an electrostatically charged nasal application product. Its U.S. Patent No. 5,674,481 disclosed and

claimed an electrostatically charged nasal topical application product. And, its U.S. Patent No. 6,844,605 disclosed and claimed an electrostatically charged nasal application product with increased strength. The '605 Patent showed the need for adjusting the concentration to make electrostatic attraction effective. Trutek researched, screened, and adjusted the concentrations of ingredients in its products over the years. However, all these products suffered from the fact that, once the product was applied to the nasal area, the harmful particles were mobile, and became dislodged almost as soon as they approached the product. The '802 Patent was the first successful effort of solving this problem. It took approximately sixteen years of experimentation to solve that problem.

Element (b):

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,

The Petitioner stated, "[a] cationic agent attracts and holds the particulate matter in place (pg. 20). Contrary to Petitioners' statement, Chen does not disclose this element. Once again, referencing Park's report (§ 77, quoting Chen at [0112]), "methods of

applying 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." While it is true that Chen discloses that his formulation sticks to the nasal mucosa, the hold function was not disclosed anywhere in Chen's specification or claims. The word, "hold," is not even mentioned in Chen's disclosure. The hold function is a vital element of the '802 Patent. The only adjusting of ingredients disclosed by Chen is for pH. While Chen adds a "viscosity modifier" ingredient to his formulation (Chen [0036]), he does not disclose how or why the viscosity is adjusted. Viscosity is often adjusted to prevent a nasal application product from dripping out of one's nose. However, as argued *supra*, adjusting cohesion is not the same as adjusting viscosity. Note the example where sand or dirt is added to crude oil, making the oil flow more viscous but not modifying the cohesion of the oil.

The HOLD function is a critical part of the claim. Unless the concentrations of ingredients are adjusted to hold the harmful particles to the thin film, many harmful particles will dislodge and be inhaled. Further, for microorganisms to be deactivated, they must remain in contact with a biocide for period of time. If a particle that

enters the person's nose and dislodges from the thin film prior to deactivation it is more likely to be inhaled as opposed to a microorganism that floats around outside the person's nose. This knowledge was not in Chen's possession when he filed his patent application.

Element (c):

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

Here, Chen discloses this feature. Chen's patent application recites and claims an antiviral pharmaceutical composition. Chen anticipated the use of at least one ingredient that would deactivate various viruses. Among those are influenza virus A and B, rhinovirus, adenovirus, corona virus, parainfluenza virus, genital herpes virus, and respiratory syncytial virus. Chen provides examples of his compositions and data showing how his compositions affect various virus particles. Chen discloses the addition of benzalkonium chloride as a cationic surfactant. The '802 Patent designates benzalkonium chloride as a biocidic agent.

The method of claim 1 requires three elemental steps (a) CATCH, (b) HOLD, and (c) KILL. The CATCH step is accomplished

by creating a nasal application formulation having a field with an electrostatic charge of sufficient magnitude to attract airborne harmful particles in the vicinity of a person's nose.

The CATCH function is contrary to common wisdom, and it is not disclosed by Chen. Rather than creating a sterile environment the keeps harmful particles away from a person's airways, the '802 Patent discloses and claims compositions that attract those particles to the main orifice into the respiratory airways.

The HOLD function insures that the harmful particles do not dislodge, and at the same time, do not have direct contact with the nasal mucosa. Further, the particles remain in contact with the formulation's thin film and are kept there long enough to be affected by the biocidal agent.

The KILL function deactivates the harmful particles. Benzalkonium chloride deactivates virus particles by membrane disruption.

In order for Chen to anticipate claim 1 under 35 U.S.C. § 102, every element of the claim must be present in Chen's disclosure. As argued here, that is not the case. So, as Petitioners' fallback position

they propose that claim 1 is obvious over Chen if they cannot prove anticipation. Here, their proposition is even weaker.

Normally, under 35 U.S.C. § 103, obviousness is shown by combining two prior art references, and showing that the combination makes obvious every element of a claim. Here, they have not done so. The Petitioners propose that a Person of Ordinary Skill in The Art (hereinafter, "POSITA") would find claim 1 to be obvious all by itself. This is almost the same argument as for anticipation. Every element of claim 1 must be obvious. A POSITA would find the CATCH, HOLD, and KILL elements obvious. As was argued earlier, the only element disclosed by Chen is KILL.

Regarding the CATCH element, both the Petitioners and Park say:

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.
(IPR Petition, page 20; Park Declaration Ex. 1002, ¶ 030.)

And, regarding the HOLD element, both the Petitioners and Park say:

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.

(IPR Petition, page 21, Park Declaration, Ex. 1002, ¶140.)

Here, Petitioners and Park do not even mention holding live viruses in place so as not to be inhaled into the person's respiratory system.

There is no doubt that a POSITA would understand the teachings of Chen in the year 2005. There is also no doubt that a POSITA would understand the teachings of the '802 Patent in the year 2012. Trutek spent those intervening years performing research and development and experimentation designed to create its formulation disclosed by the '802 Patent and the method recited in claim 1. Certainly, a POSITA looking at the '802 Patent in 2012 alongside the Chen publication in 2005 would observe similarities, but Park and the Petitioners are making their determination using impermissible hindsight. Park has seen the '802 Patent, and it cannot be unseen. Park observes the Chen publication as it would be seen alongside the '802 Patent in 2024, and not as it would have been seen in the year 2007 (when Trutek first filed its application for patent). There is not even a preponderance of evidence to show obviousness of claim1 over Chen. Except for a conclusory opinion,

neither the Petitioners nor Park can present any evidence that it would have been obvious to a POSITA in 2007 to modify Chen to produce the '802 Patent's method of claim 1.

CLAIM 2

Preamble:

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 biocidic agent, and wherein said formulation, once applied:*

The preamble limits the claim in that it recites specific steps in the process that are not recited in the body of the claim or are recited in a way that is enhanced in the body.

Element (a):

"said formulation once applied:"

a) *electrostatically attracts the particulate matter to the thin film;*

The CATCH function.

Once again the element of electrostatic attraction is not taught here. While it is true that the formulation of Chen contains a cationic agent and a cationic surfactant, Chen anticipated their use for other purposes, or at least, did not disclose a function for them to

electrostatically attract virus particles. For example, a polymer with cationic properties that is used to provide enteric coatings, delayed and sustained release pharmaceuticals, "EUDRAGIT® polymers are neutral in taste and smell, to help mask the bitterness of certain APIs or other unpleasant odors. To improve drug swallowability, they enable smooth, glossy surfaces for a pleasant feel in the mouth and are highly effective in coatings as thin as 10 to 20 μm ." (Evonik Company literature.) In addition, cationic surfactants are commonly used to relieve surface tension in liquid compounds. There is not a scintilla of information in Chen's disclosure indicating that he would take advantage of a positive charge to attract negatively charged viruses.

Element (b):

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,

The HOLD function.

Once again, nowhere does Chen disclose that his formulation holds particulate matter in place. Nor, does he speak about the possibility of dislodged live virus particles being inhaled. While, his

formulation does kill viruses, the lack of a hold function allows a greater number of live viruses to be inhaled into the person's respiratory system.

Element (c):

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

The KILL function.

Here, Chen's formulation exhibits the kill function.

However, the claimed formulation recited in claim 2 of the '802 Patent exhibits the CATCH, HOLD, **AND** KILL functions. The formulation must perform all three functions. To be anticipated by Chen under 35 U.S.C. § 102, Chen must disclose every element of claim 2, which he does not do.

Further, for claim 2 to be obvious over Chen alone under 35 U.S.C. § 103, all of the elements of the claim must be obvious. Neither the Petitioners nor Park have shown this to be the case by a preponderance of the evidence. As discussed earlier, their POSITA only discerns obviousness by using impermissible hindsight. Without the existence of the '802 Patent prior to October 20, 2005, there

would be no awareness of the problem and need for development of the formulation recited in claim 2 of the '802 Patent.

The creation of the claim 2 formulation took years of experimentation and development. Trutek sold more than seven million tubes of the gel formulation recited in claim 2 of the '802 Patent. During the three years of the Covid-19 pandemic, sales increased dramatically. These formulations have been sold under the brand names, NasalGuard[®], AllergieBLOCK[®], and ColdsFluBLOCK[®]. The success of Trutek's formulation is due to its effectiveness as well as the long felt need for a product of this type.

CLAIM 3

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

Unlike claims 1 and 2, which are independent, claim 3 depends from claim 2. Accordingly, claim 3 incorporates by reference all of the elements of claim 2 therein. Trutek admits that Chen discloses a formulation, embodiments of which contain a polymeric quaternary ammonium compound. Chen also teaches that at least one of his polymeric quaternary ammonium ingredients is cationic. However, Chen's use of this ingredient does not negate the fact that the

formulation of claim 3 must perform all of the "catch," "hold," and "kill" functions. All three elements of claim 2 must be present in claim 3. If claim 2 is not anticipated by Chen under 35 U.S.C. § 102, the same holds true for claim 3, because claim 3 incorporates all of the limitations of claim 2 by reference therein. Furthermore, the same arguments against obviousness of claim 2 over Chen alone, hold true for claim 3. In addition, the formulations sold so successfully by Trutek contain polymeric quaternary ammonium compounds as ingredients therein.

CLAIM 8

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.*

Claim 8 is an independent claim reciting a formulation that inhibits infection from nasal inhalation of harmful particles. The key term, "electrostatically inhibiting", is already explained in the specification and claims of the patent. As was argued earlier, this term refers to the ability of the claimed formulation of the '802 Patent to electrostatically attract harmful particles. As was also argued, the

concept of "electrostatic attraction," or for that matter "electrostatics" itself was not in the possession of Chen in his disclosure. Although the term "electrostatically inhibiting" appears only in the claim's preamble, that preamble serves to impose limitations on the claim. Thus, the Chen formulation must contain electrostatic charge carrying ingredients in sufficient concentration to accomplish the goal of electrostatic inhibition. Chen does not anticipate doing this.

The composition and functions of the formulation of claim 8, is explained in the specification of the '802 Patent from 4:39 to 5:54.

Neither Petitioners nor Park argue that Chen's cationic ingredients causes electrostatic inhibition inherently. However, this is not the case. The concentration of cationic ingredients along with other ingredients in a formulation created for the purpose of inducing inhibition of infection from viruses is critical. If the strength of attraction is weak or of insufficient duration, then the only virus particles that enter the person's nasal passages are those that the individual randomly inhales. Chen was not in possession of this type of formulation in 2005.

Admittedly, Chen's formulations contain biocidal agents, and they also contain quaternary ammonium compounds. Chen also

discloses viscosity modifiers, which may possibly be considered to be thickeners. However, inclusion of these ingredients in Chen's formulation is insufficient. It was argued earlier that modifying viscosity and adjusting cohesion are not the same thing. The '802 Patent teaches how to adjust adhesion and cohesion of the composition, those teachings being vital to the patent. The preamble creates limiting elements, and electrostatic inhibition is one of them. It must be considered when construing claim 8 of the '802 Patent.

Petitioner's case for anticipation of claim 8 by Chen under 35 U.S.C. § 102 is made using conclusory statements, and the above arguments were not considered by them. Further, their single paragraph argument for obviousness of Claim 8 over Chen alone is equally conclusory and without argument or evidence.

In Park's declaration (Ex. 1002, ¶186), Petitioner's expert states:

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 so.

This conclusory statement is without basis, implying that a POSITA would modify Chen's teachings to arrive at the formulations

of claim 8 because such a modification would be "obvious to try." However, the motivation for such modification would need to exist prior to the issue of the '802 Patent. That motivation became apparent in the art only after 2010, when Wahi's patent application published (US 2010/0004337 A1).

Further, the commercial success of Trutek's formulation, which contained the elements of claim 8, mitigates against Petitioners' argument of obviousness.

Petitioners did not prove their case for anticipation of claims 1, 2, 3, and 8 by Chen under 35 U.S.C. § 102 or for obviousness of these claims over Chen alone under 35 U.S.C. § 103. Their petition for invalidity of these claims for anticipation and obviousness over Chen should be denied and dismissed.

B. GROUND 2: CLAIMS 1-3 AND 8 ARE NOT ANTICIPATED BY BAKER, AND ALTERNATIVELY ARE NOT RENDERED OBVIOUS BY BAKER ALONE.

Petitioner challenges claims 1-3 and 8 of the '802 Patent alleging that they are anticipated under 35 U.S.C. § 102(a) by U.S. Patent No. 6,559,189 issued to James R. Baker, Jr. on May 6, 2003. This reference will be hereinafter referred to as "Baker.:

Baker teaches an antimicrobial composition contained within an oil-in-water nanoemulsion adjuvant. Among the disclosed embodiments are those where the composition is administered nasally. The nanoemulsion adjuvant is able to form a thin film. The function of the composition is to prevent or treat infection or disease resulting from various microbes. Among the disclosed ingredients are at least one cationic agent and at least one biocide. In at least one embodiment, the composition contains benzalkonium chloride as an ingredient.

However, Baker does not teach electrostatic attraction. This CATCH function is key to claims 1-3 and 8 of the '802 Patent. He does not teach attraction of microbes into the nasal region at all. If the harmful particles already reside in the nasal passages, Baker's composition deactivates them. In addition, applying the composition in advance of nasal contamination inhibits infection by deactivating them as they are inhaled. However, Baker's composition does not seek the microbial particles. Baker does not disclose attraction of microorganisms to the composition, electrostatic or otherwise. The only microbes upon which Baker's composition acts are those which happen to be inhaled by chance. Also, as already argued regarding

the Chen reference, whether electrostatic attraction is effective depends on the selection and concentration of ingredients for the purpose of creating an adequate charge.

Moreover, Baker does not teach HOLDING the microorganisms in place, and there is no mention of adjusting the adhesion and cohesion of the nanoemulsion to achieve impermeability. This element is critically important to the invention of the '802 Patent, and it cannot be inferred from Baker alone.

As argued *supra*, for there to be anticipation under 35 U.S.C. § 102(a), there must be a single reference that teaches all of the elements in the challenged claims. If the reference is silent regarding even a single element in the claim, then anticipation is not achieved. Further, if claim 2 is unanticipated by Baker, claim 3 cannot be anticipated because claim 3 depends from claim 2, and it incorporates by reference all of the limitations of claim 2 therein. Regarding claim 8, Baker does not teach "electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation." The term "electrostatically inhibiting" is taught in the '802 Patent's specification and claims. Without electrostatic attraction, this element is not taught. Although this term resides in the preamble, as

was argued earlier, the preamble of claims 1, 2, and 8 are limiting, and must be considered when construing these claims.

Regarding obviousness under 35 U.S.C. § 103, even if it can be inferred that the presence of a cationic agent in sufficient concentration in some nasally administered embodiment will attract the microorganisms electrostatically, the silence of Baker in holding the microorganisms in place and adjusting adhesion and cohesion of the nanoemulsion to achieve adequate impermeability renders the claims of the '802 Patent non-obvious over the Baker reference.

Perhaps one might infer the CATCH and KILL elements of the '802 Patent's claims, but nowhere does Baker teach or even suggest the HOLD element. Holding the harmful particles in place is a critical element in claims 1 and 2. Thus, claims 1 and 2 of the '802 Patent are not anticipated by Baker under 35 U.S.C § 102, nor are they obvious over Baker alone under 35 U.S.C. § 103.

C. GROUND 3: CLAIMS 1-3 AND 8 ARE NOT ANTICIPATED BY WAHI '005, AND ALTERNATIVELY ARE NOT RENDERED OBVIOUS BY WAHI '005 ALONE.

Petitioner challenges claims 1-3 and 8 of the '802 Patent alleging that they are anticipated under 35 U.S.C. § 102(a) by U.S. Patent No. 6,844,005 issued to Ashok Wahi on January 18, 2005.

This reference will be hereinafter referred to as "Wahi '005." Ashok Wahi is the sole inventor of the '005 Patent. He is also the sole inventor of the '802 Patent. Wahi '005 teaches "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."

Wahi '005 is an improvement over his U.S. Patent No.5,486,488 (hereinafter, "Wahi '488") issued to Wahi in 1995 and his U.S. Patent No. 5,674,481 (hereinafter, "Wahi '481") issued to Wahi in 1997. Wahi '488 teaches and claims a method for restricting the flow of airborne contaminants into a nasal passage. The Wahi '481 Patent is a continuation patent of and claims priority to Wahi '488. The teachings of these two patents are virtually identical. While Wahi '488 teaches and claims a method, Wahi '481 teaches and claims products that implement the method. Wahi '488, '481, and '005 all recite methods and compositions that utilize electrostatic attraction to restrict the flow of harmful airborne particles in a person's nasal passages..

Wahi '005 is titled, "Electrostatically Charged Nasal Application Product With Increased Strength." The effectiveness of a formulation

in attracting electrostatically charged harmful particles depends on the strength of the electrostatic field. Wahi '488 issued ten years prior to Wahi' 005. The improvement of the '005 Patent over the '481 Patent is that the electrostatic field created by the formulations disclosed in the latter patent is significantly stronger than that created by the formulations disclosed in the earlier patent.

In ¶91 of Exhibit 1002, Petitioner's expert, Kinam Park, states:

According to Wahi '005, the prior art already described methods and compositions for restricting airborne contaminant flow into the nose, but Wahi '005 discovered that 'utilization of at least 10% of one specific active electrostatically charged polymer provides significantly increased charge density and efficacy as compared to other electrostatic polymers at lower, the same or higher concentrations than the present invention levels of the poly (dimethyl diallyl ammonium chloride).'

For a claim of an issued patent to become invalid upon prior art, the prior art must teach or suggest each and every element of that claim. A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described, in a single prior art reference.

As argued *supra*, independent claim 1 of the '802 Patent recites a method for electrostatically inhibiting harmful particles from infecting an individual by applying a formulation to the individual's nasal

passages in a thin film. As presented *supra*, the three elements (a, b, and c, respectively) of the claim recite CATCHING (electrostatically attracting), HOLDING (holding), and KILLING (inactivating the particulate matter and rendering it harmless).

Independent claim 2 of the '802 Patent recites a formulation product for inhibiting harmful particulate matter from infecting an individual through nasal inhalation, wherein the formulation is applied to the skin or tissue of the individual's nasal passages in a thin film. The formulation contains, among other ingredients, at least one cationic agent and at least one biocidic agent. The three elements (a, b, and c, respectively) recite that the formulation CATCHES (electrostatically attracts), HOLDS, and KILLS (inactivates the particulate matter and renders it harmless).

Claim 3 depends from claim 2, and it incorporates all of the limitations of claim 2 therein. It merely recites that the cationic agent of claim 2 is a "polymeric quaternary ammonium compound."

Independent claim 8 recites a formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. As argued *supra*, the term "electrostatically inhibiting" has a specific meaning throughout the '802 Patent's

disclosure. In addition to containing at least one biocidic agent, it also contains at least one quaternary thickener.

The recitation of CATCH, HOLD, and KILL are essential elements of all four claims. In order to anticipate these claims, the prior art must teach all of the elements of CATCH, HOLD, and KILL. Further, the claims must teach application of the formulation in a thin film. HOLDING must be accomplished by adjusting the adhesion and cohesion of the formulation. And, relating to claim 2, the formulation must contain at least one cationic agent and at least one biocidic agent.

The objective of Wahi '005 is merely to restrict the flow of airborne contaminants into an individual's nose by inhalation.² Wahi '005 teaches that creation of an electrostatic field near an individual's nasal passages can inhibit (or lessen) the number of airborne contaminants that are inhaled by the individual. Nowhere in Wahi '005 is it taught that a product is applied to the skin or tissue of the nasal passages. If the electrostatic field is positively charged, then negatively charged particles will be attracted to the formulation, *i.e.*, they will be caught and will not be inhaled. However, Wahi '005 does

² The Wahi '488 method and the Wahi '481 product recite the same objective.

not teach HOLDING or KILLING. Nothing in the patent teaches that particles will not be dislodged and inhaled after being CAUGHT. Moreover, nothing in the patent teaches that the particles are KILLED (inactivated and rendered harmless). Careful reading of the '005 Patent shows that this functionality was never intended. Therefore, Wahi '005 cannot anticipate the method of claim 1 of the '802 Patent, and it cannot anticipate claims 2, 3, or 8. Further, claim 3 cannot be anticipated under 35 U.S.C. § 102 if claim 2 is not so anticipated.

Regarding the HOLD element, in ¶97 of Exhibit 1002, Petitioner's expert Park states:

Wahi '005 teaches numerous forms of nasal compositions such as 'topical solutions, semisolids, ... and vaporizable solutions ... ointments, pastes, creams and gels,' ... Each of these forms has varying viscosities, which may be adjusted by varying the components and the amount of the components of the composition. A more viscous form would enable greater adhesion of the composition to the skin, tissue, or mucosa of the nasal passages and a more cohesive composition, such as a gel.

As was argued earlier, controlling viscosity does not necessarily adjust cohesion or adhesion. As previously argued by example, adding sand or dirt to crude oil will increase its viscosity but it will not have any effect on the fluid's cohesion or adhesion. Petitioner failed

to demonstrate that Wahi '005 implements the HOLD element claimed in the '802 Patent.

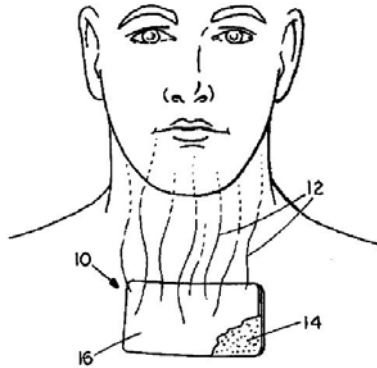
Furthermore, Examiner Henley considered both Wahi '005 during examination of the application that issued as the '802 Patent. Exhibit 1004 (attached to IPR Petition) is a copy of the image file wrapper of the application that became the '802 Patent. Pages 39-41 of Exhibit 1004 is a copy of the information disclosure statement (IDS) that was reviewed by Examiner Henley, showing the examiner's initials next to items 14, 15, and 16 (*i.e.*, '488, '481, and '005 Patents, respectively). The fact that the examiner considered these three prior art patents should be given great deference.

D. GROUND 4: CLAIMS 1-3 AND 8 ARE NOT ANTICIPATED BY ROLF, AND ALTERNATIVELY ARE NOT RENDERED OBVIOUS BY ROLF ALONE.

Petitioner challenges claims 1-3 and 8 of the '802 Patent alleging that they are anticipated under 35 U.S.C. § 102(a) by U.S. Patent Application Publication No. US 2004/0071757 A1, published on April 15, 2004 of an application by David Rolf. This reference will be hereinafter referred to as "Rolf."

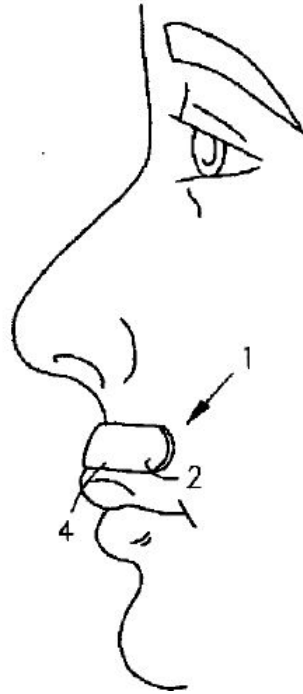
The Rolf application never issued as a patent. Attached as Exhibit 2001 are the office actions generated during prosecution of Rolf's patent application. In the office action, the examiner rejected

all of Rolf's pending claims based on obviousness double patenting and under statutes 35 U.S.C §§ 112, 102, and 103. The first of these rejections was based on a non-statutory, judicially created doctrine often referred to as obviousness double patenting. The claims of Rolf were deemed obvious over the teachings of an earlier patent listing him as an inventor, viz., U.S. Patent No. 6,090,403 ("Block") issued on July 18, 2000. A copy of Block is shown in Exhibit 2002.



The invention made by Block (shown in the above drawing) is a patch (10) impregnated with a vaporizable decongestant (12), wherein the patch adheres to the skin below the individual's face via an adhesive. This invention is similar in action to Vicks[®] Vaporub[®] ointment, a well known product that is applied to a person's chest. In both products, vaporizable decongestants evaporate and are inhaled by the individual. "Once vaporized, the aromatic decongestant is available for natural inhalation through the nose or mouth to help

relieve one or more of the symptoms of cough, colds, nasal or chest congestion and related symptoms. *Block Abstract.* Vicks® Vaporub® ointment and the Block patch function the same way.



The invention of the Rolf Application (shown in the figure above) is strikingly similar, except that the patch (1) is placed closer to the person's nose. Rolf's antiviral composition is not applied to the skin or tissue of the nasal passages, much less as a thin film. It is separated from the skin by an adhesive patch. Another difference is that Rolf's patch is impregnated with "essential oils." Rolf defines essential oils as "highly odoriferous, liquid components obtained from plant tissue. "Essential oils are usually captured by steam distillation,

a process whose origins can be traced back to ancient Mesopotamia. Their use in modern times relates to aromatherapy.

Unlike ordinary vegetable oils, such as corn and olive, plant essences are highly volatile and will evaporate if left in the open air." Rolf [0001]. Essential oils (15) typically include a mixture of one or more terpenes, esters, aldehydes, ketones, alcohols, phenols, and/or oxides. These functional classes of compounds are responsible for the therapeutic properties and distinct fragrance of the essential oil. *Id.* at [0064]. From Paragraph [0063] to [0073], Rolf lists a myriad of substances that he dubs essential oils. Paragraph [0148] provides a list of preservatives that can be used in his invention. Among them is Benzalkonium Chloride. However, this ingredient is used only as a preservative, which Rolf defines as any substance which prevents bacterial growth, mold growth, fermentation, and/or decomposition. Paragraphs [0151] - [0152] list many anti-viral agents that may be included on the adhesive patch. Among them is lysine hydrochloride. Rolf proceeds to list 87 embodiments, which are also recited in 87 claims. He also presents 16 example formulations.

Of the 87 claims, three are independent. Claim 86 is a kit claim not relevant to the current validity analysis. Claim 1 reads:

1. A method for preventing a respiratory infection in a mammal at risk thereof, the method comprises 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.

Claim 60 reads:

60. A method for preventing a respiratory viral infection in a mammal at risk thereof, the method comprises contacting a live respiratory virus with a prophylactically effective amount of an essential oil such that the live respiratory virus 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.

These two independent claims represent the essence of Rolf's teachings.

There is no doubt that Rolf is able to function similarly to Block. Were the active agent to be a vaporizable decongestant such as menthol, Rolf would exhibit improvement over Block because the activated adhesive patch is closer to the individual's nose.

However, the laws of physics do not enable Rolf's invention. Assuming a randomized distribution of harmful or infectious particles in the vicinity of Rolf's patch, some particles will graze by the patch untouched. For arguments sake, assume that Rolf's patch is

impregnated with a biocide. Those particles that contact the biocide for sufficient time period may be deactivated. The deactivated particles will then dislodge from the patch, and they will float along with all the other airborne particles. Some will be inhaled, and some will not. In any event, most of the inhaled particles will not be deactivated. Rolf does not CATCH or HOLD the particles, and the KILL function is random and insignificant.

Reviewing Pages 4-6 of the USPTO office action shown in Exhibit 2001 for Rolf's patent application, the examiner provided detailed reasoning explaining why his claims were not enabled. The examiner had serious doubts whether Rolf's invention would work as disclosed in writing.

Rolf's patch cannot function as described by Rolf. To be effective, biocidal action requires contact with bioactive particles for a certain minimum time period. If the particles are not HELD in place by the patch, they would continue to float around, remain active and be inhaled. The only adhesive property of Rolf's patch is its ability to adhere to the skin of the upper lip in the region just below the nose. The side of the patch facing the airborne particles has no adhesive properties. The Rolf invention will not work for its intended purpose.

As argued previously, "to anticipate a claim, the reference must teach every element of the claim." MPEP 2131. To anticipate the claims of the '802 Patent, Rolf must teach all the elements of CATCH, HOLD, and KILL. Rolf does not teach electrostatic attraction of harmful particles to the patch. Rolf does not teach adjustment of adhesion or cohesion of his essential oil composition. He does not teach HOLDING the harmful particles to his essential oil composition. The absence of the HOLD element alone mitigates against anticipation of claims 1-3 or 8 of the '802 Patent. While biocidal agents may be present in his composition, they are of low concentration, and they are used only as preservatives. If there is a KILL function, it is ineffective. Finally, a reference that does not contain an enabling disclosure may not be used to anticipate a claim.

Regarding a finding of obviousness under 35 U.S.C. § 103 over Rolf alone would still require that every element (*i.e.*, CATCH, HOLD, and KILL) to be obvious from the disclosure of that single reference. Rolf's patch is not applied to the skin or tissue of the person's nasal passages, nor is would it be obvious to do this. Nor do the essential oils contact the person's skin. Examination of Rolf's disclosure, it is apparent that the essential oils cannot be directly applied to the skin

or tissue. They are separated from the skin by the adhesive patch. The KILL function may be inferred from the presence of a biocide. While benzalkonium chloride has cationic properties, this ingredient was not recognized by Rolf to be used in sufficient concentration to effectively utilize its electrostatic properties. Electrostatic attraction to the oils is not obvious from Rolf's disclosure. Moreover, without the HOLD function, the claims of the '802 Patent cannot be found obvious over Rolf alone. Without first reading the '802 Patent's disclosure, there would be no suggestion or motivation for a POSITA to implement the HOLD element.

E. GROUND 5: CLAIM 3 IS NOT RENDERED OBVIOUS OVER ROLF IN VIEW OF WAHI '005.

Petitioner challenges claims 3 of the '802 Patent alleging that it is rendered obvious under 35 U.S.C. § 106 by U.S. Patent Application Publication No. US 2004/0071757 A1 ("Rolf") in view of U.S. Patent No. 6,844,005 B2 ("Wahi '005").

As argued *supra*, for a claim of an issued patent to become invalid based on prior art, the prior art must teach or suggest each and every element of that claim. 35 U.S.C. § 103 provides that even if a claim is not anticipated under § 102, it may still be unpatentable if the differences between the claimed invention and the prior art as a

whole would have been obvious before the effective filing date of the claimed invention to a person of ordinary skill. When evaluating a claim for patentability, an examiner may combine two or more prior art references to determine whether the claimed invention would have been obvious to a POSITA at the time the invention was conceived.

Pre-AIA 35 U.S.C. § 103(a).

Claim 3 of the '802 Patent reads:

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

Claim 3 depends from claim 2, and it incorporates claim 2 by reference in its entirety therein. If claim 3 is combined with claim 2, the claim will effectively be:

3. 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 polymeric quaternary ammonium compound** 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.

Under 35 U.S.C. § 103, combining prior art references must be read to encompass all of the limitations of the claim under evaluation. Expanded claim 3 encompasses the CATCH, HOLD, and KILL elements. Thus, the combination of Rolf and Wahi must fill in the elemental gaps that either one reference or the other is missing. Wahi '005 provides the CATCH element. Even if it can be inferred that Rolf provides the KILL element, neither of the two references provides the HOLD element. The function of the HOLD element is critical to claim 3. If neither of the two references provide this functionality, either expressly or inherently, combining the two references will not produce a formulation exhibiting this property. Thus, Petitioner has not presented a *prima facie* case for claim 3 being unpatentable under 35 U.S.C. § 103 as being obvious over Rolf in view of Wahi '005.

V. CONCLUSION

Respondent, Trutek Corp., presented arguments *supra* demonstrating that:

1. Petitioner did not present a *prima facie* showing in **Ground 1** that claims 1-3 and 8 of the '802 Patent are anticipated by Chen, because it failed to show that Chen disclosed every element of the challenged claims either expressly or inherently.
2. Petitioner did not present a *prima facie* showing in **Ground 1** that claims 1-3 and 8 of the '802 Patent are rendered obvious over Chen alone, because it presented only conclusory statements to support its challenge. There was no teaching, suggestion or motivation in Chen, the modification of which would produce the challenged claims. Petitioner also used impermissible hindsight in its conclusion, in spite of the fact that it took years of research, development, and experimentation to create the formulations shown in the '802 Patent.
3. Petitioner did not present a *prima facie* showing in **Ground 2** that claims 1-3 and 8 of the '802 Patent are anticipated by Baker, because it failed to show that Baker disclosed every element of the challenged claims either expressly or inherently.

4. Petitioner did not present a *prima facie* showing in **Ground 2** that claims 1-3 and 8 of the '802 Patent are rendered obvious over Baker alone, because it presented only conclusory statements to support its challenge. There was no teaching, suggestion or motivation in Baker, the modification of which would produce the challenged claims. Petitioner also used impermissible hindsight in its conclusion, in spite of the fact that it took years of research, development, and experimentation to create the formulations shown in the '802 Patent.
5. Petitioner did not present a *prima facie* showing in **Ground 3** that claims 1-3 and 8 are anticipated by Wahi '005, because it failed to show that Wahi '005 disclosed every element of the challenged claims either expressly or inherently. The '802 Patent was issued to Wahi as an improvement over the Wahi '005 Patent. Moreover, Wahi '005 was available to and considered by the examiner when he allowed the application to issue as the '802 Patent.
6. Petitioner did not present a *prima facie* showing in **Ground 3** that claims 1-3 and 8 of the '802 Patent are rendered obvious over Wahi '005 alone, because it presented only conclusory

statements to support its challenge. There was no teaching, suggestion or motivation in Wahi '005, the modification of which would produce the challenged claims. Petitioner also used impermissible hindsight in its conclusion, in spite of the fact that it took years of research, development, and experimentation by Wahi himself to create the formulations shown in the '802 Patent. Moreover, Wahi '005 was available to and considered by the examiner when he allowed the application to issue as the '802 Patent.

7. Petitioner did not present a *prima facie* showing in **Ground 4** that claims 1-3 and 8 of the '802 Patent are anticipated by Rolf, because it failed to show that Rolf disclosed every element of the challenged claims either expressly or inherently. Rolf disclosed a different type of invention that was not enabled.
8. Petitioner did not present a *prima facie* showing in **Ground 4** that claims 1-3 and 8 of the '802 Patent are rendered obvious over Rolf alone, because it presented only conclusory statements to support its challenge. There was no teaching, suggestion or motivation in Rolf, the modification of which would produce the challenged claims. Petitioner also used

impermissible hindsight in its conclusion, in spite of the fact that it took years of research, development, and experimentation to create the formulations shown in the '802 Patent.

9. Petitioner did not present a *prima facie* showing in **Ground 5** that claims 1-3 and 8 of the '802 Patent are rendered obvious over Rolf in view of Wahi '005 because it failed to show that combining the teachings of Rolf with Wahi '005 would produce the formulations of the challenged claims 2, 3, or 8 of the '802 Patent or would reproduce the methodology of claim 1. There was no teaching, suggestion or motivation in Rolf to combine it with the teachings of Wahi' 005, the modification of which would produce the challenged claims. Petitioner also used impermissible hindsight in its conclusion, in spite of the fact that it took years of research, development, and experimentation to create the formulations shown in the '802 Patent.
10. If claim 2 is neither anticipated nor obvious over the prior art presented by Petitioner, claim 3 cannot be so anticipated or obvious because claim 3 depends from claim 2, thereby incorporating all the limitations of claim 2 in their entirety therein.

11. Respondent, Trutek Corp., presented arguments of secondary considerations, in that it can produce evidence that since 2012, Trutek has sold over seven million tubes of its product worldwide, said product being protected by the '802 Patent and having said patent number marked thereon.

Because of all the statements made above and all of the arguments submitted in this response, Trutek submits that it has set forth reasons why the requested *inter partes* review should not be instituted. Trutek respectfully requests that said review not be instituted.

Dated: September 7, 2024

Respectfully submitted,

/s/Stanley H. Kremen
Stanley H. Kremen

Registered Patent Attorney
Registration No. 51900

*Attorney for Respondent,
Patent Owner, Trutek Corp.*

CERTIFICATE OF COMPLIANCE

Pursuant to 37 CFR § 42.24(d), I hereby certify that the foregoing document entitled, "Respondent/Patent Owner's Preliminary Response to Petition For *Inter Partes* Review of U.S. Patent No. 8,163,802," contains 12,247 words as measured by Microsoft Word 2003 used to prepare the document, excluding the parts of the document exempted by 37 CFR § 42.24(a)(1).

/s/ Stanley H. Kremen
Stanley H. Kremen
Registration No. 51900
Lead Counsel for Respondent

CERTIFICATION OF SERVICE

The undersigned hereby certifies that the above-captioned “Respondent/Patent Owner's Preliminary Response to Petition for *Inter Partes* Review of U.S. Patent No. 8,163,802,” regarding IPR2024-00711 was served on September 11, 2024, upon the following via email:

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/s/ Stanley H. Kremen

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*Lead Counsel for Patent
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Trutek Corp..*