

ASSERTED CLAIMS

- **Claim 1 – Independent Method Claim**
- **Claim 2 – Independent Formulation Claim**
- **Claim 3 – Formulation Claim Depends From Claim 2**
- **Claim 8 – Independent Formulation Claim**

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE - Slide 01

Claim 1 - Preamble

- 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:

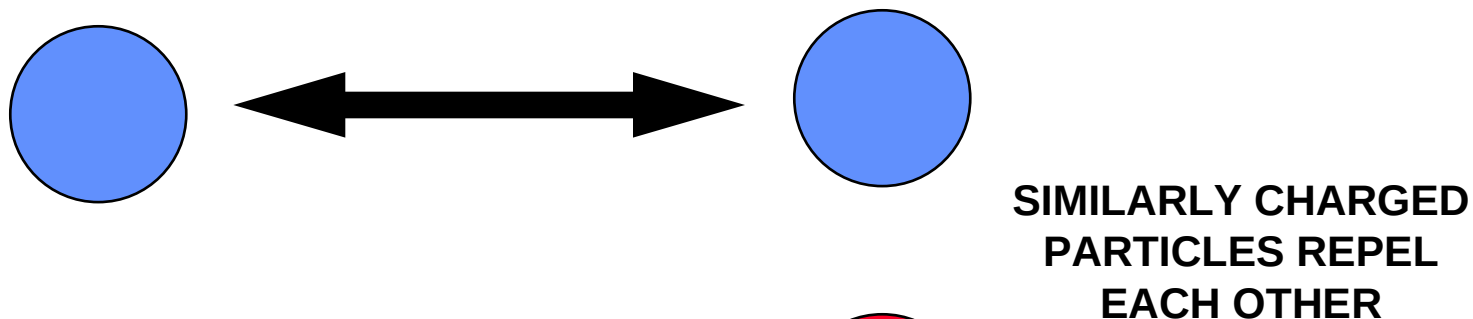
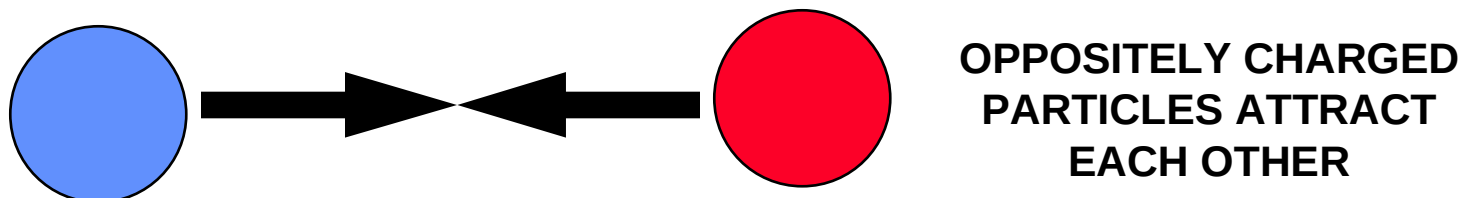


DEMONSTRATIVE EXHIBIT - NOT EVIDENCE - Slide 03

Claim 1 – Element (a) The CATCH Function

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

ELECTROSTATIC ATTRACTION & REPULSION



DEMONSTRATIVE EXHIBIT - NOT EVIDENCE - Slide 05

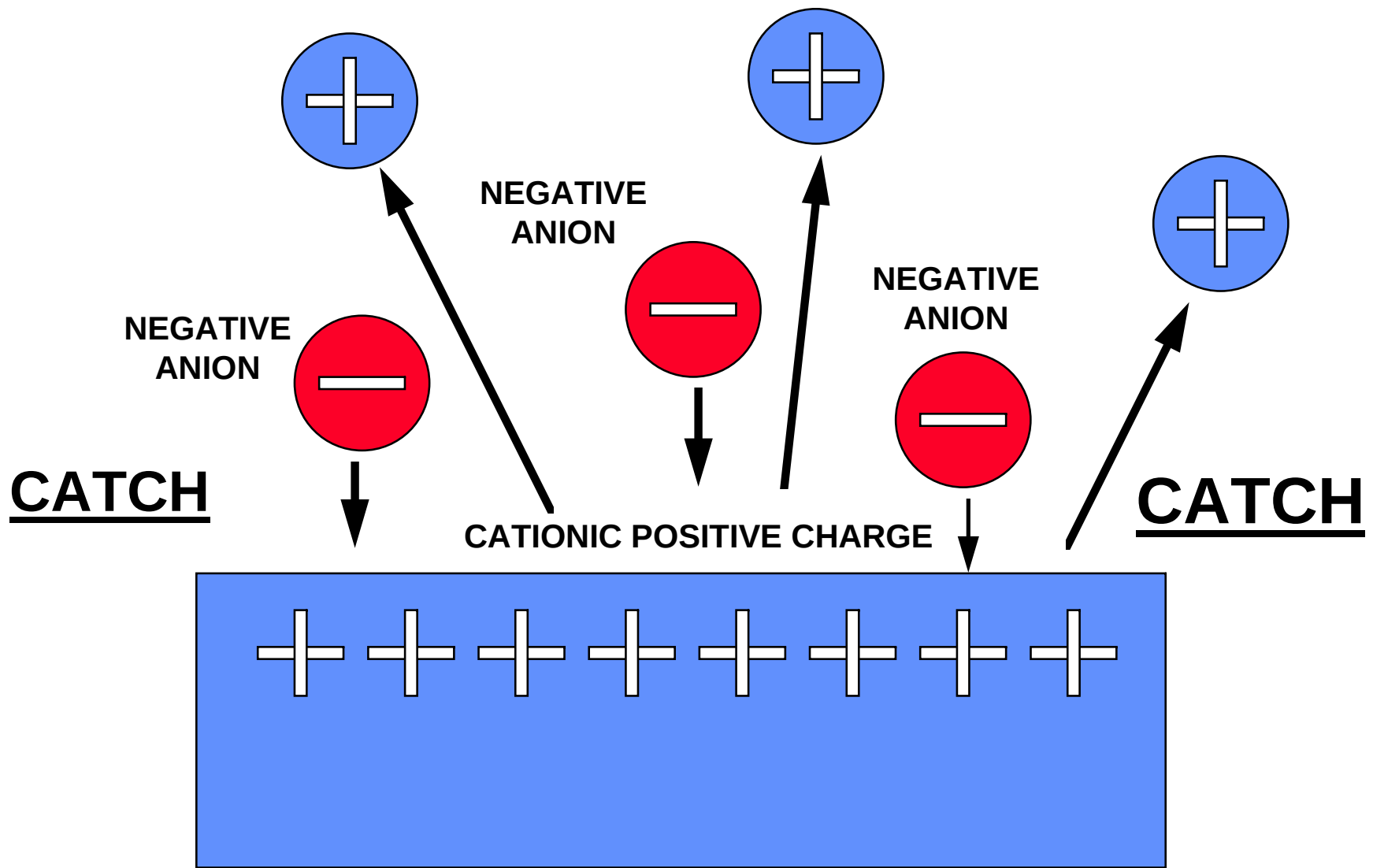
Positive Electrostatic Field

Attracts and Holds
Negatively Charged
Particles:

- Viruses & Bacteria
- Pollutants
- Dust
- Pollen



DEMONSTRATIVE EXHIBIT - NOT EVIDENCE - Slide 06



POSITIVE ELECTROSTATIC FIELD ATTRACTS NEGATIVELY CHARGED PARTICLES AND REPELS POSITIVELY CHARGED PARTICLES

DEMONSTRATIVE EXHIBIT - NOT EVIDENCE - Slide 07

Claim Construction

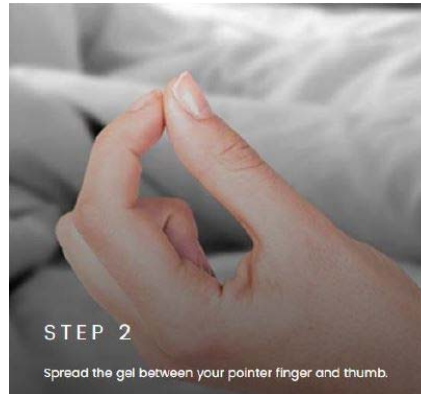
Petitioner contends that “[l]ogically, the formulation applied in a thin film must be on the exterior region around the nostril (i.e., skin) and/or slightly inside the edge of the nostril which is the tissue of nasal passages in order to prevent nasal inhalation.

Judge Erica Franklin

Paper 7, Page 10

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE - Slide 08

Applying NasalGuard Gel



Step 1: Squeeze a drop on the pointer finger.

Step 2: Spread the gel between the pointer finger and the thumb.

Step 3: Apply directly around the nostrils and above the upper lip.

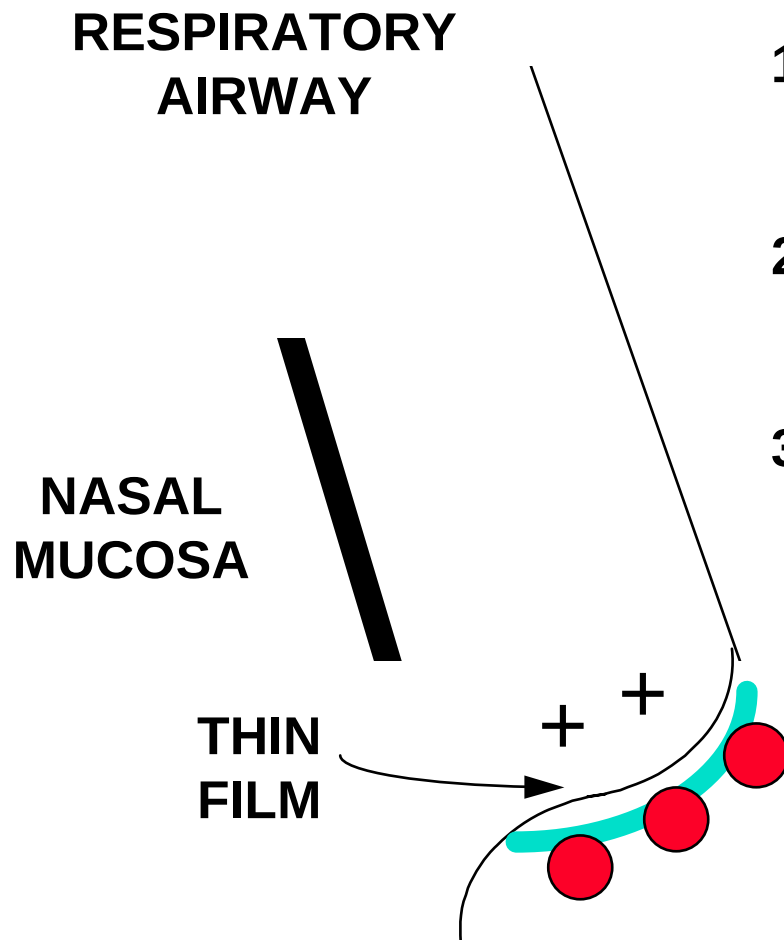
DEMONSTRATIVE EXHIBIT - NOT EVIDENCE - Slide 09

Claim 1 – Element (b)

The HOLD Function

- (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;

HOLD

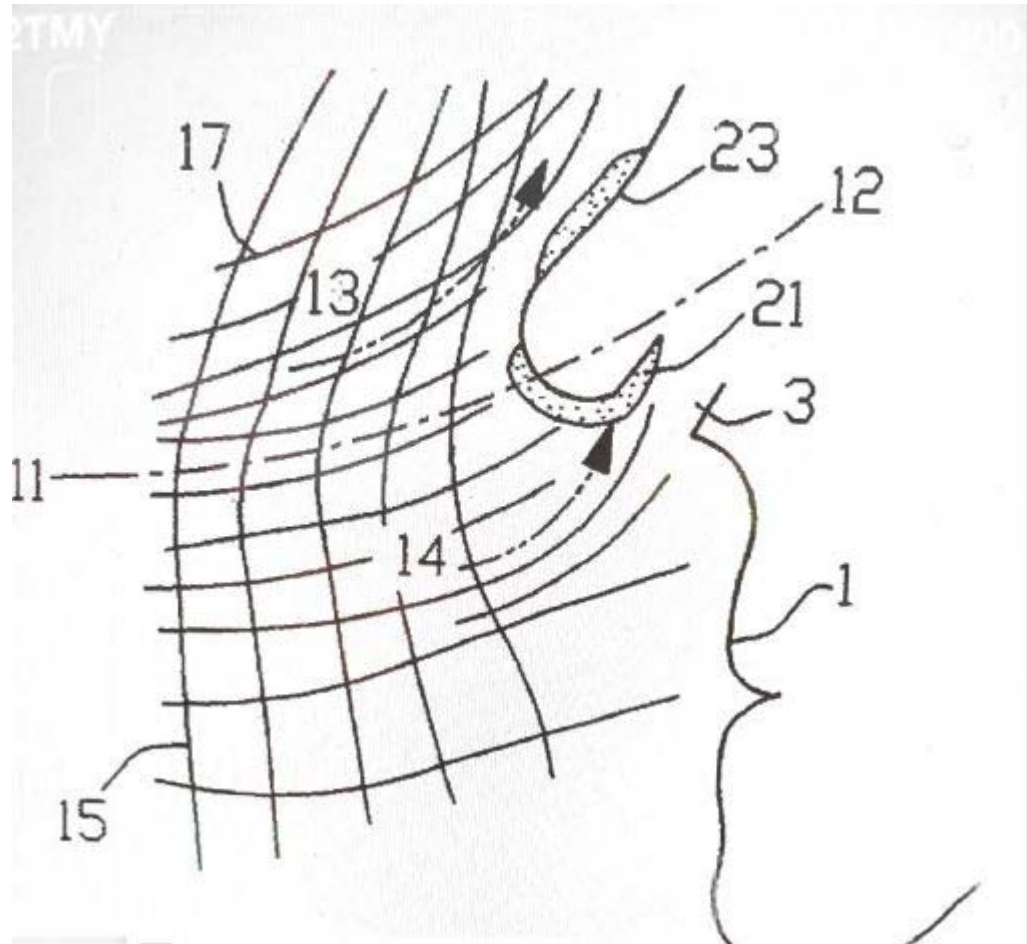


- 1) Positively Charged Thin Film Adheres to the Skin or Tissue.
- 2) Negatively Charged Harmful Particles Adhere to the Thin Film.
- 3) Thin Film is Impermeable. Harmful Particles Do Not Contact Skin or Tissue.

DEMONSTRATIVE EXHIBIT - NOT EVIDENCE - Slide 11

U.S. Patent No. 6,844,005

Wahi '005



DEMONSTRATIVE EXHIBIT - NOT EVIDENCE - Slide 12

U.S. Patent No. 6,844,005

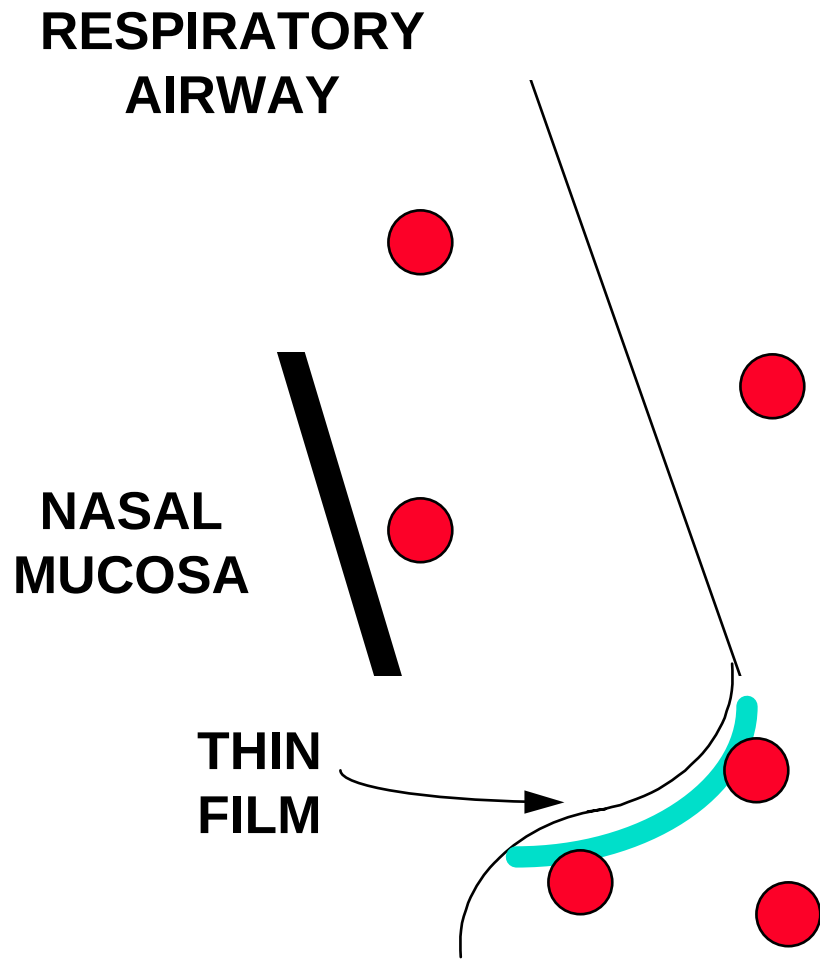
Wahi '005

'802 Patent discussing Wahi '005:

Furthermore, actions by the person having those electrostatic compositions in the vicinity of the nostrils can sufficiently displace the offending particles or organisms especially in such instances as blowing or wiping the nose, so that particles that were held captive by the former compositions could become dislodged, again set free, and be inhaled.

'802 Patent 2:52-58

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE - Slide 13



Trutek has been selling electrostatically charged gel products since 1995.

Experiments showed that particles would become dislodged after contact with the thin film, and float freely in the air.

None of Trutek's previous products exhibited the HOLD function.

DEMONSTRATIVE EXHIBIT - NOT EVIDENCE - Slide 14

Claim 1 – Element (c)

The KILL Function

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

Functions of the Formulation

■ CATCH

■ HOLD

■ KILL

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE - Slide 16

Claim 2

- Claim 2 is an independent claim.
- Claim 2 recites the formulation of Claim 1.
- The formulation implements the method of Claim 1
(1) Catch; (2) Hold; (3) Kill.

Functions of the Formulation

- The formulation contains a cationic agent that electrostatically attracts negatively charged harmful particles (the CATCH function)
- The formulation deliberately adjusts adhesion and cohesion to hold harmful particles in place (the HOLD function)
- The formulatin contains a biocide to render the particles harmless.
(the KILL function)

Wahi '005 does not implement the HOLD function

'802 Patent discussing Wahi '005:

“Furthermore, actions by the person having those electrostatic compositions in the vicinity of the nostrils can sufficiently displace the offending particles or organisms especially in such instances as blowing or wiping the nose, so that particles that were held captive by the former compositions could become dislodged, again set free, and be inhaled.”

'802 Patent 2:52-58

'802 Patent vs. Wahi 005

- **Ashok Wahi is the sole inventor of both patents.**
- **Both the '802 Patent and Wahi 005 contain a cationic agent and a biocidic agent.**
- **Both the '802 Patent and Wahi 005 implement the CATCH and KILL functions.**

'802 Patent vs. Wahi 005

- **The methodology and formulations of the '802 Patent represents a significant improvement over Wahi 005.**
- **The first time in the prior art that the HOLD function appears is in '802 Patent's criticism of Wahi 005.**
- **Implementation of the HOLD function is a deliberate improvement.**
- **Implementation requires inventor awareness of the problem, which was first pointed out in the '802 Patent.**

‘802 Patent vs. Wahi 005

The HOLD function is critical.

- **To implement the HOLD function, one must deliberately modify the adhesion and cohesion of the formulation to achieve the desired result.**
- **Wahi 005 does not have the HOLD function. Therefore, Wahi 005 cannot anticipate the ‘802 Patent under Section 102.**
- **The ‘802 Patent’s claims cannot be obvious in view of Wahi 005 because to implement the HOLD function, one needed to be aware of the problem, first indicated in ‘802 Patent.**

Claim 3

- Dependent Claim 3 depends from Claim 2, and it incorporates by reference all of the limitations of Claim 2.
- Claim 3 is the formulation of Claim 2, wherein the cationic agent is a polymeric quaternary ammonium compound.
- Claim 3 implements the CATCH, HOLD, and KILL functions.
- If Claim 2 is patentable, Claim 3 must also be patentable.

Claim 8

Claim 8 is an independent formulation claim that implements the functionality of Claim 1

ELECTROSTATICALLY INHIBITING

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE - Slide 25

Electrostatically Inhibiting

- Clearly, the PTO Examiner defined what is meant by “inhibiting.” The term was understood by the Applicant.
- The Applicant amended the claim, and the application was allowed based on the amendment.
- “Inhibiting” means that while some harmful particles are inactivated, one or more of them can infect the individual.
- “Electrostatically Inhibiting” must be interpreted as inhibiting using electrostatic means. There is no other reasonable interpretation.
- “Electrostatically Inhibiting” is a statement of use for the method of claim 1 and the formulation of Claim 2 and Claim 8.

The Asserted Prior Art

- U.S. Pat. Appl. Pub. 2005/0232895 (“Chen”)
- U.S. Pat. No. 6,559,189 (“Baker”)
- U.S. Pat. No. 6,844,005 (“Wahi 005”)
- U.S. Pat. Appl. Pub. 2004/0071757 (“Rolf”)

Claims Challenged/Grounds

1, 2, 3, 8

- 1) Claims 1,2,3,8 anticipated by Chen under §102 or rendered obvious over Chen under §103.**
- 2) Claims 1,2,3,8 anticipated by Baker under §102 or rendered obvious over Baker under §103.**
- 3) Claims 1,2,3,8 anticipated by Wahi 005 under §102 or rendered obvious overf Wahi 005 under §103.**
- 4) Claims 1,2,3,8 anticipated by Rolf under §102 or rendered obvious over Rolf under §103.**
- 5) Claim 3 rendered obvious under §103 over Rolf in view of Wahi 005.**

Anticipation - 35 U.S.C. §102

- A single prior art reference
- every element of the claim must be disclosed
- either expressly or inherently

The prior art reference must be enabled and operative.

MPEP § 2121.01

Obviousness – 35 U.S.C. §103

- Determine the scope and content of the prior art.
- Ascertain the differences between the claimed invention and the prior art.
- Determine the level of skill of ordinary skill in the art (POSITA).
- Reasons or rationale for combining prior art references by a POSITA.

Obviousness – 35 U.S.C. §103

- The combined prior art must teach or suggest every element in the claim.
- A POSITA must have a rationale for combining multiple references to foresee every element in the claim.
- For a determination of obviousness of a claim based on a single reference, a POSITA must have a rationale to foresee every element in the claim.

Wahi 005 Fails to Anticipate

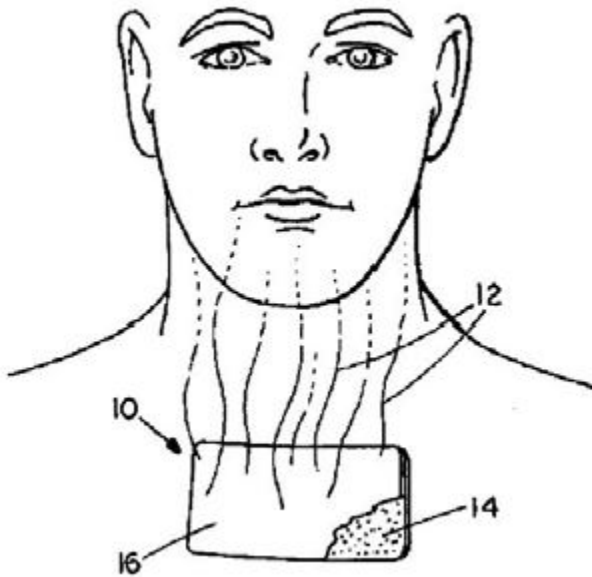
- Wahi 005 formulation is a gel that is applied externally to the nasal region.
- Wahi 005 formulation creates an electrostatic field that attracts harmful particles.
- However, Wahi 005 formulation does not exhibit the HOLD function. ('802 Pat. 2:42-58)
- Examiner was aware of and took Wahi 005 into consideration in issuing Notice of Allowance (Ex. 1004, pg. 40, #16).

'802 Patent Claims Not Obvious Over Wahi 005 Under § 103

- **Petitioner alleges obviousness using a single reference.**
- **Wahi 005 does not teach or suggest every element of the claims. The HOLD function is absent.**
- **POSITA must recognize the problem that particles dislodge before arriving at a solution that includes HOLD. No Motivation.**
- **The dislodging problem is disclosed for the first time in the '802 Patent. Referring to the '802 Patent is impermissible hindsight.**

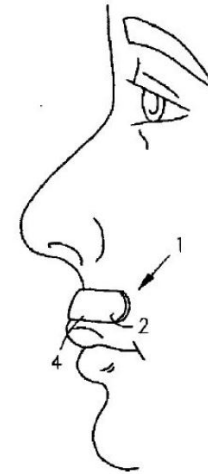
Rolf Does Not Anticipate

- Rolf's patent application never issued as a patent because all claims were rejected.
- First, all claims were "rejected under 35 U.S.C. §112 First Paragraph, as failing to comply with the enablement requirement." (Ex. 2001, pp 7-8.)
- Disclosure is inoperable (*Id.* pg 8.)
- To anticipate, prior art reference must be enabled and operative. (MPEP § 2121.01)



BLOCK

US 6,090,403



ROLF

Double Patenting
Rejection

Essential Oils

DEMONSTRATIVE EXHIBIT - NOT EVIDENCE - Slide 35

Rolf Does Not Anticipate

- Rolf is a co-inventor on the Block patent. (US 6,090,403).
- They both use the same patch. Block affixes to chest – Rolf to upper lip.
- Both patches emit vapors of essential oils that are toxic to microbes.
- The HOLD element is not taught either expressly or inherently. Particles dislodge and float free in the air.
- Those live particles that are not affected by the essential oil vapors can be inhaled.

'802 Patent Claims Not Obvious Over Rolf Under § 103

- In an obvious determination, a POSITA must foresee every element in a claim.
- This is true especially when prior art is a single prior reference rather than a combination of references.
- A POSITA is one of ordinary skill, who is aware of all prior art.
- To foresee an element, the POSITA must see a solution to a problem. Without awareness of a problem, he cannot foresee a solution.
- The only prior art where the problem of dislodged particles appears is the '802 Patent.
- A POSITA cannot foresee the HOLD element without reading the '802 Patent.

'802 Patent Claims Not Obvious Over Rolf In View of Wahi 005

- **The HOLD function is a critical element of the '802 Patent claims.**
- **Neither Rolf nor Wahi 005 exhibit the HOLD element.**
- **It is impossible for the combination of Rolf and Wahi 005 to exhibit the HOLD element.**
- **Rolf and Wahi 005 cannot possibly be combined to produce the other elements.**

Grounds Remaining

1) Chen, 2) Baker

- 1) Claims 1,2,3,8 anticipated by Chen under §102 or rendered obvious over Chen under §103.
- 2) Claims 1,2,3,8 anticipated by Baker under §102 or rendered obvious over Baker under §103.
- 3) Claims 1,2,3,8 anticipated by Wahi 005 under §102 or rendered obvious overf Wahi 005 under §103.
- 4) Claims 1,2,3,8 anticipated by Rolf under §102 or rendered obvious over Rolf under §103.
- 5) Claim 3 rendered obvious under §103 over Rolf in view of Wahi 005.

Baker Does Not Anticipate

- Baker uses an oil-in-water liquid nanoemulsion that is applied inside the nasal passages. It is not an external application (*i.e.*, skin or tissue of the nasal passages).
- Baker does not teach electrostatic attraction (the CATCH) element. The harmful particles are already inside the nose.
- Electrostatic attraction (CATCH) outside the nasal passages (the facial region) is not taught either expressly or inherently.

Baker Does Not Anticipate

- Baker does not teach or suggest the HOLD element either expressly or inherently.
- Baker does not teach or suggest holding the microorganisms in place.
- There is no mention of adjusting the adhesion and cohesion of the nanoemulsion to achieve impermeability.

'802 Patent Claims Not Obvious Over Baker Under § 103

- **A POSITA could possibly foresee the CATCH and/or KILL elements in Baker's nanoemulsion compositions.**
- **However, the problem of the microorganisms dislodging would be unknown to the POSITA. It is neither taught or suggested by Baker. It is also not inherently taught.**
- **A POSITA could not foresee the HOLD element without first reading the '802 Patent.**

Ground 1 - CHEN

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE - Slide 43

Anticipation

- Chen does not disclose or teach the HOLD element.
- Petitioner's expert makes the following statement several times:

“Cationic agents attract particulate matter and hold particulate matter in place.”

(e.g., Ex. 1002, pg. 34, ¶ 134)

Anticipation

- The HOLD element is discussed in the '802 Patent specification as the solution to the problem of the captured particles dislodging from the applied formulation only to be inhaled.
- Dr. Park's conclusion is an opinion without providing a basis.
- Dr. Park's opinion ignores the '802 Patent's use of the HOLD element to prevent particles from being dislodged and inhaled.
- The HOLD element is the primary improvement in the '802 Patent.

Anticipation

- **Chen incorporates a viscosity modifier in his composition. (Chen [0036])**
- **Dr. Park said, “it is known in the art to adjust the adhesion and cohesion of the composition by adjusting the viscosity. (Ex. 1002, ¶ 76, pg. 22.)**
- **Adjusting viscosity and cohesion are two different things. Viscosity is related to fluid flow. Cohesion is forming a bond between the same or similar materials.**

Anticipation

- While Chen modifies the viscosity of his composition, he does not adjust its cohesion.
- In Claim 8, addition of a quaternary thickener increases the cohesion by bonding to the other ingredients in the formulation. It is not merely viscosity.

Anticipation

- In Paper 7, Judge Franklin wrote, “*The ‘802 Patent recognizes that other patents have ‘describe[d] electro-statically charged compositions that may be applied externally in the vicinity of the nostril and attract oppositely charged materials that would otherwise be inhaled.*”
- However, those patents were all prior inventions by Ashok Wahi. The ‘802 Patent distinguished from and improved upon those prior patents.

(Paper 7, pg. 3)

Anticipation

- Judge Franklin further wrote, “*According to the Specification, those compositions ‘cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as micro-organisms that are motile within the air stream.’*” (citing ‘802 Pat. At 2:45-52)
- “*Further, the Specification states that particles held captive by the former compositions could become dislodged when blowing or wiping the nose.*” (citing *Id.* at 2:52-58)

(Paper 7, pg. 3)

Anticipation

- Judge Franklin next wrote, “*Petitioner contends that ‘[I]logically, the formula- tions applied in a thin film must e on the exterior region around he nostril (i.e., skin) and/or slightly inside he ege of the nostril which is the tissue of nasal passages in order to prevent nasal inhalation.’*” (Paper 7, pg 10)
- However, CHEN does not contemplate this external application on the “exterior region around the nostril.”

Anticipation

- Chen does not expressly teach electrostatic attraction of harmful particles.
- Chen incorporates several cationic ingredients into his anti-viral compositions. These will establish a positively charged electrostatic field that will inherently attract negatively charged harmful particles.
- If his composition is applied inside the nostrils, it will increase the probability of those harmful particles will be inhaled into the respiratory system.
- Chen does not teach or suggest (or even contemplate) external application onto the exterior skin or tissue of the nasal passages.

Anticipation

Chen [110] states, “The compositions of the present invention may be administered to a subject locally. The term ‘local’ encompasses application in and around the site of intended treatment, and excludes peroral. ... Exemplary local administration includes, but is not limited to (1) ‘topical’ application, including the treatment on the human skin, hair and nail, (2) ‘mucosal’ application, including the treatment on the nasal mucos membrane, oral mucos membrane (also referred to as oral cavity) vaginal mucous membrane, or in general, the genitalia area, and (3) ‘ophthalmic’ application, including the treatment in the eye.”

Emphasis added.

Anticipation

- From Chen [110], while he anticipates applying his antiviral composition to the human skin and the nasal mucous membrane, he did not contemplate applying the composition to the exterior of the nostrils to capture airborne virus particles and prevent them from being inhaled.
- Chen anticipates applying his composition to the nasal mucosa, but if he does this, the inherent attraction of airborne viruses will cause them to be inhaled.

Anticipation

- In Paper 7, Judge Franklin wrote, “*Petitioner asserts that Chen describes its formulations as providing ‘muco-adheviveness by forming a physical barrier over the mucous membrrane.’*” (Pqper 7, pg 16)
- In the ‘802 Patent, the gel is not applied to the mucous membrane. Application to the mucous membrane would cause the virus particles to be inhaled.

Anticipation

On Page 17 of Paper 7, Judge Franklin wrote, *“Petitioner asserts that Chen’s formulation ‘holds th particulate matter in place by adjusting the adhesion to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film.’ as required by claim 2 ... According to Petitioner and Dr. Park, Chen’s formulation functions in this way because Chen’s cationic agent in the formulation attracts and holds particulate mater and the thin film comprising the cationic agent and formulated as a gel, lotion, cream, or ointment holds the particulate matter in the film.”*

(citing Ex. 1005 ¶ 38, Ex. 1002 ¶ ¶ 77, 134)

Anticipation

- The primary difference between the compositions of the '802 Patent and Wahi 005 is the HOLD element.
- Both patents electrostatically CATCH harmful particles due to their cationic agents attracting these particles to their thin films.
- However, the HOLD element prevents captured particles from being later dislodged.
- Petitioner and Dr. Park fail to show how Chen prevents capture particles from being later dislodged.
- Chen does not implement the HOLD element of the '802 Patent's claims.

Anticipation

The claims of the '802 Patent each recite the three elements:

■ CATCH

■ HOLD

■ KILL

Anticipation

- Chen employs cationic agents in his formulations.
- While his formulations attract harmful particles, he does not contemplate external application to the “exterior region around the nostril and/or slightly inside the edge of the nostril.” (‘802 Patent 2:63-65)
- If Chen’s liquid, gel, lotion, or cream is applied to the nasal mucosa, the individual would be inhaling the virus particles.
- Chen is mainly interested in destroying viruses already infecting an individual rather than electrostatically attracting live viruses to his formulation.
- Without proper application, Chen’s formulation will not inherently electrostatically inhibit infection.

Anticipation

- Chen does not expressly teach electrostatic attraction of viruses.
- For the CATCH element to function, the cationic agent must create an electro-static field that surrounds the person's nose. That requires exterior application to the skin in the vicinity of the nose.
- Application of Chen's formulation to the mucosa will only perform the KILL element on those viruses already inhaled.

Anticipation

- Chen does not expressly or inherently teach the HOLD element.
- No prior art earlier than the '802 Patent expressly or inherently teaches the HOLD element (*i.e.*, prevents captured harmful particles from dislodging and being inhaled into the individual's respiratory system.
- The problem was first recognized by Ashok Wahi, and that led to inventing the formulations of the '802 Patent.

Anticipation

- Claims 1 and 2 expressly recite the CATCH, HOLD, and KILL elements.
- Claim 3 implicitly recites the CATCH, HOLD, and KILL elements.
- Claim 8 is a formulation claim. The preamble breathes life into the claim, and it is limiting.
- In claim 8, the term electrostatically inhibiting takes on the same meaning as in the preambles of claims 1, 2, and 3.
- In claim 8, inclusion of the quaternary thickener ingredient is done to adjust the cohesion of the formulation for adequate impermeability.

Anticipation

- Chen does not expressly or inherently teach external application of his compositions to the “exterior region around the nostril and/or slightly inside the edge of the nostril. Without this, the CATCH element will not function to electrostatically inhibit infection through inhalation.
- Chen does not expressly or inherently teach the HOLD element that prevents harmful particles from dislodging and being inhaled.
- CHEN DOES NOT ANTICIPATE THE CLAIMS OF THE ‘802 PATENT.

Obviousness

- A POSITA is a fictional individual of ordinary skill who is aware of all prior art in his field and all analagous art.
- Chen does not expressly or inherently teach application of his composition to the exterior region in the vicinity of the nostrils.
- However, Ashok Wahi's prior patents (notably Wahi 005) do expressly teach this application as well as the CATCH element.
- A POSITA would understand that Wahi 005 already taught the CATCH element, and that Chen could be modified to incorporate it.

Obviousness

- However, no published art prior to the '802 Patent teaches either expressly or inherently, or even discusses the problem of captured virus particles dislodging from the gel and being inhaled into the respiratory system.
- Without an understanding of this problem, a POSITA would not be motivated to modify Chen to include the HOLD element in his disclosure.
- Therefore, the claims of the '802 Patent are not obvious over Chen.

Obviousness

- Patent Owner, Trutek Corp, has had significant commercial success in selling the product protected by the '802 Patent in the United States and worldwide. This secondary consideration should mitigate against obviousness of the '802 Patent's claims.
- Evidence of commercial success presented to the Board is currently in dispute between the parties. That dispute is awaiting Board ruling.

To the Board

Patent Owner's Oral Argument relies on:

- Exhibits 1001-1002
- Exhibits 1004-1009
- Exhibits 2001-2002
- The IPR Petition
- Paper No. 7