

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SALVACION USA, INC.
Petitioner

v.

TRUTEK CORP.
Patent Owner

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

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

Inter Partes Review No. IPR-2024-00711

**PATENT OWNER'S SUR-REPLY TO
PETITIONER'S REPLY**

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STATUTES

35 U.S.C. § 102 13, 16, 19, 20, 26, 27, 28, 30

35 U.S.C. § 103 13, 20, 26, 27, 28, 30

Certificate of Compliance

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LIST OF EXHIBITS

Exhibit No.

2003	Declaration of Ashok Wahi
2004	Representative NasalGuard® Products
2005	How To Use NasalGuard®
2006	Max Neeman Clinical Study
2007	'802 Patent Commercialization Website Links

I. INTRODUCTION

Claims 1-3 and 8 of the '802 Patent is neither anticipated nor obvious over the Grounds set forth by the Petitioner. Claim construction was performed by the United States District Court for the Eastern District of Michigan on January 10, 2023.¹ The Michigan District Court made this ruling following a Markman hearing held in November 2022.² Petitioner is aware of the court's claim construction because it was filed with its Petition as Exhibit 1010. In performing its own claim construction, the Petitioner's input was not inconsistent with the court's own construction. Petitioner accepted the court's definition of a person having ordinary skill in the art ("POSITA").³ Patent Owner does not dispute Petitioner's POSITA qualifications. Here, the district court adopted Trutek's definition of a POSITA.

The district court construed the terms: (i) "electrostatically inhibiting," (ii) "electrostatically attracting," (iii) "adequate impermeability," (iv) and "renders said particulate matter harmless." The court held all four terms definite, and it adopted Patent Owner's proposed construction of these terms. Petitioner provided its

¹ *Trutek Corp. v. BlueWillow Biologics, Inc.*, 2:21-cv-1012 (E.D.MI. 2021). ECF No. 53 (01/10/2023).

² *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996).

³ See Petition pg. 12 and Also Ex. 1010 pp. 8-10.

proposed construction of terms: (a) "biocidal agent," (b) "adequate impermeability," (c) and "skin or tissue of the nasal passages of the individual." Petitioner adopted the district court's construction of the terms, "biocidal agent" and "adequate impermeability" as proposed by Patent Owner to the district court. Petitioner's proposed construction of the term, "skin or tissue of the nasal passages of the individual," is wholly consistent with the '802 Patent specification. It is also consistent with Hon. Erica Franklin's construction of these terms in PTAB's decision to institute an *inter partes* review. (Paper7.)

In the introduction to its reply, Petitioner argued that, "Patent Owner has refused to accept Petitioner's claim construction, but instead has offered a claim construction that is incorrect and unsupported by any evidence of record." Patent Owner does not challenge Petitioner's claim constructions. Further, Patent Owner adopts the PTAB construction of those terms not addressed in its Petition.⁴

Regarding Petitioner's allegation that Patent Owner's lack of response to Grounds 2-5, Patent Owner's Preliminary Response to the Petition (Paper 6) fully responded to these grounds. In effect, it

⁴ Paper 7, pp. 8-13.

represents a complete reply to the Petition. It is a matter of record, and it was considered by the Panel in its decision to institute a trial. Thus, it should be considered as part of the Patent Owner's reply just as any other exhibit originally attached to the Petition. Regardless, The substance of the arguments related to Grounds 2-5 is implicitly presented by the broader discussion of the '802 Patent's distinct features, particularly of the HOLD function, which overcomes all prior art submitted by the Petitioner.

However, in the PTAB's decision to institute an *inter partes* review, Hon. Erica A. Franklin, addressed only Patent Application Publication US 2005/0232895 by Andrew Xian Chen ("Chen") as PTAB's basis for instituting a trial. The PTAB decision introduced additional arguments that claims 1-3 and 8 are either anticipated by or obvious over Chen. Paper 6 was intended to be a complete reply to the Petition, and it should not be ignored. Moreover, Petitioner acknowledged and addressed the technical content of Paper 6.⁵ Since Paper 6 addressed each and every ground set forth by Petitioner, the additional arguments put forth in the decision needed

⁵ For example, see Petitioner's Reply, pg. 23 where it argues that the response in Patent Owner's Preliminary Response (Paper 6) fails to adequately address Grounds 2-5. In its reply, Petitioner addressed technical deficiencies in the Preliminary Response. Here, Petitioner opens the door to consideration of these arguments.

to be addressed. Patent Owner addressed Judge Franklin's arguments in its reply to the Petition.

II. PETITIONER'S CLAIM CONSTRUCTION

In addition to the terms construed by Petitioner in the Petition, in its reply, Petitioner added several terms not originally addressed. Those are "biocidic agent," and "adequate impermeability," These constructions are consistent with the district court's ruling as well as the PTAB decision (Paper 7). The Patent Owner does not dispute these additional term constructions. However, Petitioner provided additional argument regarding the term "skin or tissue of the nasal passages." At the bottom of page 3, Petitioner stated, "[t]herefore, the formulations must be in or near the nasal passages in order to prevent nasal inhalation." Patent Owner does not challenge this construction.

Petitioner has engaged the services of Dr. Kinam Park to act as its technical expert in this matter. From his CV, he appears to be a person of extraordinary skill in the art. Dr. Park has provided his opinion on the qualifications of a POSITA. His opinion is consistent with that of the district court, and it follows Patent Owner's proposed qualifications of such a person. Whether or not he is "qualified to

opine on how a POSITA would interpret the claims" is yet to be determined.

Petitioner stated that Dr. Park submitted expert testimony in this matter. Patent Owner intends to cross examine him to ascertain the validity of his opinions testified to in his declaration. (Exhibit 1002.)

A. The Three Element Process and Formulation

Page 7 of Petitioner's Reply refers to Patent Owner's characterization of the claims as a three-step process, *i.e.*, "CATCH, ... HOLD, ... [and] KILL." Patent Owner agrees with Petitioner that these terms do not appear in the language of the claims. Claims 1 and 2 each comprise three main elements (a, b, and c). In both claims, Element (a) recites electrostatic attraction of particulate matter to the thin film. The formulation thus 'CATCHES' the particulate matter. Element (b) recites holding the particulate matter in place. The formulation thus 'HOLDS' the particulate matter in place. Finally, Element (c) recites inactivating the particulate matter by use of a biocidic agent to render the particulate matter harmless. Thus, the formulation 'KILLS' the particulate matter. Patent Owner's use of the words, CATCH, HOLD, and KILL, is not an attempt at claim construction. The terms in the claims themselves are as the

district court, the PTAB, and the Petitioner construed them. Patent Owner does not challenge Petitioner's claim construction. However, Patent Owner believes that the abbreviations CATCH, HOLD, and KILL would assist a POSITA to understand the claims. These terms are merely abbreviations or aliases for Claim Elements (a), (b), and (c), respectively. These terms are defined in Patent Owner's Reply on page 8.

1. Element (a) - The CATCH function

On page 8 of Petitioner's Reply, Petitioner states, "Patent Owner alleges that the claims require: 'a *purposeful adjustment* of the positive charge so as to *effectively create an electrostatic field surrounding the user's nose and face that would attract airborne particles that float in the vicinity of the nostrils.*'"⁶ The claims require that the particles must be attracted to the individual's nose *via* the process of electrostatic attraction. Without that attraction, the invention would be useless. Most harmful particles are negatively charged. A cationic agent is an ingredient in the formulation that establishes a positively charged electrostatic field. The preamble

⁶ Emphasis supplied.

states the purpose for the invention as being "a method ⁷/formulation⁸ for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation ..." In order to accomplish this intended function, the harmful particles would need to be captured by the thin film. Otherwise, the particles would be inhaled by the individual. From the claim language and specification, it is obvious that there must be a purposeful adjustment of the electrostatic field to attract these particles to prevent them from entering the respiratory tract. An electrostatic field that is too weak defeats the intended function of the invention. Proper adjustment of the electrostatic field is provided in the example formulations shown in Tables 1-10 of the specification.

On page 9 of its Reply, Petitioner stated that Dr. Park "opined that a POSITA would not interpret Claim Element a) of claims 1 and 2 as requiring 'a purposeful adjustment of the positive charge so as to effectively create an electrostatic field surrounding the user's nose and face that would attract airborne particles that float in the vicinity of the nostrils.'" Here, Dr. Park is mistaken. A POSITA is expected to be able to use logic. Example formulations from Tables 1-10 are

⁷ Claim 1.

⁸ Claims, 2, 3, and 8.

effective if and only if the concentrations of ingredients are within the stated ranges. Logic dictates that if inhalation of airborne harmful particles is to be inhibited, the electrostatic field must be strong enough to attract those particles that would otherwise be inhaled. Thus, the concentration of the cationic agent must be within a given range. If it is too dilute, the formulation will be ineffective. Also, an experienced pharmaceutical formulator, who is a POSITA, would understand that if the concentration of the cationic agent is too high, the formulation itself would be harmful to the individual. Further, government regulations provide regulation and guidance as to maximum concentrations of ingredients.

On pages 9 and 10 of Patent Owner's Response to the Petition, Patent Owner admits that "Chen's antiviral pharmaceutical compositions contain cationic agent(s) and/or cationic surfactant(s)." All cationic substances inherently create a positively charged electrostatic field. Consequently, some negatively charged particles may be attracted to Chen's composition when applied to an individual's nose. However, unless there is a purposeful adjustment of the concentration of cationic ingredients, the invention will fail in its essential purpose, *i.e.*, to inhibit infection of the individual due to

inhalation of the negatively charged harmful particles. Those particles that are not captured by the thin film due to electrostatic attraction (*i.e.*, Element (a)) cannot be held in place by the thin film (*i.e.*, Element (b)), and they cannot be deactivated and rendered harmless (*i.e.*, Element (c)). The particles not captured, held, and deactivated will be inhaled. A POSITA with any experience pharmaceutical formulation will understand that this step is essential from reading the specification and the claims. Except for the Wahi '005 reference, neither Chen nor any of the other patent documents in Grounds 2-5 recite purposeful adjustment of the positive charge to inhibit infection *via* nasal inhalation.

2. Element (b) - The HOLD function

Elements (b) of claims 1 and 2 recite "[holding/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." The specification of the '802 Patent states:

Patents such as U.S. Pat. No. 6,844,005 describe electrostatically 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 compositions simply create an electrostatic field that helps to filter out oppositely charged materials. While this

*action may offer suitable protection against particles that are inhaled passively, they suffer from the fact that they cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as microorganisms that are motile within the air stream. 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.*⁹

This paragraph recites the rationale for the existence of the HOLD element. Elements (b) of claims 1 and 2 provide that the thin film is sticky and impermeable. The adhesion of the thin film is adjusted to that the film sticks to the nasal skin or tissue. The HOLD element requires the thin film to hold the particles in place and to not be inhaled into the respiratory system. However, the cohesion of the formulation is adjusted to have adequate impermeability so that the harmful particles will have no contact with the skin or tissue of the nasal passages. The HOLD function is essential, because it inhibits inhalation of the particles. The HOLD function is not implied by Chen, either expressly or inherently. It is also important to note that viscosity and cohesion are two different attributes. Viscosity relates to retarding the fluid flow of the formulation. On page 12 of the PTAB decision granting institution of *inter partes* review (Paper 7), Judge

⁹ '802 Patent at 2:43.

Franklin construes the term "cohesion" as "the tendency of similar or identical particles or surfaces to cling to one-another."¹⁰ A material can be viscous and not cohesive. However, it is the cohesive property of the formulation that provides its "adequate impermeability."

3. Element (c) - The KILL Function

Element (c) of claims 1 and 2 recites, "[inactivating/inactivates] the particulate matter and renders said particulate matter harmless." Claim 2 recites that the formulation contains at least one biocidal agent. The inclusion of a biocide is important in the rare instance where a particle becomes dislodged from the thin film (e.g., if the individual sneezes) and is accidentally inhaled. In that instance, the particle would be deactivated.

B. The Importance of All Elements Working Together

The claims require the presence of the CATCH function (Element (a)), the HOLD function (Element (b)), and the KILL function (Element (c)) working in concert.¹¹ The result is synergistic in preventing or inhibiting infection due to nasal inhalation of harmful particulate matter. Merely because one prior art reference exhibits

¹⁰ Petitioner does not contest the PTAB construction of "cohesion."

¹¹ Once again, the terms CATCH, HOLD, and KILL are mere abbreviations of the functions of Elements (a), (b), and (c), respectively. They are not terms requiring construction because these terms are not recited in the claims.

mild electrostatic attraction and it also contains a biocide, it would not be obvious to a POSITA to utilize the knowledge which the prior art teaches to formulate a product that would prevent or inhibit infection due to nasal inhalation of harmful airborne particles. That would require an inventive step by an inventor having extraordinary skill in the art. The formulations of the '802 Patent require cationic ingredients in concentrations that produce a strong enough electrostatic field to attract airborne particles that would be otherwise inhaled. The formulation's ingredients would require adjustment of their adhesive and cohesive properties to adequately hold the particles in place. Finally, the formulation would require the use of a biocide to inactivate those particles that may be accidentally inhaled or that would penetrate the thin film to contact the skin or tissue of the nasal passages.

On page 12 of Petitioner's Reply Brief, the Petitioner states that, "[i]nherent properties of compositions may be achieved accidentally (and may not be recognized)." While this statement may be true, the synergy of the actions of inherent properties of multiple combined ingredients are generally not achieved accidentally. The synergy resulting from said combination is an inventive step and not

accidental or unrealized. Such synergy in the '802 Patent is achieved purposely as an inventive step. All inventions are achieved by inventors combining known elements having known properties that work together synergistically to produce a result that was previously unknown. A claimed invention consisting of several combined elements is anticipated under 35 U.S.C. § 102 if and only if all elements of the claim are present in a single reference. The Petitioner correctly cited the Federal Circuit holding that, "a claimed function or property satisfies a claim limitation, even if the property was unknown or unintended by the inventor or alleged infringer."¹² However, this holding applies to anticipation only.

A claimed invention consisting of combined elements is considered obvious under 35 U.S.C. § 103 if and only if a POSITA would understand that combining all the elements from one or several sources to produce the desired result. Here, if the inherent properties of the synergistic result of combining multiple ingredients is not be recognized by a POSITA, the invention is not obvious.

The claimed compositions and method combines the three elements in such a manner as to prevent or inhibit infection of an

¹² *In re. Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002).

individual by inhalation of airborne harmful particles. To accomplish this invention, (1) there must be sufficient electrostatic attraction of the particles to a thin film; (2) the particles must be held by the film so that they are not inhaled and do not contact the skin or tissue; and (3) the particles must be deactivated and rendered harmless in the event that some may be accidentally inhaled. The HOLD function is critical, and it differentiates the '802 Patent from the prior art. This specific combination of elements requires an inventive step that would not be recognized by a POSITA to achieve the desired result.

C. Claim Construction To Be Used In This Matter

With regard to the '802 Patent, construction of claim terms was performed by three entities: (1) the district court¹³, (2) the PTAB¹⁴, and (3) the Petitioner¹⁵.

¹³ *Trutek Corp. v BlueWillow Biologics, Inc.*, 2:21-cv-1012 (E.D. Mich. 2021) ECF No. 53 (01/10/2023), as submitted by Petitioner as Exhibit 1010.

¹⁴ Decision Granting Institution of *Inter-Partes* Review (Paper 7).

¹⁵ Petition and Petitioner's Reply.

<u>Term</u>	<u>Court</u>	<u>PTAB</u>	<u>Petitioner</u>
Adequate Impermeability	X	X	X
Adhesion		X	
Biocidal Agent		X	X
Cationic Agent		X	
Cohesion		X	
Electrostatically Attracting	X	X	
Electrostatically Inhibiting	X	X	
Harmful Particulate Matter		X	
Inactivating		X	
Renders Said Particulate Matter Harmless	X		
Skin or Tissue of Nasal Passages		X	X

As may be observed in the above table, the Petitioner and its expert, Dr. Park, performed claim construction on only three claim terms. Judge Franklin of the PTAB performed claim construction on every claim term except for the term "*renders said particulate matter harmless*." The term constructions proposed by the district court, the PTAB, and the Petitioner are consistent with each other. Considering that the PTAB construction is more comprehensive, Patent Owner suggests that the PTAB constructions should prevail, except that the district court's construction of "*renders said particulate matter harmless*" should be used.

III. CLAIMS 1-3 AND 8 ARE NOT ANTICIPATED OR RENDERED OBVIOUS BY CHEN

A. Anticipation

Chen does not anticipate the claims of the '802 Patent under 35 U.S.C. § 102. For anticipation of these claims to occur, all of the elements of claims 1-3 and 8 must be performed by the Chen reference. It must be noted that both the district court¹⁶ and the PTAB¹⁷ held that the claim preambles were limiting and must be included in the claim construction.

It is true that Chen's composition contains at least one cationic agent which would create a positively charged electrostatic field that would inherently attract some negatively charged airborne particles. It is also true that Chen's composition contains at least one biocidal agent. However, Chen does not teach the HOLD function of claims 1-3. Element (b) of Claim 1 recites:

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,

and Element (b) of claim 2 recites:

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

¹⁶ The District Court's claim construction in Exhibit 1010.

¹⁷ Decision Granting Institution of *Inter-Partes* Review (Paper 7)

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

This claim element recites the following terms:

- a requirement that the particulate matter be held in place;
- by adjusting the adhesion of the 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.

We begin with the construction of the claim term skin or tissue. On page 10 of Paper 7, Judge Franklin construed "skin or tissue" to mean "the exterior region around the nostril and/or slightly inside the edge of the nostril."

The Petitioner stated, "the formulations applied in a thin film must be positioned 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."

The '802 Patent specification recites, "It is therefore an object of the invention to provide a composition that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release with method

and compositions capable of capturing particulates and microorganisms."

Petitioner did not provide ample evidence that Chen's composition exhibits the HOLD function either expressly or inherently. In Paragraph 112 of Dr. Park's Declaration, he offers the following conclusory opinion, "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 a cationic agent would attract a virus, it cannot perform the hold function as discussed above. A cationic agent alone cannot prevent harmful particles from being dislodged. Dr. Park further attempts to indicate that Chen performs the HOLD function by citing Chen [121] and [148].

[121] *The gel formulation prepared herein is a viscous gel, which provides excellent muco-adhesiveness by forming a physical barrier over the mucous membrane for a prolonged period of time.*

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

Here, we are comparing apples to oranges. Petitioner's construction of the "skin or tissue of the nasal passages" is external not internal. ***It does not include the mucosa.*** The formulation is not applied to the mucous membrane. The mucosal membrane is deep inside the nostril. It is generally wet and runny. When a person sneezes or blows his nose, the virus particles dislodge only to be re-inhaled. Chen provides no indication that the virus particles are held in place. Also, once the virus arrives at the mucous membrane, it is already inside the nose, and it can potentially be inhaled. Moreover, although Chen states that the composition provides excellent muco-adhesiveness by forming a physical barrier over the mucous membrane for a prolonged period of time, Chen provides no indication that the cohesion is adjusted to provide adequate impermeability. A thin film is expected to form a physical barrier, but there is no indication that it is impermeable. Chen does not perform the HOLD function required by Elements (b) of the claims of the '802 Patent.

Anticipation under 35 U.S.C. § 102 requires a single reference that teaches every claimed element, either expressly or inherently, and because Chen does not teach the HOLD function of Elements (b)

of the claims, the claims of the '802 Patent cannot be anticipated by Chen under 35 U.S.C. § 102.

B. Obviousness

Petitioner alleges that even if the claims of the '802 Patent are not anticipated under 35 U.S.C. § 102, it would nonetheless be obvious over Chen alone to a POSITA and therefore unpatentable under 35 U.S.C. § 103. Once again, the POSITA would need to take the teachings of Chen and from them derive the claimed invention as a whole. Here, Chen did not perform any human testing. Hence, he was not aware that particles would dislodge and be inhaled by the user. Therefore, a POSITA would be unaware of this problem unless he first read the '802 Patent. A POSITA could not appreciate the HOLD function without impermissible hindsight. The POSITA would necessarily be able to create every claimed element as arranged in the claim.

As stated in the previous section, while it might be obvious to a POSITA to duplicate the CATCH function (Element (a)) as well as the KILL function (Element (c)), it would not be obvious to duplicate the HOLD function (Element (b)).

Chen does not even suggest that his composition can even be applied to the nose externally¹⁸, a feature that is required by the '802 Patent. There is no indication in Chen that external application would work to prevent infection by inhalation into the respiratory system. Chen applies his composition exclusively to the inside of the nose and to the nasal mucosa. In Chen, there are many ways that the virus particles would be dislodged be inhaled. The fact that the particles are already inside the nose, Chen must rely on the KILL function hoping that the dislodged particles will be deactivated prior to inhalation. However, external application of the formulation of the '802 Patent provides the extra protection of preventing the airborne particles from entering the nose. Chen does not teach or suggest external application, and a POSITA would not derive this essential element of the claims without first reading the '802 Patent. He would not be aware of the problem. Reproduction of the HOLD function of the claims (Elements (b)) by a POSITA requires some teaching, suggestion, or motivation to be present in the Chen reference.

Therefore, because there is no teaching, suggestion, or motivation in Chen that would lead a POSITA to duplicate every

¹⁸ See Exhibit 2005 - How To Use NasalGuard® Product.

element in the claims, claims 1-3 and 8 are not rendered obvious and unpatentable over Chen alone.

IV. SECONDARY CONSIDERATIONS INDICATING NON-OBVIOUSNESS

The objective indicia of non-obviousness – particularly the commercial success of Trutek's NasalGuard® product provides compelling evidence that the claimed invention was not obvious to a POSITA. As required under *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), the Board should consider such secondary considerations as part of the totality of the obviousness inquiry. Here, the commercial success of the claimed invention, and its causal nexus to the claimed features, weigh strongly against a finding of obviousness.

Commercial success is a recognized secondary consideration that can rebut a *prima facie* showing of obviousness. (*Transocean Offshore Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012)). To establish commercial success, a patent owner must show:

1. That the product embodying the claimed invention has achieved significant commercial success; and

2. That a nexus exists between the claimed features and the success. (*In re. Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996).
3. The product embodying the claimed invention is commercially successful because it satisfies the long-felt need of inhibiting infection of individuals due to inhalation of airborne pathogens.

Trutek's NasalGuard[®] product, which practices the challenged claims of the '802 Patent, has realized substantial commercial success, evidenced by:

- Sales of more than fifteen million tubes having several brand names, including NasalGuard[®] products worldwide since 2012.¹⁹ In the United States, each tube of the NasalGuard[®] product currently sells for \$14.99 to \$24.99 on Shopify and Amazon.com, amongst other online stores worldwide..
- Positive media and industry recognition on major networks including MSNBC, ABC and CBS affiliates in the United States.

To demonstrate a nexus, the success must derive from features recited in the challenged claims. Here:

- The specific features recited in the claims (*viz.*, (1) strong electrostatic attraction by the NasalGuard[®] gel and capture of

¹⁹ Declaration of Ashok Wahi. (Exhibit 2003)

airborne pathogens surrounding a user's nose; (2) prevention of the captured airborne pathogens from being inhaled resulting from being held in place by the gel; and (3) those few pathogens that may dislodge and be inhaled are deactivated by a biocide present in the gel) are directly responsible for the product's market differentiation. The result is that users of the NasalGuard[®] get fewer respiratory infections.²⁰

- Consumer demand and purchasing decisions are driven by the patented invention. The more than fifteen million tubes of the NasalGuard[®] gel products (having several brand names),²¹ and based on the '802 Patent, do not represent sales to fifteen million people. Many of the NasalGuard[®] gel tubes represent repeat sales to satisfied individuals.

A nexus may be presumed when the product is the invention disclosed and claimed in the patent. (*WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016)).

In this case, the NasalGuard[®] product practices each element of the challenged claims, and its success stems from these claimed features.

²⁰ See Exhibit 2006 - Max Neeman Clinical Study

²¹ See Exhibit 2004

In addition to unit sales and media recognition, NasalGuard[®] has demonstrated commercial success through its online retail performance, particularly on Amazon.com, the largest e-commerce platform in the United States. As of this filing, NasalGuard[®] has received over 4,000 customer ratings and maintains a rating above 4 stars.²² This reflects sustained consumer interest, strong customer satisfaction, and repeat purchases. The ratings are protected by Amazon's strict anti-manipulation policies, and Trutek has never solicited or compensated for any customer feedback, ensuring authenticity.

The volume and positive nature of verified customer responses support the product's success and provide further validation of the claimed features of the '802 Patent. Customers frequently cite NasalGuard's ability to block airborne particles and reduce respiratory symptoms, which directly relates to the electrostatic capture, hold, and kill functions of the invention.

Courts and the PTAB have recognized that unsolicited consumer praise and behavior can support secondary considerations

²² See Exhibit 2007, particularly with respect to Amazon.com.

of non-obviousness when a clear connection to the patented features is demonstrated, as in *WBIP, LLC v. Kohler Co.*, 829 F.3d at 1329.

When considered in the context of the totality of the record the objective evidence of commercial success tied directly to the claimed invention, demonstrates that the invention was not obvious. The Board should give this evidence substantial weight in the obviousness determination and hold that the '802 Patent's claims are not obvious over any of the prior art references...

V. GROUNDS 2-5 OF PETITIONER'S ALLIGATIONS OF INVALIDITY

A. Ground 2:

Petitioner alleges that Claims 1-3 and 8 are anticipated under 35 U.S.C. § 102(b) or alternatively rendered obvious under 35 U.S.C. § 103 by U.S. Patent No. 6,559,189 issued to Baker on May 6, 2003.

While it is true that Baker employs cationic agents and surfactants as well as biocidic agents, like Chen, Baker fails to disclose the hold functions of claims 1-3 either expressly or inherently. Baker does not adjust the adhesion and cohesion to hold pathogens and to provide impermeability. Baker does utilize a viscosity modifier, but as discussed earlier, viscosity and cohesiveness are two different concepts. It is possible for a fluid to

be viscous and not cohesive. The claims of the '802 Patent are not anticipated by Baker, nor are they obvious of Baker alone. Baker's composition was never marketed, while Trutek's formulation achieved worldwide success.

B. Ground 3:

Petitioner alleges that Claims 1-3 and 8 are anticipated under 35 U.S.C. § 102(b) or alternatively rendered obvious under 35 U.S.C. § 103 by U.S. Patent No. 6,844,005 issued to Wahi on January 18, 2005 ("Wahi '005").

First, it should be noted that the Examiner of the application was aware of Wahi '005 at time of his Notice of Allowance. Wahi '005 is listed in the cross reference to related applications²³ as well as on an information disclosure statement ("IDS") that was submitted to the USPTO along with the application. Further, while the composition of Wahi '005 exhibits electrostatic attraction, the '802 Patent expressly stated that this prior patent did not exhibit the hold function.²⁴ Thus, the '802 Patent claims cannot be anticipated by nor rendered obvious over Wahi '005 because it does not disclose or claim all the elements of the '802 claims.

²³ '802 Patent at 1:49-54.

²⁴ '802 Patent at 2:43-58.

C. Ground 4:

Petitioner alleges that Claims 1-3 and 8 are anticipated under 35 U.S.C. § 102(b) or alternatively rendered obvious under 35 U.S.C. § 103 by U.S. Patent Application Publication No. 2004/0071757 on April 15, 2004 by Rolf ("Rolf").

First, it should be noted that during the prosecution history of the Rolf application, the USPTO did not issue a notice of allowance to Rolf due to a lack of enablement.

The only similarity of the '802 Patent's disclosure and claims to Rolf is that Rolf is applied as a patch in proximity to the user's nose. There is no electrostatic attraction of airborne particles, and the hold function is entirely absent. The teachings of Rolf alone cannot possibly anticipate the claims of the '802 Patent nor can they render them obvious.

D. Ground 5:

Petitioner alleges that claim 3 is rendered obvious under 35 U.S.C. § 103 by Rolf in view of Wahi '005.

Combining Wahi '005 with Rolf might (or might not) add electrostatic attraction to the Rolf reference, as it would depend on whether the adhesive is on both sides of the patch. However, as

shown above, neither Rolf nor Wahi '005 exhibit the hold function. While the Rolf patch adheres to the skin, Rolf relies on essential oils to deactivate airborne pathogens, it is not taught or suggested by Rolf that particles coming in contact with the patch would not dislodge. Rolf's invention is not much different from a Vicks Vaporub patch. Without first reading the '802 Patent, it would not be obvious to a POSITA to combine Wahi '005 with Rolf. It would be impermissible hindsight.

VI. CONCLUSION

The HOLD function is the central distinction between the claims of the '802 Patent and the prior art. This element is not a routine formulation feature. It is a purposeful and novel adjustment of adhesion and cohesion that directly addresses the problem of dislodgement and subsequent inhalation of harmful airborne particles. Prior art references, including Chen, may incidentally attract particles or include biocidal agents, but they do not teach or suggest a mechanism that actively holds particles in place on the skin or tissue outside the nasal passages. The HOLD function is a unique and unexpected solution to a problem not resolved by earlier formulations.

Anticipation under 35 U.S.C. § 102 requires every claim element to be disclosed clearly and completely in a single reference. Because the HOLD function is not present in Chen, either expressly or inherently, the claims of the '802 Patent cannot be anticipated. Likewise, obviousness under 35 U.S.C. § 103 requires some teaching, suggestion, or motivation to combine elements in a way that results in the claimed invention. The prior art does not provide such guidance, especially regarding the specific HOLD mechanism disclosed in the '802 Patent. Moreover, the secondary consideration of commercial success should overcome obviousness of the patent claims over the prior art.

Based upon the arguments presented above, Patent Owner respectfully requests that the Board hold that the challenged claims are neither anticipated nor rendered obvious by the prior art references submitted by the Petitioner.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 CFR § 42.24(d), I hereby certify that the foregoing document entitled, "Patent Owner's Sur-Reply To Petitioner's Reply," contains 5,594 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 "Patent Owner's Sur-Reply To Petitioner's Reply," regarding IPR2024-00711 was served on July 8, 2025, upon the following via email:

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/s/ Stanley H. Kremen

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