

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

Before ERICA A. FRANKLIN, ULRIKE W. JENKS, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*

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I. INTRODUCTION

On June 13, 2024, a petition generated by Salvacion USA, Inc. ("Petitioner") was entered at the Patent Trial and Appeal Board challenging U.S. Patent No. 8,163,802 ("the '802 Patent") issued to Ashok Wahi and assigned to Trutek Corp. ("Patent Owner" or "Trutek") on April 24, 2012. The petition was a request for an *Inter-Partes* Review No. IPR2024-00711 ("the Petition"). The '802 Patent issued after allowance of U.S. Patent Application 12/467,271 ("the '271 Application"), which was filed on May 8, 2009. The '271 Application claimed priority to two U.S. provisional patent applications, the earliest filed priority date for said provisional applications being July 7, 2008.

A. THE CHALLENGED CLAIMS

The Petition challenged claims 1, 3, and 8 of the '802 Patent under both 35 U.S.C. §§ 102 and 103. The Petitioner alleged that the challenged claims were unpatentable on the following grounds:

<u>No.</u>	<u>Claims Challenged</u>	<u>35 U.S.C. §</u>	<u>References</u>
1	1, 3, 8	102(b)	Chen
2	1, 3, 8	103	Chen
3	1, 3, 8	102(b)	Baker
4	1, 3, 8	103	Baker
5	1, 3, 8	102(b)	Wahi '005
6	1, 3, 8	103	Wahi '005

7	1, 3, 8	102(b)	Rolf
8	1, 3, 8	103	Rolf
9	2	103	Rolf, Wahi 005

References:

1, 2	Chen	Chen, U.S. Patent App. Pub.2005/0232895 A1 published October 20, 2005 Ex. 1005, "Chen"
3, 4	Baker	Baker, Jr., <i>et.al.</i> , U.S. Patent No. 6,559,189 B2 Issued May 5, 2003 (Ex. 1006, "Baker")
5, 6, 9	Wahi '005	Wahi, <i>et.al.</i> , U.S. Patent No. 6,844,005 B2 Issued January 18, 2005 (Ex. 1007, "Wahi '005")
7, 8, 9	Rolf	Rolf, U.S. Patent App. Pub. 2004/0071757 A1 Published April 15, 2004 (Ex. 1008, "Rolf")

Petitioner's allegations challenging Trutek's claims were based entirely on anticipation under 35 U.S.C. § 102(b). In Challenges Nos. 2, 4, 6, and 8, Petitioners alleged arbitrarily, and without any further basis, that should these claims be shown as not being anticipated, they should nonetheless be ruled obvious under 35 U.S.C. § 103. These allegations asserted obviousness over a single cited reference and not over a combination of references. Only Ground No. 9 alleged obviousness based on a combination of two references.

Included as an exhibit to the Petition (Ex. 1002) was a declaration by Kinam Park, Ph.D. Dr. Park apparently serves as Petitioner's expert. While Petitioner presents both legal and technical

arguments supporting its allegations, the technical arguments contained in the Petition were copied from Dr. Park's declaration.

B. TRUTEK'S PRELIMINARY RESPONSE AND PTAB DECISION GRANTING *INTER-PARTES* REVIEW

On September 7, 2024, Trutek submitted its preliminary response to the Petition. Said preliminary response is incorporated by reference in its entirety herein. In that preliminary response, Trutek argued against all of Petitioner's grounds challenging the claims of the '802 Patent. To the extent that any of Trutek's arguments are not presented herein, the arguments presented in said preliminary response are incorporated by reference herein, and they are asserted as though they were made in this present document.

In its preliminary response, Trutek presented both legal and detailed technical arguments to rebut each and every allegation set forth by Petitioner and Dr. Park. Trutek argued that the challenged claims were not anticipated by Chen, Baker, Wahi '005, and/or Rolf, and that Petitioner failed to present a *prima facie* case of obviousness of the claims over the references.

In his declaration, Dr. Park presented his construction of the terms used in the challenged claims as well as his assumption of the qualifications of a person having ordinary skill in the art ("POSITA").

In its preliminary response to the Petition, Trutek did not challenge Dr. Park's claim term constructions, nor did it challenge his qualification of a POSITA. However, Trutek does challenge Dr. Park's ability to view Trutek's technology from the point of view of a POSITA.

On December 6, 2024, Administrative Patent Judge, Erica A. Franklin, issued a decision granting institution of an *Inter-Partes* Review under 35 U.S.C. § 314. Judge Franklin accepted Petitioner's qualification of a POSITA as well as its construction of claim terms. However, Trutek objects to Petitioner's interpretations of the '802 Patent's claims.

In the Board's decision, Judge Franklin agreed with Trutek that the preambles of '802 Patent's claims are limiting. Claim 1 is a method (process) claim, and the remaining claims are formulation (composition of matter) claims. Claims 1, 2, and 8 are independent claims, while claims 3-7 depend from claim 2, and claims 9-23 depend from claim 8. The independent claim preambles all recite, "electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation." They further recite, "a

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

The bodies of claims 1 and 2 each have three elements, *i.e.*, (a), (b), and (c). Elements (a) involve electrostatic attraction of the harmful particulate matter to the thin film. Elements (b) involve holding the particulate matter to the thin film. Elements (c) involve inactivating the particulate matter and rendering it harmless.

The element of electrostatic attraction of harmful particles to the nostrils so as to inhibit infection due to inhalation is not new to the '802 Patent. Trutek began work on solving this problem during the early 1990's. U.S. Patent Nos. 5,468,488 ("Wahi '488"), 5,674,481 ("Wahi '481"), and 6,844,005 ("Wahi '005"), issued in 1995, 1997, and 2005, respectively, represented Trutek's inventive efforts to address this problem. These issued patents along with several other patent applications showing progress through the years are enumerated in Column 1 of the '802 Patent in the "Cross Reference" section.¹ As is evident from the specification and drawings of all three patents, Trutek created formulations to be applied as a thin film in the vicinity of a person's nasal passages. Once applied, the formulation attracts

¹ Wahi '005 (Petition Ex. 1007) is cited as prior art in Grounds 3 and 5 of the Petition challenging the claims of the '802 Patent.

harmful particles to the thin film. The particles are not already in the person's nostrils, but rather in the air surrounding the person's face. In Wahi '488, '481, and '005, the harmful particles were to be captured by the thin film so that fewer of them would be inhaled. Wahi '488 was a method patent based on an application that was filed in 1993. This was followed by an application for a formulation patent filed in 1995 (issued as the '481 Patent in 1997). Almost seven years later, Ashok Wahi filed the application that issued as the '005 Patent. The '005 Patent issued in 2005. It soon became apparent to Wahi that the formulation needed adjustment to create a stronger electrostatic field. With a stronger electrostatic field, more particles would be trapped.

The formulations covered by the three patents were very effective in alleviating the symptoms due to airborne allergies. However, once captured, some particles would dislodge from the formulation's thin film, and they would be inhaled. The solution to the problem came in 2007. The '271 Application which ultimately issued as the '802 Patent was filed in 2009. The '802 Patent issued in 2012.

The '802 Patent's technology solved the problem of the dislodged particles that would be inhaled despite their being

captured. Not only must the formulation capture harmful particles, but it must also hold them in place such that they would not be inhaled. The formulation must also be impermeable to prevent contact with the nasal mucosa. Finally, the formulation contains a biocidic agent that would inactivate any microorganisms that were captured. These new formulations proved very effective not only to alleviate symptoms resulting from airborne allergens but also to inhibit infections from bacterial and viral microorganisms.

When the application for the '802 Patent was filed, the claims recited preventing infection caused by inhalation of harmful airborne particles. The examiner of the '271 Application required that the Applicant amend the claims to change the word "preventing" to "inhibiting" because preventing infection implies that not even one particle would be inhaled. However, the product protected by the '802 Patent, that was sold worldwide since 2012, has proven very effective against infection of users caused by inhaling a wide variety of microorganisms.

The mechanism used by the '802 Patent's formulations to inhibit infection of individuals due to nasal inhalation utilizes a three step process:

- a) CATCH - The formulation electrostatically attracts the harmful airborne particles.
- b) HOLD - The formulation holds the captured particles in place to prevent them from being inhaled.
- c) KILL - The formulation uses a biocide to inactivate any living material that was captured and held.

In its initial response to the IPR Petition, Trutek addressed each and every ground challenging the claims of the '802 Patent. Petitioner cited four alleged prior art references in support of its challenges under 35 U.S.C. §§ 102(b) and 103. Those references were Chen², Baker³, Rolf⁴, and Wahi '005. It should be noted that Wahi '005 was disclosed to the USPTO during its application, and also that the examiner of the '271 Application was aware of this prior art reference before allowance.⁵

Petitioner did not respond to Trutek's preliminary response. In the PTAB decision to institute the *Inter-Partes* Review, Judge Franklin stated the reasons for her decision. In her decision, Judge

² U.S. Patent Publication No. 2005/0232895 ("Chen")

³ U.S. Patent No. 6,889,189 ("Baker")

⁴ U.S. Patent Publication No. 2004/0071757 ("Rolf")

⁵ The examiner of the '271 Application was aware of all of Ashok Wahi's issued patents and patent applications ('802 Patent, Column 1).

Franklin concentrated on grounds based on the Chen reference, and not on the other cited references. Judge Franklin stated;

*We do not provide an analysis of these remaining grounds, as we have already determined that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of each of the challenged claims based upon similar teachings in Chen and over similar arguments raised by Patent Owner. In view of that determination, we institute an **inter-partes review** of all the challenged claims based upon all grounds raised in the Petition.*

II. ARGUMENT

Because Judge Franklin's arguments were based almost solely on the Chen reference, this response will concentrate primarily on the challenges based on Chen, *i.e.*, Ground Nos. 1 and 2.

A. ELECTROSTATIC ATTRACTION

This feature is recited in Elements (a) of claims 1 and 2 of the '802 Patent. As discussed in Trutek's preliminary response, Chen did not anticipate electrostatically attracting airborne virus particles to a person's nostrils. Airborne viruses are known to be negatively charged electrostatically. Chen's antiviral pharmaceutical compositions contain cationic agent(s) and/or cationic surfactant(s). Thus, the compositions exhibit a positive electrostatic charge. Because oppositely charged particles attract each other, it stands to

reason that Chen's positively charged composition would inherently attract negatively charged viruses. In his specification, Chen recites that his composition may be "administered locally" to the nasal membrane (Chen [0044]). Chen's compositions are designed to deactivate various viruses which they contact. While there is some attraction of these negatively charged particles to the positively charged composition, there is no indication that there is a purposeful adjustment of the positive charge so as to effectively create an electrostatic field surrounding the user's nose and face that would attract airborne particles that float in the vicinity of the nostrils. In the '802 Patent's specification, the meaning of "electrostatic attraction" being of airborne particles is stated repeatedly.⁶ However, Wahi's earlier patents clearly recite this feature, and the examiner of the '271 Application was aware of these patents. This feature is the CATCH element of the '802 Patent.

B. BIOCIDIC AGENT DEACTIVATES HARMFUL PARTICLES

Trutek agrees that Chen recites this feature. Clearly, Chen's compositions comprise at least one biocidal agent.⁷ The purpose and

⁶ '802 Patent at 1:65,67; 3:37,46,54,61,67; 4:2.

⁷ Chen at [0086] - Benzalkonium Chloride

function of Chen's compositions is to deactivate viruses and to render them harmless.

C. THE HOLD FUNCTION

The HOLD function (Element (b) of claims 1 and 2) represents the essential innovation in the '802 Patent's method and formulation. It is what sets the '802 Patent apart from the prior art. Claim 1, Element (b) states:

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said 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 film

This is a key feature both for the method of claim 1 and the formulation of claim 2 (and its progeny). The thin film is both sticky and impermeable. It is important that the harmful particles do not dislodge to be inhaled, but also that they remain in contact with the formulation long enough for the biocidic agent to KILL any living particles. In this way, not only are most particles held in place, but in the event that a few are inhaled, they would not harm the individual. Further, the harmful particles are prevented from direct contact with the skin or tissue of the nasal passages.

The '802 Patent specification comprises ten tables of various formulations that exhibit all of the claimed elements – CATCH, HOLD, and KILL. While the ingredient concentrations are listed in ranges, any formulation containing the ingredients in those ranges will exhibit all of the elements recited in the claims.

The HOLD element attribute of the formulation cannot be achieved accidentally. It is a solution to a problem that surfaced in formulations taught in Wahi's prior patents. It was observed that harmful particles which were electrostatically attracted to Trutek's earlier formulations dislodged and were inhaled by users.⁸ Research and development by Wahi leading to formulation of a solution to this problem culminated upon filing of the '271 Application.

Chen recites several exemplary antiviral compositions in Paragraph [0097] of his published specification. His drawing Figures 1-6 demonstrate the efficacy of his sample compositions *in vitro*. There is no indication whether there has been FDA approval for any human trials of Chen's compositions. If the compositions were not tested on human beings, no knowledge could exist as to whether virus particles are dislodged from his composition when subjected to

⁸ '802 Patent, 2:57

air flow resulting from nasal breathing. Chen was not in possession of that information prior to publication of the '271 Application. Chen is silent regarding holding the virus particles in place. Chen is silent regarding preventing virus particles from becoming free agents. Chen does not blow air over his anti-viral compositions to simulate nasal breathing and to determine whether live viruses can escape into the air stream. He was unaware of the problem.

In his specification, Chen recites the following:

[0036] *In certain embodiments, the antiviral of the present invention further comprise pharmaceutically acceptable excipients such as a pH adjusting agent, pH buffer, a viscosity modifier,⁹ an osmotic agent, flavor, sweetener, colorant, and adhesive.⁹*

He repeats this in [0095], adding that, "[t]he selection and use of each agent are determined based on the practices known to those skilled in the art."

As discussed in Trutek's preliminary response, while viscosity modifiers can render a formulation more viscous,¹⁰ they have no effect on cohesion. Cohesion is the ability of molecules of the same material to bond together. While increased cohesion will increase viscosity, the converse is not necessarily true. Guar gum is often

⁹ Emphasis added.

¹⁰ Increasing viscosity of a material decreases its ability to flow freely.

used as a viscosity modifier to increase the flow of oil through cylindrical pipes, inclusion of guar does not make the oil less cohesive. Mud or clay in a fluid increases the viscosity of the fluid, but it does not increase the bonding strength of the fluid molecules. To increase the cohesiveness of a polymer gel, one increases the length of the molecular chain and the molecular weight of the polymer. Permeability depends upon cohesion rather than viscosity.

Chen states, "[b]y forming a viscous membrane over nasal mucosa and by deactivating viruses on contact, the formulation of the present invention could provide an effective means to prevent the virus from spreading." (at [0115].) While adding a viscosity modifier to his anti-viral compositions, Chen could create a viscous material to coat the nasal mucosa, there is no indication that this action would provide the HOLD function of Trutek's '802 Patent claims. Similarly, In Chen's EXAMPLE 1 composition listed in Table 1.1:

Chitosan Hydrochloride	1.50%
Zinc Chloride	0.10%
Benzalkonium Chloride	0.02%
Water	98.38%

All three solutes are cationic. They were dissolved together in water and then formulated as a gel. The gel was diluted 20 times, and then tested *in vitro* against the adenovirus target. The test results show

that this formulation was an effective biocide.¹¹ Chen is silent regarding whether the viral material was applied over the gel or whether the gel was applied over the viral specimen. However, the gel, as prepared for this test, would have been too dilute to produce the effects presented in Paragraph [121] of his specification.

In his specification, Chen said:

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

Chen's testing was designed to mimic human testing. Most of his tests were performed *in vitro*, although Chen did perform some animal testing. Because of the *in vitro* testing of Chen's formulations, Chen would have not been concerned with virus particles dislodging from his gel product. As a result of this, he would not have been aware of the problem experienced by Trutek's products that were being sold at the time. Wahi was aware of this problem, and he devoted significant development, reformulation, and testing to solve this problem. Chen would not have been motivated to develop a

¹¹ See FIG. 1, right panel.

formulation that would hold the virus particles in place because he was unaware of the problem. For that matter, while Chen, who is a **person of extraordinary skill in the art**, was not motivated to solve this problem, neither would a POSITA be so motivated.

In Paragraph 137 of his declaration, Dr. Park said:

As defined in Section VII., adequate impermeability refers to the "thin film holding harmful particles in place and inhibiting them from penetrating the thin film and contacting the skin or tissue of an individual's nasal passages. This is done by varying the concentration of ingredients[,] thereby adjusting the adhesion and cohesion of the thin film."

While adequate permeability refers to "inhibiting harmful particles from penetrating the thin film and contacting the skin or tissue of an individual's nasal passages," **it does not provide for "holding the particulate matter in place" as recited in the claims of the '802 Patent**. This is a critical element of the claims of the '802 Patent, and it is not present in Chen.

In Paragraph, 140, Dr. Park states:

A POSITA would understand that, if Chen's thin films were not adequately impermeable, Chen would not achieve the desired antiviral activity. Therefore, thin films of Chen's compositions must be adequately impermeable to viruses. Thus, in the event that this element is not taught, a POSITA would find it obvious to modify Chen's formulations per Chen's teachings and suggestions such that they would hold the particulate matter and that they

would have adequate impermeability to prevent the viruses from reaching the skin, tissue, or mucosa of the nasal passages. A POSITA would have a reasonable expectation of success of such modifications.

Here once again, Dr. Park confuses impermeability with holding. Adequate impermeability is but one component of the HOLD function. For the effect desired by the '802 Patent, the formulation must protect the individual **against inhaling harmful particles** such as live viruses (and in some cases, even dead viruses). Not only would a POSITA, reading the Chen publication, not be motivated to implement the HOLD element, but even Dr. Park did not realize that Chen did not teach or suggest HOLDING the harmful particles in place so that they would not be inhaled. The '802 Patent specification clearly recited the problem that needed solution. The purpose of the claimed invention is to inhibit infection by inhalation. The problem first surfaced with publication of the '271 Application. Without understanding the problem, a POSITA would have no motivation to solve it.

D. ANTICIPATION *versus* OBVIOUSNESS

On Page 17 of the Petition, the Petitioner states, "In the event that one or more of claims 1-3 or 8 are not found to be anticipated by Chen, claims 1-3 and 8 would nevertheless have been obvious over

Chen to a POSITA at the Critical Date." Petitioner provides no additional information to arrive at a *prima facie* argument that the '802 Patent's claims are obvious over a single reference other than what is stated in Dr. Park's declaration. Without further discovery, Trutek does not doubt Dr. Park's qualifications. However, Dr. Park is not a POSITA, but instead he is **Person of Extraordinary Skill in the Art.** Dr. Park is not a patent examiner. There is no evidence that Dr. Park is able to construe the '802 Patent specification and claims in the mind of a person of ordinary skill without impermissible hindsight.

On Page 14 of the PTAB decision to institute an *inter-partes* review, Judge Franklin set forth the standards that will be used to determine anticipation and obviousness of the claims of the '802 Patent. She cited several cases¹² holding that "[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." Trutek argued herein that the basic difference between the claims of the '802 Patent and the teachings of Chen is the formulation of a nasal composition that would prevent harmful

¹² *Schering Corp. v. Geneva Pharms*, 339 F.3d 1373 (Fed. Cir. 2003) (quoting *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

particles from being dislodged and inhaled by the user. Trutek argued that this property is not taught by Chen either expressly or inherently. The problem that sparked the development of the formulations shown in the '802 Patent was first discovered by Wahi after being observed in Trutek's then existing product line.

Judge Franklin also cited case law¹³ which establishes that “a reference can anticipate a claim even if it ‘d[oes] not expressly spell out’ all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would ‘at once envisage’ the claimed arrangement or combination.” Respectfully, the only way that a POSITA would envisage the HOLD function is if he or she recognized the necessity of that function. There is no evidence that that would occur unless the POSITA was aware of the '802 Patent's teachings.¹⁴

The holdings in *Kennametal, Inc.* and *Petering* are very similar to determining obviousness under 35 U.S.C. § 103 in that there is almost no difference between a POSITA envisioning an element and

¹³ *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (quoting *In re Petering*, 301 F.2d 676, 681 (1962)).

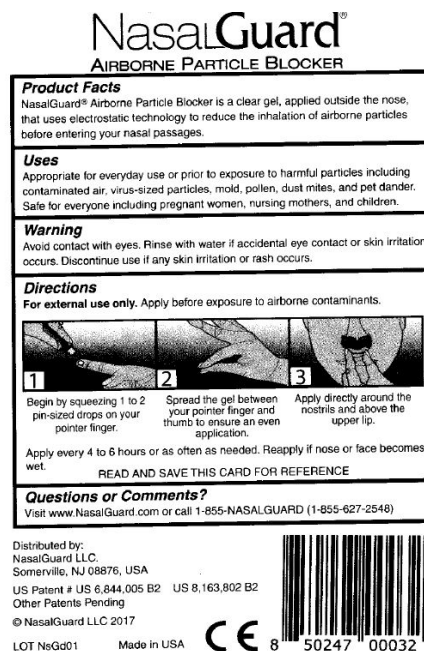
¹⁴ See MPEP § 2141.

finding the element obvious. Judge Franklin also cited case law¹⁵ to establish obviousness, even over a single prior art reference. She wrote, “An obviousness determination requires finding both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” However, the claim must be considered as a whole.¹⁶ As argued previously, at the time of invention of the '802 Patent, a POSITA would have only been motivated to include ingredients to implement the HOLD function in Chen's anti-viral compositions if the problem of dislodged viruses had been recited in the prior art. However, there is no evidence of the problem's revelation earlier than the '271 Application publication. Thus a POSITA would not have been motivated to implement this function. Therefore, there could be no determination of obviousness unless the prior art either revealed the dislodging problem or demonstrated that Chen's compositions already implemented this feature.

¹⁵ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). See also, *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367– 68 (Fed. Cir. 2016)).

¹⁶ MPEP § 2141.01.

1. SECONDARY CONSIDERATION OF COMMERCIAL SUCCESS TO OVERCOME OBVIOUSNESS DETERMINATION



The above photographs show the front and back of the packaging of Trutek's NasalGuard® Airborne Particle Blocker that has

been sold continuously throughout the United States since 2012, *i.e.*, the issue date of the '802 Patent. Trutek's sales of this product have been very successful within the United States. This same product, with different packaging has been sold in several other countries. Please note that the '802 Patent number is marked at the bottom of the back side of the product's package.

III. CONCLUSION

This document is a supplemental response to *Inter-Partes* Review Petition No. IPR2024-00711. It supplements Patent Owner's preliminary response dated September 7, 2024 which is incorporated by reference in its entirety herein. Thus, every statement made by Patent Owner in the preliminary response must be understood as though it was included word-for-word in this document.

This document is also a response to the PTAB decision to institute an *Inter-Partes* Review dated December 26, 2024. In that decision, Judge Franklin only analyzed the Chen reference. For that reason, the present document presented an analysis only of the Chen reference. That analysis supplements the analysis of Chen presented in Trutek's preliminary response, which is also included herein by reference.

In the present response, Patent Owner argued that Chen cannot anticipate the claims of the '802 Patent because one crucial element is missing. That element is the HOLD function. While Chen uses chitosan to create a thin film, and alleges that it forms an impermeable barrier, he performed no tests to verify this feature. It is mere conjecture. However, even if accepted as true, Chen did not teach or suggest either explicitly or inherently that his composition would **hold** viruses in place in the subject's nasal cavity so as not to be dislodged by the subject's breathing and to be subsequently inhaled. A POSITA would not have been aware of the problem because it appears nowhere in the prior art. Therefore, without prior disclosure in the art, it would have been a solution in search of a problem. As a whole, the claims are not anticipated by Chen because their subject matter is not taught by Chen, and they are not obvious over Chen because a POSITA would not have been motivated to implement the HOLD feature in Chen's anti-viral compositions.

Furthermore, commercial success since 2012 of the NasalGuard® product, which is protected by the '802 Patent, attests to non-obviousness of the '802 Patent claims.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 CFR § 42.24(d), I hereby certify that the foregoing document entitled, "Respondent/Patent Owner's Response to Petition For *Inter Partes* Review of U.S. Patent No. 8,163,802," contains 4,368 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
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Registration No. 51900
Lead Counsel for Respondent

CERTIFICATION OF SERVICE

The undersigned hereby certifies that the above-captioned “Respondent/Patent Owner's Response to Petition for *Inter Partes* Review of U.S. Patent No. 8,163,802,” regarding IPR2024-00711 was served on March 4, 2025, upon the following via email:

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