

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

**DECLARATION OF
KINAM PARK, PH.D.**

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TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 8,163,802 (the “’802 Patent”)
1002	Declaration of Kinam Park, Ph.D.
1003	<i>Curriculum Vitae</i> of Kinam Park, Ph.D.
1004	File History of U.S. Patent No. 8,163,802
1005	U.S. Patent Publication No. 2005/0232895 (“Chen”)
1006	U.S. Patent No. 6,559,189 (“Baker”)
1007	U.S. Patent No. 6,844,005 (“Wahi ’005”)
1008	U.S. Patent Publication No. US 2004/0071757 (“Rolf”)
1009	U.S. Patent No. 5,674,481 (“Wahi ’481”)
1010	<i>Trutek Corp. v. Bluwillow Biologics, Inc.</i> , Case No. 2:21cv10312 (E.D. Mich. Feb. 10, 2021), ECF No. 53, CLAIM CONSTRUCTION OPINION AND ORDER
1011	Reserved
1012	Reserved
1013	Reserved
1014	Docket, <i>Trutek Corp. v. Cho et al.</i> (“Cho”), Case No. 2:23cv3709 (D. N.J. Jul. 11, 2023), printed March 20, 2024
1015	Scheduling Order in <i>Cho</i> , ECF No. 75 (Feb. 28, 2024)
1016	Interim Procedure Memorandum issued by Director Vidal on June 21, 2022
1017	District of New Jersey, Judicial Caseload Profile, December 31, 2023, excerpted from fcms_na_distprofile1231.2023.pdf and downloaded from https://www.uscourts.gov/statistics/table/na/Federal-court-

Exhibit No.	Description
	management-statistics/2023/12/31-1 on March 11 , 2024
1018	Rahn, O. and Van Eseltine, W.P., <i>Quaternary ammonium compounds</i> , Annual Review of Microbiology, 1, 173-192 (1947)
1019	Shelton et al., <i>Quaternary ammonium salts as germicides. I. Non-acylated quaternary ammonium salts derived from aliphatic amines</i> , J. Am. Chem. Soc., 68 (5): 753-755 (1946)
1020	Denyer, S.P., <i>Mechanisms of action of antibacterial biocides</i> , International Biodeterioration & Biodegradation 36(3-4): 221-245 (1995)
1021	Knowde Compound Summary for CelquatSC-240C
1022	Maillard, Jean-Yves, <i>Antimicrobial biocides in the healthcare environment: efficacy, usage, policies, and perceived problems</i> (2005)
1023	Block, Seymour S., <i>Disinfection, Sterilization, and Preservation</i> , (4th Ed. 1991)
1024	U.S. Patent Publication No. 2007/0243237 to Khaled et al.
1025	U.S. Patent Publication No. 2007/0134302 to Koenig et al.
1026	Moore et al., <i>Microbiological standards for nasal solutions</i> , Journal of Applied Bacteriology (1976)
1027	U.S. Patent No. 7,776,798 to Subramanian et al.
1028	Reserved
1029	U.S. Patent Publication No. 2007/0048356 A1 to Schorr et al.

I, Kinam Park, Ph.D., hereby declare as follows:

I. INTRODUCTION AND QUALIFICATIONS

1. I have been retained by Vorys, Sater, Seymour and Pease LLP on behalf of Salvacion USA, Inc. (“Salvacion”) to provide my opinion concerning the validity of claims 1-3 and 8 (the “Challenged Claims”) of U.S. Patent No. 8,163,802 (“the ’802 Patent”) in support of Salvacion’s Petition for *Inter Partes* Review (the “Petition”) of the ’802 Patent (Ex. 1001).

2. I am being compensated at a rate of \$600 per hour for my work in this proceeding, and my compensation is in no way contingent on the nature of my findings, the presentation of my finding in testimony, or the outcome of this or any other proceeding. I have no other interest in this proceeding or in Salvacion. It is conceivable that I may own investments in mutual funds which themselves own shares in Patent Owner or Salvacion, if either is publicly traded. However, I have no knowledge of any such holdings, which, in any event, would not constitute a material portion of my net worth.

3. I am the Showalter Distinguished Professor of Biomedical Engineering, as well as a full Professor of Pharmaceutics at Purdue University. A copy of my *Curriculum Vitae* is attached as Exhibit 1003. It contains a description of my education, academic appointments, professional activities, service on the editorial board of professional journals, books, referenced articles in scholarly journals,

journal cover stories, patents, presentations, book reviews, teaching responsibilities, and thesis supervision, as well as recent matters in which I have testified as an expert.

4. I obtained my Ph.D. in Pharmaceutics from the University of Wisconsin in 1983, and completed a postdoctoral training in Chemical Engineering from the University of Wisconsin in 1985. I joined Purdue University as an Assistant Professor in 1986, and since 1994, I have been a Professor in the Department of Pharmaceutics at Purdue University. I also have been a Professor in the Department of Biomedical Engineering since 1998, and became the Showalter Distinguished Professor of Biomedical Engineering at Purdue University in 2006.

5. Since 1986, I have been involved in the research, development, and manufacture of various pharmaceutical formulations. I have conducted numerous research activities at Purdue University related to drug delivery technologies utilizing various polymers and biomedical devices.

6. Since the early 1990s, one of my research interests has been developing biodegradable, pH-sensitive, and temperature-sensitive polymers and hydrogels for applications in drug delivery and biomaterials. One of the polymers I used was polymeric quaternary ammonium compounds. In addition, the biocidal nature of quaternary ammonium compounds has been taught in one of my courses (Polymers in Biomedical and Pharmaceutical Systems).

7. I have published 321 papers in peer reviewed journal articles, 100 book

chapters, 98 conference proceedings, 28 patents, 223 journal cover stories, and 13 books, and given 336 invited lectures.

8. Over the years, I have received numerous honors and awards, including the Research Achievement Award (Pharmaceutics and Drug Delivery Section) (2001), the Clemson Award (basic research category) of Society for Biomaterials (2001), the Controlled Release Society Founders Award (2004), the Louis W. Busse Lectureship of School of Pharmacy at University of Wisconsin (2008), the Sigma Xi Research Award (Purdue University Chapter) (2009), Thomson Reuters' list of "The World's Most Influential Scientific Minds: 2014" (2014), Korean-American Society in Biotech and Pharmaceuticals-Daewoong Award (2014), and Controlled Release Society Distinguished Service Award (2015), Special Government Employee at FDA CDER (2016), the University of Auckland Distinguished Visitor Award (2017), the CRS Foundation Award (2018), One of the Most Impactful Faculty Inventors, Purdue University (2019, 2020, 2021), and Clarivate Analytics' List of "Highly Cited Researchers (2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023)."

9. I have also been on the Board of Governors of the Controlled Release Society (1993-1996), a Fellow at the American Association for Pharmaceutical Scientists (AAPS) (1993), the President of the Korean-American Pharmaceutical Scientists Association (1995-1997), a Fellow at the American Institute for Medical and Biological Engineering (1996), a Fellow at the Biomaterials Science and

Engineering of the Society for Biomaterials (2000), the President of the Controlled Release Society (2001-2002), and a Fellow of the Controlled Release Society (2010).

10. I have been a member of numerous Advisory Boards, including the Advisory Panel on Polymeric Excipients, USP (1995-2005), the ACS Books Advisory Board (1997-2000), the Scientific Advisory Board, International Symposium on Recent Advances in Drug Delivery Systems (2000-2001), International Nanomedicine and Drug Delivery Symposium (2005), Board of Directors & Chairman of Fellowship Committee, CRS Foundation (2008-2013), Scientific Advisory Board, the International Conference on Biomaterials Science in Tokyo (2016), External Advisor for Internal Projects at Korea Institute of Science and Technology (KIST) (2017), International Organizing/Advisory Committee, 5th Symposium on Innovative Polymers for Controlled Delivery, Suzhou, China (2018-2020), Expert Advisor for USP's PLGA Joint Subcommittee, USP (2021-2022), and the International Advisory Committee of the 12th World Biomaterials Congress (WBC) (2023-2024).

11. I was on editorial boards of more than 20 journals, including for the Journal of Biomaterials Science – Polymer Edition; the Journal of Bioactive and Compatible Polymers, Colloids and Surfaces B: Biointerfaces; Archives of Pharmacal Research, Advanced Drug Delivery Reviews, Biomaterials Research, the

Journal of Pharmacy and Pharmacology, the Journal of Drug Delivery Science and Technology, Nano Reviews, Frontiers in Drug Delivery Biotechnology, and Regenerative Engineering and Translational Medicine. In 2023, I resigned from all editorial boards for the next generation of scientists.

12. I served as the Editor-in-Chief for the Journal of Controlled Release during 2005-2019. I previously have been a journal editor for several publications, including Pharmaceutical Research (Associate Editor); Pharmaceutical Research (Book Review Editor); Advanced Drug Delivery Reviews (Guest Editor); and Journal of Controlled Release (Editor, Americas).

13. Accordingly, I believe I am an expert in the field of pharmaceutical formulations, including nasal pharmaceutical products. Additional details of my education, experience, and credentials are set forth in my aforementioned *Curriculum Vitae* (Ex. 1003).

14. I have previously served as an expert in over 30 cases concerning pharmaceuticals.

15. The statements made and opinions provided in this Declaration are based on my own personal knowledge and, if called as a witness, I could and would testify in a manner consistent with this Declaration.

II. UNDERSTANDING OF U.S. PATENT LAW

16. I am not an attorney. For purposes of the Petition, I have been instructed about specific sections of law that are relevant to my declaration and opinions. Listed below is my understanding of the related law.

Claim Construction

17. In an *inter partes* review petition, a claim must be construed under the *Phillips* standard. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). This means the words of a claim are construed with their plain and ordinary meaning as understood by a person of ordinary skill in the art (a “POSITA”) at the time of the invention, in light of the specification and patent prosecution history, and pertinent extrinsic evidence. An exception arises if the specification and patent prosecution history show an intent to depart from this meaning.

Invalidity by Anticipation

18. I understand 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, in the way as arranged in the claims. Thus, a claim is anticipated under 35 U.S.C. § 102 (pre-AIA)¹ when a single prior art reference teaches every

¹ Each reference to 35 U.S.C. § 102 and 35 U.S.C. § 103 in this declaration means 35 U.S.C. § 102 (pre-AIA) and 35 U.S.C. § 103 (pre-AIA), respectively.

element required by the claim as construed under the *Phillips* standard. I am informed that a finding of an unrecognized or unappreciated property of a prior art composition, or of a scientific explanation for how a prior art composition operates, does not make the old composition patentably new and can render a prior art reference anticipating through inherency. I am also informed that for anticipation, the prior art reference disclosure must provide an enabling discourse without undue experimentation.

Invalidity by Obviousness

19. I understand that a claim is unpatentable for obviousness under 35 U.S.C. § 103(a) “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” Obviousness may be based upon a combination of prior art references if the combination is obvious to a POSITA.

20. In the event that all of the claim’s elements are not found in a single reference, or references to be combined, the claim is not patentable if the differences between the claim and the prior art references’ teachings would have been obvious to a POSITA at the time of the invention, in view of, for example, common sense that does not require a specific hint or suggestion in a particular reference, only supported by evidence and a reasoned explanation.

21. I understand that determining whether a claim would have been obvious requires consideration of the following factors, among others:

The level of a person of ordinary skill in the art when the application was filed,

The scope and content of the prior art, and

The differences (if any) between the claim and the prior art.

22. When determining whether a single reference or a combination of references would have rendered a claim obvious, the following factors should be considered:

Whether the teachings in the reference(s) include known concepts combined in a usual manner to yield predictable results,

Whether a POSITA could modify the teachings of the reference(s) in a predictable way, for a predictable benefit,

Whether the claim elements are one of a limited number of known design choices, and a POSITA would have a reasonable expectation of success,

Whether a POSITA would have known the reason to combine the teachings of references in the manner set forth in the claim,

Whether the reference(s) includes a teaching or suggestion to modify or combine the claim elements, and

Whether the claim applies a known technique to improve a similar composition or method in a similar manner.

23. I understand that a POSITA has ordinary creativity, and is not an automaton. Further, the benefit of hindsight from the patent may not be used when determining whether a claim is obvious.

24. I understand that the '802 Patent is assumed, for purposes of the Petition, to have a priority date of July 7, 2008, and a critical date of July 7, 2007 ("Critical Date"). I further understand that the patents and published applications provided to me in connection with the Petition and relied upon in my anticipation and obviousness opinions are prior art to the '802 Patent.

25. I understand that other factors, called "secondary considerations" may support or refute a prima facie case of obviousness.

A. Basis for My Opinion and Materials Considered

26. In forming my opinion, I have reviewed and am familiar with the '802 Patent and its prosecution history, as well as the exhibits to the Petition listed below (including prior art) relied on in my opinion.

27. U.S. Patent No. 6,559,189 (Ex. 1006) to Baker Jr. et al. ("Baker") is entitled "Non-Toxic Antimicrobial Compositions and Methods of Use," was issued on May 6, 2003, and I understand constitutes prior art against the '802 Patent under 35 U.S.C. § 102(b).

28. U.S. Patent Publication No. 2004/0071757 (Ex. 1008) to Rolf ("Rolf") is entitled "Inhalation Device," was published on April 15, 2004, and I understand

constitutes prior art against the '802 Patent under 35 U.S.C. § 102(b).

29. U.S. Patent No. 6,844,005 (Ex. 1007) to Wahi ("Wahi '005") is entitled "Electrostatically Charged Nasal Application Product With Increased Strength," was issued on January 18, 2005, and I understand constitutes prior art against the '802 Patent under 35 U.S.C. § 102(b).

30. U.S. Patent Publication No. 2005/0232895 (Ex. 1005) to Chen ("Chen") is entitled "Anti-Viral Pharmaceutical Compositions," was published on October 20, 2005, and I understand constitutes prior art against the '802 Patent under 35 U.S.C. § 102(b).

31. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the '802 Patent. Unless otherwise stated, my testimony below refers to the knowledge of a POSITA as of the Critical Date or before.

III. SUMMARY OF MY OPINIONS

32. It is my opinion that claims 1-3 and 8 of the '802 Patent are anticipated or rendered obvious over Chen.

33. It is my opinion that claims 1-3 and 8 of the '802 Patent are anticipated or rendered obvious over Baker.

34. It is my opinion that claims 1-3 and 8 of the '802 Patent are anticipated or rendered obvious over Wahi '005.

35. It is my opinion that claims 1, 2 and 8 of the '802 Patent are anticipated or rendered obvious over Rolf.

36. It is my opinion that claim 3 of the '802 Patent is rendered obvious over Rolf in view of Wahi '005.

37. My opinion does not rely on any secondary considerations of non-obviousness of the '802 Patent's claims. If secondary considerations are alleged by the Patent Owner, I reserve the right to consider them and respond.

IV. LEVEL OF ORDINARY SKILL IN THE ART IN THE RELEVANT TIMEFRAME

38. Having read the '802 Patent and its prosecution history, the relevant art is pharmaceutical formulation.

39. A POSITA at the time of the Critical Date would have had at least an undergraduate degree in pharmacy, chemistry, biochemistry, biomedical engineering, or a closely related field, such that a POSITA generally understands pharmaceutical formulation. A POSITA would be familiar with the chemical ingredients in the '802 patent, biocidal agents, and cationic agents, have knowledge of airborne particles including viruses and bacteria, and understand electrostatic fields, electrostatic attraction and repulsion, adhesion and cohesion.

V. TECHNOLOGY BACKGROUND

40. In this section, I discuss the state of the art as of the Critical Date with respect to certain technologies relevant to the subject matter of the '802 Patent.

A. Biocidal and Cationic Agents

41. Biocidal agents may exhibit a range of antimicrobial activity from inhibition of growth to killing microbes. (Ex. 1029 at [0026].) These agents are used for sterilization, disinfection, and preservation. (Ex. 1022 at 307.) The concentration of the agent determines which use is employed. (*Id.* at 307-308.) Sterilization destroys or eliminates the microbes, disinfection eliminates many or all pathogenic microbes, while preservation prevents microorganisms from growing and thus deteriorating the underlying material, but does not involve killing microorganisms. (*See, e.g.*, Ex. 1021 at 8 (sterilization); *id.* (disinfection); and Ex. 1023 at 22 (preservation).) Quaternary ammonium compounds (“QACs” or more commonly known as “QUATS”) are useful for both disinfection and preservation. (*Id.* at 247 (disinfection) and 250 (preservation).)

42. Cationic agents are positively charged. Quaternary ammonium compounds, including polymeric QUATS, maintain a permanent positive charge in both acid and alkaline aqueous environment, and thus are cationic agents.

43. Well before the Critical Date, QUATS, including polymeric QUATS, were known to be both cationic and biocidal agents. (Ex. 1023 at 230.) The antibacterial properties of QUATS were well known even in the 1940s. (Ex. 1018 at 173-192; Ex. 1019 at 753-755; and *see also* Ex. 1020 at 227-245.)

44. Bacteria and viruses are often negatively charged. (Ex. 1023 at 251.)

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

45. QUATS kill bacteria or viruses by adsorption onto the bacterial surface, diffusion into the cell, binding with the cytoplasmic membrane, which disrupts the membrane causing release of cytoplasmic elements, and the death of the cell. *Id.*

46. QUATS have been used since before the Critical Date as protective coatings on many surfaces and personal protective equipment. (*See* Ex. 1024 (surfaces) and Ex. 1025 (personal protective equipment).)

47. CELQUAT SC-240C, which is polyquaterium-10, is a polymeric QUAT and a quaternary thickener. (*See* Ex. 1021)

48. Benzalkonium Chloride (“BAC”) is a class of QUATS that has been used since before the Critical Date as a preservative and disinfectant. (Ex. 1023 at 226). BAC has been used in nasal formulations as a preservative since at least the 1970s. (Ex. 1026 at 380.)

B. Prevention of Inhalation of Harmful Airborne Particulates

49. Harmful airborne particulates, such as bacteria and viruses, may be inhaled and then cause harm to the human body.

50. While human nasal passages have some defense mechanisms naturally, it has been long desired to provide additional defenses.

51. One additional defense is face masks. These may keep out a certain amount of airborne particles, but some airborne particles go around the mask and are inhaled through the nasal passages.

52. Another defense is a gas mask. These typically provide a hermetic seal between the face and the mask.

53. However, these masks are cumbersome and cannot easily be used for day-to-day activities.

VI. OVERVIEW OF THE '802 PATENT

54. The '802 Patent covers a pharmaceutical formulation and method for “reducing the risk of inhalation of harmful substances[.]” (Ex. 1001 at Abstract.)

55. The '802 Patent states:

The Present Invention relates to the field of protective compositions against assault by various irritants and noxious substances as well as against assault by assorted microorganisms that typically gain entry into the body through the airway and/or nasal mucosa. The Present Invention also relates to anti-viral, anti-bacterial, and anti-microbial products and methods that involve the use of products heretofore developed for restricting the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. This reduced the inflow of airborne contaminants to the nasal passages by capturing the contaminants and keeping them from entering the body. In the present invention, these electrostatically charged nasal application products capture and hold the contaminants

including viruses, bacteria, and other harmful microorganisms or toxic particulates, inactivate them dermally outside the body and render them harmless.

(Ex. 1001 1:58-2:7.)

56. The '802 Patent addresses the problem of various irritants and harmful substances, including microorganisms such as bacteria and viruses (generally referred to in the '802 patent as particulates), entering the human body, specifically the nasal passages, via inhalation by restricting the inflow of the airborne contaminants to the nasal passages.

57. Both a formulation and a method for reducing the risk of inhalation of harmful particulates are claimed in the '802 Patent.

58. The '802 Patent relates to “electrostatically charged multi-acting nasal application, product and method.” (Ex. 1001 1:1-3.)

59. The '802 Patent includes the following claims which are the subject of the Petition:

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

- a) electrostatically attracting the particulate matter to the thin film;
- b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate

impermeability to the thin film; and

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

(Ex. 1001 10:19-33.)

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidal agent, and wherein said formulation, once applied:

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

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

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

(*Id.* 10:34-48.)

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

(*Id.* 10:49-51.)

8. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:

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

(*Id.* 11:1-7.)

60. I understand that the '802 Patent issued on April 24, 2012. Only one Office Action was sent during the prosecution of the '802 Patent, which rejected all claims for reasons other than anticipation or obviousness. (*See* Ex. 1004 at 55, 90.) One amendment changed the claim language from “preventing” to “inhibiting” and then the application was allowed.

61. I understand that the '802 Patent incorporates by reference U.S. Application Nos. 61/085555; 61/078478; 60/570103; 61/078472; 60/598462 and 10/082978; and U.S. Patent Nos. 5468488; 5674481; and 6844005.

VII. CLAIM CONSTRUCTION

62. I understand that claim terms, in the absence of an express definition or disclaimer, are given their ordinary and customary meaning, as would have been understood by a POSITA, at the time of the alleged invention.

63. In considering the meaning of the claims, however, I understand that one must consider the language of the claims in light of “the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” 37 C.F.R. § 42.100(b).

64. In the '802 Patent, except as discussed below, the terms can be given their ordinary meaning or, in any event, the ordinary meaning they would have to a POSITA in the field of pharmaceutical formulation.

65. I understand that there was a litigation involving the '802 Patent and the court in that litigation accepted the patent owner's claim construction for the terms of the claims. I understand for purposes of the Petition, certain terms are given the same meaning as the court order in *Trutek Corp. v. Bluewillow Biologics, Inc.*, Case No. 2:21cv10312 (E.D. Mich. Feb. 10, 2021) (Ex. 1010).

"Biocidic Agent"

66. I understand that, as used in the '802 Patent claims, the phrase "biocidic agent" means an agent which has the capacity to neutralize, inactivate, render harmless, or kill airborne particles, which include microorganisms, for example viruses and/or bacteria because this is consistent with the definition offered by Trutek in its proposed claim construction (which was adopted by the court) in *Trutek Corp. v. Bluewillow Biologics, Inc.*, Case No. 2:21cv10312 (E.D. Mich. Feb. 10, 2021) (Ex. 1010).

67. This meaning is consistent with the '802 Patent specification, which states:

[A]n electrostatically charged composition ... creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically

trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless.

(Ex. 1001 at 3:33-40.)

“Adequate Impermeability”

68. I understand that for purposes of the Petition, as used in the '802 Patent claims, the term “adequate impermeability” will have the definition proposed by Trutek and accepted as the claim construction by the court in the same case listed above.

69. “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.” (Ex. 1010, p. 17.)

“Skin or Tissue of Nasal Passages of the Individual”

70. I understand that the phrase “skin or tissue of nasal passages” means skin near the nasal passages or tissue of the nasal passages. This is clear from the '802 Patent and also Wahi '488 and Wahi '481, each of which is incorporated by reference in its entirety into the '802 Patent.

71. “Skin” itself means skin in or near the nasal passages because independent claims 1, 2, and 8 each state that the formulations and method are

applying a formulation in a thin film “for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.” (Ex. 1001 10:19-21; 10:34-36; 11:1-3.) The object of the invention of the ’802 patent describes that a composition can be “readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril.” (Ex. 1001 2:62-65 and *see* 3:6-7 and 3:15-16.) Logically, the formulations 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.

“Applied ... in a thin film”

72. Wahi ’481, which is incorporated by reference in its entirety into the ’802 Patent, states that “[e]ach patient was provided with the gel along with directions for use which included that a very thin film should be applied with the finger on the outside of the nostril and above the upper lip” (Ex. 1009 6:52-55.)

73. Wahi ’481 states that the nasal application product may be a lotion or a gel. (Ex. 1009 9:10.)

74. I understand that based on the ’802 Patent itself (which incorporates Wahi ’481), a lotion or a gel is “applied ... in a thin film.”

VIII. OVERVIEW OF PRIOR ART REFERENCES

A. U.S. Patent Publication No. 2005/0232895 (“Chen”)

75. Chen (Ex. 1005) is entitled “Anti-Viral Pharmaceutical Compositions,” and was published on October 20, 2005, and I understand Chen constitutes prior art against the ’802 Patent.

76. Chen teaches “antiviral compositions and methods of ... using such compositions.” (Ex. 1005 at [0021].) The compositions comprise “a cationic polymer” such as “poly(dimethyl-aminoethylmethacrylate...EUDRAGIT®E” (*id.* at [0022] and [0078]) and poly(meth)acrylic acid) based copolymers with cationic groups (*i.e.*, ... quaternary amine). The compositions also comprise “a cationic surfactant” that includes those in the form of quaternary ammonium salts, such as cetyl trimethyl ammonium chloride or alkylbenzyl dimethyl ammonium chloride (*e.g.*, benzalkonium or benzethonium type preservative, disinfectant, and fungicide). (*Id.* at [0083] and [0084].) Chen discloses poly(methyl methacrylate-*b*-N-methyl-4-vinyl pyridinium iodide). (*Id.* at [0078].) Additionally, a biocidal agent may be present in the composition, as seen *e.g.*, in Antiviral Compositions 9, 12, and 14, with benzalkonium chloride. (*Id.* at [0097].) The compositions may take various forms such as “nasal ointments [or] nasal drops” which may be administered locally, including topically and in a mucosal application on the “the nasal mucous membrane.” (*Id.* at [0111] and [0110]); *see e.g.*, at [0110] (discussing where to apply

the compositions).) These various types of compositions may have different viscosities (for example, a nasal ointment is more viscous than a nasal spray), and it is known in the art to adjust the adhesion and cohesion of the composition by adjusting the viscosity. (Ex. 1010, p. 17.)

77. According to Chen, methods of applying the compositions “generally cause the formulation to coat and remain in contact with those membrane or skin surfaces for a period of time, like a chemical barrier at those sites.” (Ex. 1005 at [0112]).) For example, Chen’s formulation of Example 1 is a viscous gel, which provides excellent muco-adhesiveness by forming a physical barrier over the mucous membrane. (*Id.* at [0121].) This is showing that a thin film of the composition is applied and sticks to the membrane or skin.

78. A POSITA would see Chen’s Antiviral Compositions 9, 12, and 14, including EUDRAGIT E100 and BAC, and Compositions 1, 2, and 11, including chitosan hydrochloride and BAC, which are applied topically on the nasal mucous membrane and which coat the membrane or skin surfaces, and know that Chen is teaching thin films of the formulations on the skin and nasal membranes.

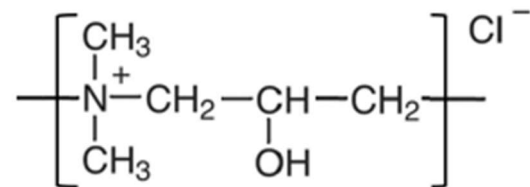
B. U.S. Patent No. 6,559,189 (“Baker”)

79. Baker (Ex. 1006) is entitled “Non-Toxic Antimicrobial Compositions and Methods of Use” and was issued on May 6, 2003.

80. Baker is solving the problem of reducing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses with various methods and compositions. (Ex. 1006 at Abstract.) Baker also teaches a method of “decontaminating a sample comprising ... treating a sample ... [with] physical contact [of the compositions described above] with bacteria, [and/or] virus” (*Id.* 69:23-33.)

81. Baker provides a composition applied to the surface of the skin and mucosal cells and tissues (including nasal mucosa) comprising a quaternary ammonium compound, for example N,N-dimethyl-2-hydroxypropyl ammonium chloride polymer. (*Id.* 5:66-67; 7:1-2; 13:24-26; and 36:12-14.) N,N-dimethyl-2-hydroxypropyl ammonium chloride polymer is a cationic agent and also a poly quaternary ammonium compound.

82. Below is the structure of N,N-dimethyl-2-hydroxypropyl ammonium chloride polymer.



83. It is well known to use polymers as thickeners, and because N,N-dimethyl-2-hydroxypropyl ammonium chloride polymer is a polymer, it can be employed as a quaternary thickener. (Ex. 1027 at 1:7-9 and 7:19-21.)

84. Additional cationic halogen containing compounds, which are also cationic agents, may be present in the compositions. (Ex. 1006 at 17:5-41.)

85. Baker also teaches virucidal agents in the composition, for example, TWEEN 60 (polyoxyethylene sorbitan monostearate), and/or TRITON (a pheoxypolyethoxyethanol), each of which has virucidal effects. (*Id.* 16:38-54.) Each of these agents was known to have virucidal effects at the Critical Date. Baker, in fact, also states that TWEEN 60 is known to have virucidal effects. (*Id.* 16:43-46.)

86. Baker's compositions may have the form of cream, foam, lotion, gel, among other forms. (*Id.* 36:32-33.) These compositions may be formulated with varying components in varying amounts, resulting in different viscosities. (Ex. 1006 FIGS. 29A-29E.)

87. When Baker's compositions are applied to the skin and mucosal cells and tissues, a thin film of the composition sticks on the skin and mucosal cells and tissues.

C. U.S. Patent No. 6,844,005 (“Wahi ’005”)

88. Wahi ’005 (Ex. 1007) is entitled “Electrostatically Charged Nasal Application Product With Increased Strength,” and was issued on January 18, 2005.

89. Wahi ’005 and the ’802 Patent have one inventor in common, Ashok Wahi.

90. Wahi ’005 discloses a “nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage” by an electrostatic field. (Ex. 1007 2:9-12.) The electrostatic polymer, which creates the electrostatic field “is a poly (dimethyl diallyl ammonium chloride) polymer.” (*Id.* 2:16-18.)

91. According to Wahi ’005, the prior art already described methods and compositions for restricting airborne contaminant flow into the nose, but Wahi ’005 discovered that “utilization of at least 10% of one specific active electrostatically charged polymer provides significantly increased charge density and efficacy as compared to other electrostatic polymers at lower, the same or higher concentrations than the present invention levels of the poly (dimethyl diallyl ammonium chloride).” (*Id.* 1:65-2:4.) Wahi ’005 refers to Wahi ’488 and Wahi ’481 as providing these teachings.

92. Therefore Wahi ’005 confirms that prior art methods and compositions existed to restrict airborne particulates from being inhaled.

93. Wahi '005 teaches Celquat SC-240C, which is a polyquaternaryammonium cellulose, and Agequat 400, which is poly (dimethyl diallyl ammonium chloride). (Ex. 1007 4:32-33 and 3:34-35.) Each of these components is known to be a cationic agent. Each of these components is also known to be a biocidal agent.

94. Celquat SC-240C is a poly quaternary ammonium compound whose chemical name is polyquaternium-10, and Wahi '005 confirms that by stating "Celquat SC-240C is a polyquaternary [sic] ammonium [sic] cellulose" (4:32-33). It was known at least at the Critical Date that Celquat SC-240C may be used as a thickener in a composition due to the chemical structure of the compound and, therefore, Celquat SC-240C is also an example of a quaternary thickener.

95. As discussed in Section VIII.B., TWEEN 60 is known to have virucidal benefits, and is a biocidal agent. TWEEN 60 is also disclosed and used in formulations with Celquat SC-240C and Agequat 400.

96. Therefore, Wahi '005's nasal product includes a cationic agent and a biocidal agent. One example of this nasal product is Example #4 of Wahi '005 comprising Celquat SC-240C and Agequat 400, each of which functions as a cationic agent and a biocidal agent; and also TWEEN 60, which is a biocidal agent. (Ex. 1007 4:50-63.)

97. Wahi '005 teaches numerous forms of the nasal composition such as “topical solutions, semisolids, ... and vaporizable solutions ... ointments, pastes, creams and gels.” (Ex. 1007 2:22-26.) Each of these forms has varying viscosities, which may be adjusted by varying the components and the amount of the components of the composition. A more viscous form would enable greater adhesion of the composition to the skin, tissue, or mucosa of the nasal passages, and a more cohesive composition, such as a gel. Wahi '005 incorporates Wahi '481 (Pat. No. 5,674,481) by reference in its entirety. Wahi '481 describes that its gel formulation is applied in a thin film with the finger on the outside of the nostril and above the upper lip and to repeat the application four times a day. (Ex. 1009 6:23-26.)

98. A POSITA would understand at the Critical Date that the nasal compositions in Wahi '005 would be applied to the skin, tissue, or mucosa of the nasal passages in a thin film.

99. Wahi '005's thin film with the cationic agent(s) would electrostatically attract and hold the airborne contaminants, rendering harmless with the biocidal agent.

D. U.S. Patent Publication No. 2004/0071757 (“Rolf”)

100. Rolf (Ex. 1008) is entitled “Inhalation Device,” and was published on April 15, 2004.

101. Rolf teaches “a method for preventing respiratory infection” by “contacting a live respiratory pathogen at risk of entering the respiratory tract...with a therapeutically effective amount of an essential oil.” (Ex. 1008 at Abstract.) “[T]he live respiratory virus is inactivated upon contact with the essential oil[.]” (*Id.* at [0021])

102. Rolf discloses a device including “an ointment or gel on a backing” that is applied “in the vicinity of the nasal passageway.” (Ex. 1008 at FIG. 9, [0018], [0021], and [0042].) The backing has “a front side 3 (the side exposed to the skin during use) and a back side 4 (the side exposed to the environment during use).” (*Id.* [0047].) The formulation is positioned “on,” “in,” or “on and in” (*i.e.*, not embedded, fully embedded or partially embedded in) a portion of the backing. (*Id.* [0026], [0042], and [0058].)

103. Rolf’s formulation will therefore be on the skin in a thin film.

104. Essential oils were known in the art to be effective to inactivate viruses at the Critical Date.

105. Given the definition above of a “biocidal agent,” which includes inactivating microorganisms such as viruses, Rolf teaches an essential oil as a biocidal agent.

106. Rolf also teaches compositions comprising cationic agents, for example quat-15, which is a quaternary ammonium compound. (*Id.* at [0148], and [0268]-[0283].)

107. Quat-15 thickens formulations, for example, Examples 1-16 in Rolf. (*Id.* at [0268]-[0283].) Thus, quat-15 in Rolf is a quaternary thickener.

IX. DETAILED ANALYSIS OF GROUNDS OF INVALIDITY

A. Detailed Analysis of Ground 1: Claims 1-3 and 8 Are Anticipated or Rendered Obvious by Chen

1. Claim 2²

a. “A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”

108. In my opinion, Chen teaches the claimed formulation preamble.

109. Chen discloses an “antiviral composition[] ... administered locally, such as to skin ... [or] nasal membrane.” (Ex. 1005 at [0044].) With respect to infection by inhalation, Chen discloses that “the formulations disclosed herein may prevent the spreading of the severe acute respiratory syndrome (SARS). SARS is spread when someone with SARS coughs or sneezes droplets into the air and someone else inhales them. By forming a viscous membrane over nasal mucous and

² My analysis follows the order of the claims in the Petition (claims 2, 3, 1, and 8) for Grounds 1-4.

by deactivating viruses on contact, the formulation of the present invention could provide an effective means to prevent the virus from spreading.” (*Id.* at [0115].) Therefore Chen is inhibiting harmful particulate matter, that is, a virus, from being inhaled.

110. Chen discloses a “cationic polymer, such as ... poly(dimethyl-aminoethylmethacrylate)” (commercially available as EUDRAGIT®E by Degussa) (*id.* at [0078]) and chitosan hydrochloride (*id.* at [0055] and [0079]-[0081].)

111. As discussed above, cationic agents electrostatically attract negatively-charged microorganisms, such as the viruses in Chen.

112. Thus, in my opinion, the composition comprising the cationic polymer placed on skin near the nose or in the nasal membrane would perform the function of electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. The cationic agent in Chen’s composition would attract and hold the virus, inhibiting the virus from entering the body via inhalation, and therefore would prevent infection.

b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film”

113. Chen discloses this element because Chen discloses an “antiviral composition[] ... administered locally, such as to skin ... [or] nasal membrane.” (*Id.* at [0044].) The formulation forms a viscous membrane over nasal mucous and deactivates viruses on contact. (*Id.* at [0115].)

114. Chen's formulations may be applied in forms such as a "paste, gel,... lotion, cream, ..., lacquer, or ointment ... for local application." (*Id.* at [0111].)

115. Chen's example formulations are applied to the skin or mucosal tissues in order to prevent infection by a pathogenic virus (*e.g.*, coronavirus, rhinovirus, respiratory syncytial virus), and are tested for the antiviral effect (*Id.* at [0127]-[0149] and Fig. 6.) The formulations with sufficient muco-adhesiveness form a physical barrier over the mucous membrane. (*Id.* at [0121] and [0148].) Accordingly, Chen teaches or suggests a formulation applied to skin or tissue of nasal passages in a thin film. In addition, a POSITA would understand that a "paste, gel, ... lotion, cream, ..., lacquer, or ointment ..." is "applied ... in a thin film."

c. "said formulation comprising at least one cationic agent and"

116. Chen discloses this element when it discloses a "cationic polymer ... poly(dimethyl-aminoethylmethacrylate) (commercially available as EUDRAGIT®E by Degussa)" and "poly(meth)acrylic acid) based copolymers with cationic groups (*i.e.* ... quaternary amine)." (*Id.* at [0078].)

117. Chen discloses poly(methyl methacrylate-*b*-N-methyl-4-vinyl pyridinium iodide). (*Id.*). This is a polymeric quaternary ammonium compound.

118. Chen additionally discloses various cationic surfactants at various concentrations. (*Id.* at [0082]-[0093].)

119. Chen additionally discloses various cationic polymers at various

concentrations. (*Id.* at [0076]-[0081].)

120. Chen additionally discloses “cationic polymers [such as] poly-(D, L or DL)-arginine salts.” (*Id.* at [0078].)

121. Chen additionally discloses examples with a cationic agent, poly(dimethyl-aminoethylmethacrylate) (known as EUDRAGIT®), and a biocidal agent, benzalkonium chloride. (*Id.* at [0097].) Shown below is Antiviral Composition 12, which is the same as Antiviral Formulation II tested for its antiviral effect against rhinovirus. (*Id.* at [0097], [0130], [0144], and Fig. 6.)

Antiviral Composition 12

EUDRAGIT® E100	1.50%
Zinc chloride	0.10%
Benzalkonium chloride	0.02%
Sodium chloride	0.27
Water to add to	100%
NaCl/HCl to adjust pH to	pH 6

d. “at least one biocidal agent”

122. The '802 Patent itself lists benzalkonium chloride or BAC as a biocidal agent and claims BAC as a biocidal agent in claims 7 and 9.

123. Chen discloses this element when benzalkonium chloride was disclosed. (*Id.* at [0086].)

124. Therefore, Chen discloses one of the same biocidal agents that the '802 Patent claims.

125. Chen then provides examples of compositions including EUDRAGIT E100 and BAC: Antiviral Compositions 9, 12, and 14.

- e. **“and wherein said formulation, once applied:
a) electrostatically attracts the particulate matter to
the thin film;”**

126. Chen discloses this element.

127. Chen’s formulations may include various cationic agents, including chitosan hydrochloride or poly(dimethyl-aminoethylmethacrylate) (EUDRAGIT®), which attract the negatively-charged virus (the particulate matter). Indeed, cationic agents, particularly quaternary ammonium compounds, necessarily attract “particulate matter” as they are used in the formulation of claim 2.

128. The compositions may be “nasal ointments [or] nasal drops” which may be administered locally, including topically and in a mucosal application on “the nasal mucous membrane.” (*Id.* at [0111] and [0111]; *see e.g.*, [0111].)

129. According to Chen, applying the compositions “generally cause the formulation to coat and remain in contact with those membrane or skin surfaces for a period of time, like a chemical barrier at those sites.” (*Id.* at [0112].) This is showing that a thin film of the composition sticks to the membrane or skin.

130. In the event that it were found that this element is not expressly taught, a POSITA would understand that Chen’s formulations with cationic polymers inherently electrostatically attract the particulate matter.

- f. **“b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film”**

131. Chen discloses this element.

132. As discussed above, Chen’s compositions can be a “gel, lotion ... cream, ointment ... for local application for the treatment or prevention of viral infectious diseases.” (*Id.* at [0038].)

133. A POSITA would understand that a gel, lotion, cream, or ointment is applied as a thin film.

134. Chen discloses multiple examples showing different formulations that “vary the concentration of ingredients.” (*Id.* at [0097].) For instance, cationic poly(dimethyl-aminoethylmethacrylate), may be adjusted from 1.5 wt.% in Antiviral Composition 12 to 0.15 wt.% in Antiviral Composition 14. (*Id.*) Changing the amount of cationic polymer in a composition will change the adhesion and cohesion of a formulation applied as a thin film. Cationic agents attract particulate matter and hold particulate matter in place.

135. Therefore, Chen teaches these various types of compositions and varies the viscosities (for example a nasal ointment is more viscous than a nasal spray), which is known in the art to adjust the adhesion and cohesion of the composition.

136. As discussed above, Chen states that the compositions “generally cause

the formulation to coat and remain in contact with those membrane or skin surfaces for a period of time, like a chemical barrier at those sites.” (*Id.* at [0112].) For example, the Chen formulation of Example 1 is a viscous gel, which provides excellent muco-adhesiveness by forming a physical barrier over the mucous membrane. (*Id.* at [0121].) According to Chen, the cationic agent (chitosan chloride) used in Example 1 has been used as a bioadhesive especially for nasal delivery of a drug for its net positive charge, large molecular weight, gelation and film-forming characteristics. (*Id.* at [0080].)

137. 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.”

138. Because Chen is solving the problem of virus infection via inhalation, a POSITA would understand that the thin films of Chen’s compositions have adequate impermeability to prevent the viruses from reaching the skin, tissue, or mucosa of the nasal passages. 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.

139. Chen’s Antiviral Compositions 9, 12, and 14, including EUDRAGIT

E100 and BAC which are applied topically and on the nasal mucous membrane and which coat the membrane or skin surfaces, teach thin films of the compositions on the skin and nasal membranes.

140. A POSITA would understand that, if Chen's thin films were not adequately impermeable, Chen would not achieve the desired antiviral activity. Therefore, thin films of Chen's compositions must be adequately impermeable to viruses. Thus, in the event that this element is not taught, a POSITA would find it obvious to modify Chen's formulations per Chen's teachings and suggestions such that they would hold the particulate matter and that they would have adequate impermeability to prevent the viruses from reaching the skin, tissue, or mucosa of the nasal passages. A POSITA would have a reasonable expectation of success of such modifications.

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

141. In my opinion, Chen discloses this element.

142. Chen discloses BAC, which is the same biocidic agent recited in claims 7 and 9 of the '802 Patent. (*Id.* at [0086] and Ex. 1001 10:64-65 and 11:8-9.)

143. Chen's Antiviral Compositions 9, 12, and 14, including EUDRAGIT E100 and BAC, would each inactivate and render harmless the virus (particulate matter).

144. In the event that it were found that this element is not expressly taught,

a POSITA would understand that Chen's formulations with a biocidal agent inherently inactivate the particulate matter and render the particulate matter harmless.

145. In my opinion, Chen teaches each element of claim 2 of the '802 Patent and therefore anticipates claim 2 of the '802 Patent.

146. In the event that claim 2 is not found anticipated by Chen, Chen renders claim 2 obvious because all of the claim elements are taught or suggested by Chen, and the combination of the elements as taught or suggested by Chen would result in the formulation of claim 2 with a reasonable expectation of success in reaching the formulation as recited in the claim.

2. Claim 3

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

147. In my opinion, Chen discloses this element. Claim 3 depends from claim 2, and therefore all of claim 2's elements and the discussion thereof are incorporated herein.

148. Chen discloses "cationic polymers ... [such as] "poly(meth)acrylic acid) based copolymers with cationic groups (i.e. ... quaternary amine)." (Ex. 1005 at [0078].)

149. Chen discloses poly(methyl methacrylate-b-N-methyl-4-vinyl

pyridinium iodide). (*Id.*) This is a polymeric quaternary ammonium compound.

150. In my opinion, Chen teaches each element of claim 3 of the '802 Patent and therefore anticipates claim 3 of the '802 Patent.

151. In the event that claim 3 is not found anticipated by Chen, Chen renders claim 3 obvious because all of the claim elements are taught or suggested by Chen and the claimed combination of the elements would be obvious to a POSITA at the Critical Date.

3. Claim 1

a. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation

152. In my opinion, Chen discloses this element.

153. Claim 1 is identical to claim 2 except that 1) it claims a method rather than a formulation, 2) it does not include the following additional element: “said formulation comprising at least one cationic agent and at least one biocidal agent,” and 3) parts a, b, and c are method steps, rather than descriptions of the formulation. (*See* Section VI.)

154. The discussion of claim 2 is incorporated herein.

155. Chen discloses “a method for ameliorating viral infection comprising administering to a subject in need thereof the composition described herein in an amount effective to ameliorate viral infection.” (Ex. 1005 at [0109].)

156. Chen discloses that “ameliorating viral infection” includes “reducing or eliminating the likelihood that a person or an animal exposed to potentially infective viral particles will be infected with the viral particles” (*Id.*)

157. Chen discloses an “antiviral composition[] ... administered locally, such as to skin ... [or] nasal membrane. (*Id.* at [0044].) The composition used in Chen’s method “electrostatically inhibit[s] harmful particulate matter from infecting an individual through nasal inhalation.” Refer to Section IX.A.1.a.

158. In the event that this element is not taught, the element is obvious as of the Critical Date because it is obvious to use a formulation that has the purpose of “deactivating viruses on contact” in a method to attract and inactivate viruses. (Ex. 1005 at [0115].)

b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:”

159. In my opinion, Chen discloses this element. Refer to Section IX.A.1.b.

160. Chen discloses an “antiviral composition[] ... administered locally, such as to skin ... [or] nasal membrane. (Ex. 1005 at [044].)

161. Chen’s compositions may be applied as a “paste, gel, ... lotion, cream, ..., lacquer, or ointment ... for local application.” (*Id.* at [0111].) Chen’s examples are applied to the skin or mucosal tissues to prevent infection by a pathogenic virus (*e.g.*, coronavirus, rhinovirus, respiratory syncytial virus). The

Examples are tested for the antiviral effect. (*Id.* at [0127]-[0149] and Fig. 6.). The muco-adhesive formulations form a physical barrier over the mucous membrane. (*Id.* at [0121] and [0148].) Accordingly, Chen teaches or suggests a formulation applied to skin or tissue of nasal passages in a thin film. In addition, a POSITA would understand that a “paste, gel, ... lotion, cream, ..., lacquer, or ointment ...” is “applied ... in a thin film.”

c. “a) electrostatically attracting the particulate matter to the thin film”

162. In my opinion, Chen discloses this element. Refer to Section IX.A.1.e.

163. Chen discloses cationic agents, such as EUDRAGIT E100. (Ex. 1005 at [0097].)

164. Cationic polymers are cationic agents, and cationic agents attract particulate matter.

d. “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”

165. In my opinion, Chen discloses this element. Refer to Section IX.A.1.f.

166. Cationic agents in Chen’s formulations electrostatically attract “particulate matter.”

167. Chen discloses that its compositions can be “gel, lotion, ... cream, ointment, or other formulation appropriate for local application for the treatment or

prevention of viral infectious diseases.” (Ex. 1005 at [0038].) Thus, Chen discloses a formulation that when applied “electrostatically attracts the particulate matter to the thin film.”

168. The formulation holds particulate matter in place once it is applied, and the adhesion and cohesion of the thin film can be adjusted via varying the concentration of ingredients.

169. In the event that this element is not taught, a POSITA would find it obvious that Chen’s formulations hold the particulate matter and would understand that the thin films of Chen’s compositions have adequate impermeability to prevent the viruses from reaching the skin, tissue, or mucosa of the nasal passages. 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.

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

170. In my opinion, Chen discloses this element. Refer to Section IX.A.1.g.

171. The “at least one ingredient that would render said particulate matter harmless” is the biocidic agent in Section IX.A.1.g.

172. Chen discloses BAC. (Ex. 1005 at [0086].)

173. The ’802 Patent lists BAC as a biocidic agent. (Ex. 1001 10:64-65 and

11:8-9.)

174. Additionally, Chen's Antiviral Compositions 9, 12, and 14 each teach a cationic agent, EUDRAGIT E100, and a biocidal agent, BAC.

175. In my opinion, Chen teaches each element of claim 1 of the '802 Patent and therefore anticipates claim 1 of the '802 Patent.

176. In the event that this element is not expressly taught, a POSITA would understand that Chen's formulations with a biocidal agent inherently inactivate the particulate matter and render the particulate matter harmless.

177. In the event that claim 1 is not found anticipated by Chen, Chen renders claim 1 obvious because all of the claim elements are taught or suggested by Chen and the claimed combination of the elements would be obvious to a POSITA at the Critical Date.

4. Claim 8

- a. "A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:
 - a) at least one biocidal agent, and**
 - b) at least one quaternary thickener."****

178. In my opinion, Chen discloses claim 8.

179. Chen discloses a formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. Refer to

Section IX.A.1.a.

180. Chen discloses “wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film.” Refer to Section IX.A.1.b.

181. Chen discloses “at least one biocidal agent.” Refer to Section IX.A.1.d.

182. Chen discloses cationic polymers for “antiviral compositions” such as “poly(meth)acrylic acid) based copolymers with cationic groups (i.e. ... quaternary amine).” (Ex. 1005 at [0078].)

183. Chen discloses poly(methyl methacrylate-*b*-N-methyl-4-vinyl pyridinium iodide). (*Id.*) This is a polymeric quaternary ammonium compound.

184. Inclusion of this polymer in compositions would increase the thickness of the compositions. Thus, they are quaternary thickeners.

185. In my opinion, Chen teaches each element of claim 8 of the '802 Patent and therefore anticipates claim 8 of the '802 Patent.

186. In the event that claim 8 is not found anticipated by Chen, a POSITA would find it obvious to modify Chen's formulations per Chen's teaching and suggestions to arrive at the formulation of claim 8 and would have a reasonable expectation of success in doing so.

B. Detailed Analysis of Ground 2: Claims 1-3 and 8 of the '802 Patent

Are Anticipated or Rendered Obvious by Baker

1. Claim 2

- a. “A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”**

187. In my opinion, Baker teaches the claimed formulation’s preamble.

188. Baker’s formulation has the same use as the ’802 patent’s formulation: inhibiting infection. Baker teaches reducing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses with various methods and compositions. As discussed above, Baker provides a composition applied to the surface of the skin and mucosal cells and tissues (including nasal mucosa), which may include a cationic agent, which are by definition positively charged. (*Id.* 5:66-67; 7:1-2; 13:24-26; and 36:12-14.)

189. Baker teaches reducing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses with various methods and compositions. As discussed above, Baker provides a composition applied to the surface of the skin and mucosal cells and tissues (including nasal mucosa), which may include a cationic agent, which are by definition positively charged. (*Id.* 5:66-67; 7:1-2; 13:24-26; and 36:12-14.) Baker teaches compositions in various forms, including creams, foams, lotions, and gels. (*Id.* 36:32-33.)

190. In particular, Baker discloses N,N-dimethyl-2-hydroxypropylammonium chloride polymer. (Ex. 1006 7:1-2.)

191. N,N-dimethyl-2-hydroxypropylammonium chloride polymer is a polymeric quaternary ammonium compound.

192. According to the '802 Patent, a polymeric quaternary ammonium compound is a cationic agent. (*E.g.*, Ex. 1001 10:49-51 (claim 3.)).

193. The '802 Patent teaches electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation by an electrostatic field (created by a cationic agent) that is oppositely charged from airborne particles, which are negatively charged. (Ex. 1001 3:32-40.)

194. Baker's compositions, comprising cationic agents, when applied to the skin, mucosal cells, and tissues (including the nasal mucosa), would create an electrostatic field.

195. Because bacteria is negatively charged, Baker's compositions with a cationic agent would attract the bacteria.

196. Since the bacteria is attracted to the cationic agents and held by Baker's composition with a cationic agent, the bacteria would be inhibited from entering and infecting the individual.

197. Therefore, Baker's compositions, placed in or near the nasal passages would "electrostatically inhibit harmful particulate matter from infecting an individual through nasal inhalation," as claimed in claim 2 of the '802 Patent.

b. “wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film”

198. In my opinion, Baker discloses this element.

199. Baker teaches compositions that may be applied, for example, as a topical, including as applied to the nasal passages. (Ex. 1006 36:12-16.) In certain examples, Baker applies the compositions to the nasal passages of mice. (*Id.* 51:15-18).

200. It is common to test compositions for human use on mammals such as mice. In my opinion, a POSITA who has read Baker’s discussion of applying the formulation to the nasal passages of mice would understand that the formulation was designed for application to the skin or tissue of the nasal passages of an individual.

201. Baker teaches compositions in various forms, including creams, foams, lotions, and gels. (*Id.* 36:32-33.) They all have good film forming properties. In addition, Baker also discloses that its “inventive emulsions ... have good film forming/residue properties.” (*Id.* 39:26-36.)

202. Thus, Baker discloses this element.

203. In the event that it were found that this element is not taught, a POSITA would be motivated per Baker’s teachings and suggestions to apply Baker’s creams, foams, lotions, and gels in a thin film in or near nasal passages and would have a reasonable expectation of success in doing so.

c. “said formulation comprising at least one cationic agent and”

204. In my opinion, Baker discloses this element.

205. Baker discloses cationic agents, such as cationic halogen containing compounds, for example cetylpyridinium chloride (CPC). (Ex. 1006 17:5-41) and benzalkonium chloride. (Ex. 1005 17:5-41; 17:24-27; and 25:28-29, 63.)

206. Baker also discloses that the composition may comprise cationic agents which are poly quaternary ammonium compounds, including N,N-dimethyl-2-hydroxypropylammonium chloride polymer. (*Id.* 1006 5:64-7:12 and claim 9.)

d. “at least one biocidic agent”

207. In my opinion, Baker discloses this element.

208. Baker discloses BAC as a quaternary ammonium compound. (Ex. 1006 30:39.) In addition, Baker discloses multiple embodiments with BAC. (*Id.* 25:28-29 and 25:63.)

209. Baker discloses multiple compounds that meet this element, for example, “TWEEN 60 (polyoxyethylenesorbitan monostearate).” (Ex. 1006 16:38.) According to Baker, “TWEEN surfactants [] appear to have virucidal effects on lipid-enveloped viruses.” (Ex. 1006 16:43-46.)

210. Virucidal effects are encompassed in the definition of the capacity of a biocidic agent (having the capacity to neutralize, inactivate, render harmless, or kill airborne particles such as viruses). Refer to Section VII. (“biocidic agent.”)

211. Thus, TWEEN 60 is at least one biocidal agent.

212. Baker also discloses other compounds that are biocidal agents such as phenoxypolyethoxyethanols such as TRITON X-100 (Ex. 1006 16:47-49) and phosphonate-based solvents such as tri-n-butyl phosphate (Ex. 1006 15:55).

213. Baker states that TRITON X-100 is used to “extract lipids and proteins from biological structures.” (*Id.* 16:51-52.) Extracting lipids and proteins from biological structures kills the biological structures.

214. Accordingly, Baker discloses a biocidal agent.

e. **“and wherein said formulation, once applied:
a) electrostatically attracts the particulate matter to
the thin film;”**

215. In my opinion, Baker discloses this element.

216. As discussed above, cationic agents are positive and viruses are negatively charged. The '802 Patent itself states that microorganisms are negatively charged. (Ex. 1001 3:36-37.)

217. A POSITA knows that negatively-charged microbes and microorganisms are attracted to cationic agents via electrostatic attraction.

218. Baker discloses applying a composition with at least one cationic agent, such as poly quaternary ammonium compounds. (Ex. 1006 5:64-7:12.)

219. Therefore, Baker's composition electrostatically attracts particulate matter.

220. Baker discloses that its compositions may be creams, foams, lotion, or gels. (Ex. 1006 36:31-33.) A POSITA would understand that these compositions are applied as a thin film.

221. In my opinion, Baker discloses a formulation that when applied “electrostatically attracts the particulate matter to the thin film.”

222. In the event that it were found that this element is not expressly taught, a POSITA would understand that cationic agents inherently attract negatively-charged particulate matter. Alternatively, a POSITA would be motivated per Baker’s teachings and suggestions to use cationic agents in this manner given Baker’s purpose of “decreasing the infectivity ... associated with a variety of pathogenic organisms and viruses” and would have a reasonable expectation of success in doing so. (Ex. 1006 Abstract.)

f. “b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film”

223. In my opinion, Baker discloses this element.

224. The composition in Baker can take the form of a topical, cream, lotion, or gel and can include emulsifiers, gelling agents, and other components. (Ex. 1006 36:31-34.) A POSITA would understand that these compositions are applied as a thin film.

225. Baker's thin films can include cationic agents such as cationic halogen containing compounds (Ex. 1006 17:5-41) and/or quaternary ammonium compounds (Ex. 1006 5:64-7:12) including N,N-dimethyl-2-hydroxypropylammonium chloride polymer. (*Id.* 7:1-2.)

226. Cationic agents electrostatically attract and hold the particulate matter. Thus, the thin film comprising a cationic agent holds the particulate matter.

227. Baker compositions are in the form of creams, foams, lotions and gels, etc. FIGS. 29A to 29E show 20 different formulations with varying concentrations of ingredients. (Ex. 1006 FIGS. 29A-29E.)

228. For example, Baker discloses formulation ATB_Tween 20 E has 22% DiH₂O and 8% alcohol (FIG. 29E), and formulation ATB-X has 49% DiH₂O (FIG. 29A). Changing the amount of water and adding an alcohol to a composition will adjust the adhesion and cohesion of the composition.

229. 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."

230. Baker therefore teaches varying viscosities, which adjusts the adhesion and cohesion of the formulation to provide adequate impermeability to the thin film.

231. Baker describes that the formulations should form a stable emulsion and also have good filming/residue properties. (Ex. 1006 39:35-36.) For the aqueous carrier, water alone or a miscible mixture of alcohol and water, the alcohol can be used to adjust the viscosity of the compositions. (*Id.* 39:35-42.)

232. In the event that it were found that this element is not expressly taught, a POSITA would understand that that cationic agents inherently attract negatively-charged particulate matter. Alternatively, a POSITA would be motivated to use cationic agents in this manner given Baker's purpose of "decreasing the infectivity ... associated with a variety of pathogenic organisms and viruses" and would have a reasonable expectation of success in doing so (Ex. 1006 Abstract.)

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

233. In my opinion, Baker discloses this element.

234. Baker discloses compositions with at least one biocidal agent, which is noted as having virucidal effects. (Ex. 1006 16: 38-54.)

235. Further, Baker's specification shows evidence that its compositions with these concentrations have "virucidal effectiveness[.]" (*E.g.*, Ex. 1006 67:9-10; *see generally*, 47:60-69:8 (discussing the biocidal activity of various formulations of the compositions disclosed in Baker).)

236. In the event that it were found that this element is not expressly taught, a POSITA would understand that Baker's formulations with virucidal effectiveness

and the ability to disrupt the membranes of target pathogens (*e.g.*, bacteria) inherently inactivate and render the particulate matter harmless. In my opinion, Baker teaches each element of claim 2 of the '802 Patent and therefore anticipates claim 2 of the '802 Patent.

237. In the event that claim 2 is not found anticipated by Baker, Baker renders claim 2 obvious because all of the claim elements are taught or suggested by Baker, and the combination of the elements as taught or suggested by Baker would result in the formulation of claim 2 with a reasonable expectation of success in reaching the formulation as recited in the claim.

2. Claim 3

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

238. In my opinion, Baker discloses this claim. Claim 3 depends from claim 2, and therefore incorporates all of claim 2's elements, and the discussion of claim 2 is incorporated herein by reference.

239. Baker discloses that its composition can comprise N,N-dimethyl-2-hydroxypropylammonium chloride polymer, which is a polymeric quaternary ammonium compound. (Ex. 1006 7:1-2.)

240. In my opinion, Baker teaches each element of claim 3 of the '802 Patent and therefore anticipates claim 3 of the '802 Patent.

241. In the event that claim 3 is not found anticipated by Baker, Baker renders claim 3 obvious because all of the claim elements are taught or suggested by Baker and the claimed combination of the elements would be obvious to a POSITA at the Critical Date.

3. Claim 1

a. **“A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”**

242. In my opinion, Baker discloses this element.

243. Claim 1 is identical to claim 2 except that 1) it claims a method rather than a formulation, 2) it does not include the following additional element: “said formulation comprising at least one cationic agent and at least one biocidal agent,” and 3) parts a, b, and c are method steps, rather than descriptions of the formulation. (See Section VI.)

244. The discussion of claim 2 is incorporated herein.

245. Baker discloses that its composition is used in a method for “decreasing the infectivity ... associated with a variety of pathogens.” (Ex. 1006 2:66-67; *see also* 3:7-16.)

246. Thus, Baker’s method has the same use as the ’802 Patent’s method: inhibiting infection.

247. Baker discloses “[a] method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.” (Section IX.B.1.a.)

b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising”

248. In my opinion, Baker discloses this element. Refer to Section IX.B.1.b.

249. Baker’s composition can be applied, for example, as a topical, and therefore these compositions are applied to the nasal passages. (Ex. 1006 36:12-16.) In certain examples, Baker applies the compositions to the nasal passages of mice. (*Id.* 51:15-18).

250. It is common to test compositions for human use on mammals such as mice. In my opinion, a POSITA who has read Baker’s discussion of applying the formulation to the nasal passages of mice would understand that the formulation was designed to be applied to the nasal passages of an individual.

251. Baker’s composition can be applied as a topical cream, lotion, or gel. (Ex. 1006 36:31-33.)

252. In addition, Baker also discloses that its “inventive emulsions ... have good filming/residue properties.” (*Id.* 39:26-36.)

253. Thus, Baker discloses this element.

254. In the event that it were found that this element is not taught, a POSITA would be motivated per Baker's teachings and suggestions to apply Baker's creams, foams, lotions, and gels in a thin film in or near nasal passages and would have a reasonable expectation of success in doing so.

c. "a) electrostatically attracting the particulate matter to the thin film"

255. In my opinion, Baker discloses this element. Refer to Section IX.B.1.e.

256. As discussed above, Baker's thin film includes a cationic agent, which is positively charged, and creates an electrostatic field.

257. The formulation as applied to the skin or nasal passages of the individual electrostatically attracts the particulate matter to the thin film.

258. In the event that it were found that this element is not expressly taught, a POSITA would understand that cationic agents inherently attract negatively-charged particulate matter. Alternatively, a POSITA would be motivated per Baker's teachings and suggestions to use cationic agents in a formulation in a method for "electrostatically attracting" particulate matter to the thin film given Baker's purpose of "decreasing the infectivity ... associated with a variety of pathogenic organisms and viruses" and would have a reasonable expectation of success in doing so (Ex. 1006 Abstract.)

d. "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”

259. In my opinion, Baker discloses this element. Refer to Section IX.B.1.f.

260. As discussed above, Baker’s formulation holds particulate matter in place once it is applied, and the adhesion and cohesion of the thin film can be adjusted via varying the concentration of ingredients.

261. In the event that it were found that this element is not expressly taught, a POSITA would understand that cationic agents inherently attract negatively-charged particulate matter. Alternatively, a POSITA would be motivated to use cationic agents in a method to “hold[] ... particulate matter” given Baker’s purpose of “decreasing the infectivity ... associated with a variety of pathogenic organisms and viruses” (Ex. 1006 Abstract) (holding particulate matter would prevent inhalation and thus infectivity), and would have a reasonable expectation of success in doing so.

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

262. In my opinion, Baker discloses this element. Refer to Section IX.B.1.g.

263. Baker discloses compositions with at least one biocidal agent, such as TWEEN 60, which is noted as having virucidal effects. (Ex. 1006 16: 38-54.) Baker also discloses BAC. (Ex. 1006 25:28-29.)

264. In the event that it were found that this element is not expressly taught, a POSITA would understand that Baker's formulations with virucidal effectiveness and the ability to disrupt the membranes of target pathogens (*e.g.*, bacteria) inherently inactivate and render the particulate matter harmless.

265. In my opinion, Baker teaches each element of claim 1 of the '802 Patent and therefore anticipates claim 1 of the '802 Patent.

266. In the event that claim 1 is not found anticipated by Baker, Baker renders claim 1 obvious because all of the claim elements are taught or suggested by Baker and the claimed combination of the elements would be obvious to a POSITA at the Critical Date.

4. Claim 8

- a. "A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:
 - a) at least one biocidal agent, and**
 - b) at least one quaternary thickener."****

267. In my opinion, Baker discloses claim 8.

268. Baker discloses "[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation." Refer to Section IX.B.1.a.

269. Baker discloses "wherein the formulation is applied to skin or tissue of

nasal passages of the individual in a thin film.” (Section IX.B.1.b.) Baker discloses “at least one biocidal agent.” (Section IX.B.1.d.)

270. Regarding the quaternary thickener, Baker discloses that its composition can comprise N,N-dimethyl-2-hydroxypropylammonium chloride polymer. (Ex. 1006 7:1-2.) N,N-dimethyl-2-hydroxypropylammonium chloride polymer can have varying viscosities based on its molecular weight.

271. Given that the function of a “quaternary thickener” is to thicken the formulation, it would be obvious for a POSITA to use a high molecular weight N,N-dimethyl-2-hydroxypropylammonium chloride polymer in the composition to thicken the composition.

272. In my opinion, Baker teaches each element of claim 8 of the ’802 Patent and therefore anticipates claim 8 of the ’802 Patent.

273. In the event that claim 8 is not found anticipated by Baker, a POSITA would find it obvious to modify Baker’s formulations per Baker’s teaching and suggestions to arrive at the formulation of claim 8 and would have a reasonable expectation of success in doing so.

C. Detailed Analysis of Ground 3: Claims 1-3 and 8 Are Anticipated

or Rendered Obvious by Wahi '005.

1. Claim 2

- a. “A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”**

274. In my opinion, Wahi '005 discloses this element.

275. Wahi '005 discloses “products for restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage. This prevents or reduces the inflow of airborne contaminants to the nasal passage.” (Ex. 1007 1:21-26.)

276. Therefore, Wahi '005 teaches, like the '802 Patent, formulations to inhibit harmful particulate matter (airborne contaminants) from infecting an individual via inhalation.

277. In the event that this element is not taught, the element is obvious as of the Critical Date because Wahi '005 discloses formulations including electrostatic polymers for the purpose of “restricting the flow of airborne contaminants into a human nasal passage.” (Ex. 1007 Abstract.)

- b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film”**

278. In my opinion, Wahi '005 discloses this element.

279. Wahi '005 discloses that the “nasal application product” may be an ointment, paste, cream, or gel. (Ex. 1007 2:22-26.)

280. The “nasal application product” is applied to skin or tissue of nasal passages of the individual. (Ex. 1007 FIGS. 2-5.)

281. A POSITA would understand that a “nasal application product” is applied to skin or tissue of nasal passages in a thin film.

282. In the event that this element is not taught, the element is obvious as of the Critical Date because Wahi '005 discloses a “product for restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage. This prevents or reduces the inflow of airborne contaminants to the nasal passage.” (Ex. 1007 1:21-26.) It would be obvious to a POSITA to apply a formulation near the nasal passage to create an electrostatic field with a reasonable expectation of success.

c. “said formulation comprising at least one cationic agent and”

283. In my opinion, Wahi '005 discloses this element.

284. Wahi '005 discloses Celquat SC-240C, which “is a polyquaternary [sic] animonium [sic] cellulose.” (Ex. 1007 4:32-33.)

285. In addition, Wahi '005 discloses Agequat 400 which is poly (dimethyl diallyl ammonium chloride). (*Id.* 3:34-35.)

286. Each of these are in Example 4 of Wahi '005.

287. Each of Celquat SC-240C and Agequat 400 is a cationic agent.

d. “at least one biocidic agent”

288. In my opinion, Wahi '005 discloses this element.

289. Some cationic agents may also be biocidic agents, as is acknowledged in the '802 Patent. (Ex. 1001 10:64-67 (BAC is claimed both as a cationic agent and biocidic agent).) Celquat SC-240C and Agequat 400 are cationic agents and biocidic agents. As described in Wahi '005, “Celquat SC-240C is a polyquaternary [sic] animonium [sic] cellulose” (Ex. 1007 4:32-33), and Agequat 400 is “Poly(Dimethyl Diallyl Ammonium Chloride).” (*Id.* 4:25.) Poly(dimethyl diallyl ammonium chloride) is a quaternary ammonium compound.

290. Quaternary ammonium compounds are biocidic as discussed in Section V.A.

291. Wahi '005 discloses numerous biocidic agents, including Celquat SC-240C, Agequat 400 and TWEEN 60. (Ex. 1007 4:47-62.)

292. As I discussed earlier, Baker evidences that it was known that TWEEN 60 can have “virucidal effects” at the Critical Date. (Ex. 1006 16:43-46.) Therefore Wahi 005’s disclosure of TWEEN 60 constitutes a disclosure of a biocidic agent.

**e. “and wherein said formulation, once applied:
a) electrostatically attracts the particulate matter to
the thin film;”**

293. In my opinion, Wahi '005 discloses this element.

294. Wahi '005 discloses compositions with a cationic agent, such as Example 4 with Celquat SC-240C, and Agequat 400 (Ex. 1007 4:32-35.)

295. Further, Wahi '005 discloses a composition which creates an “artificial electrostatic field near the human nose.” (Ex. 1007 5:39-53.)

296. Wahi '005 teaches numerous forms of the nasal composition such as “topical solutions, semisolids, ... vaporizable solutions ... ointments, pastes, creams and gels.” (Ex. 1007 2:22-26.)

297. A POSITA would understand at the Critical Date that the nasal compositions in Wahi '005 would coat the skin, tissue, or mucosa of the nasal passages in a thin film.

298. Wahi '005's thin film with the cationic agent(s) would electrostatically attract the airborne contaminants.

299. In the event that it were found that this element is not expressly taught, a POSITA would understand that Wahi '005's thin film with the cationic agent(s) for restricting the flow of airborne negatively-charged contaminants into a nasal passage inherently creates an electrostatic field of increased charge in an area about the nasal passage. Alternatively, a POSITA would be motivated to use Wahi '005's thin film to electrostatically attract the particulate matter per Wahi's '005's teachings and suggestions and would have a reasonable expectation of success in doing so.

f. “b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to

stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film”

300. In my opinion, Wahi '005 discloses this element.

301. Wahi '005's formulation discloses attracting and holding particulate matter to the thin film because Wahi '005's formulations include a cationic agent, which attracts and holds the particulate matter. (Ex. 1007 2:9-12.) The cationic polymer will continually attract the particulate matter and thus hold the particulate matter in place.

302. The topical compositions in Wahi '005 may be in the form of ointments, pastes, creams, and gels. (*Id.* 2:25-26.)

303. Wahi '005 discloses multiple examples showing different formulations that “vary the concentration of ingredients.” (Ex. 1007 3:45-4:63.)

304. For instance, Example 1 has 5 wt. % of Agequat 400 and Example 4 has 11 wt. %. Agequat is a polymer. (*Id.*)

305. Changing the amount of cationic polymer in a formulation, for example, will change the adhesion and cohesion of a formulation applied as a thin film.

306. 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.”

307. Therefore, Wahi '005 discloses adjusting the adhesion and cohesion of the formulation to provide adequate impermeability to the thin film.

308. In the event that it were found that this element is not expressly taught, a POSITA would understand that Wahi '005 teaches formulations with a cationic agent and that cationic agents inherently attract and hold negatively-charged particulate matter. Alternatively, a POSITA would be motivated to use Wahi '005's formulations in this manner per Wahi's '005's teachings and suggestions and would have a reasonable expectation of success in doing so because Wahi's purpose is restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage, which prevents or reduces the inflow of airborne contaminants to the nasal passage.

g. “c) inactivates the particulate matter and renders said particulate matter harmless.”

309. In my opinion, Wahi '005 discloses this element.

310. As discussed in Section IX.C.1.d, Wahi '005 discloses biocidal agents such as TWEEN 60, Celquat SC-240C, and Agequat 400. By definition, each of these biocidal agents would inactivate and render harmless the particulate matter.

311. In the event that this element is not taught, a POSITA would find it obvious that Wahi's formulations comprising a biocidic agent inactivate and render harmless the particulate matter.

312. In my opinion, Wahi '005 teaches each element of claim 2 of the '802 Patent and therefore anticipates claim 2 of the '802 Patent.

313. In the event that claim 2 is not found anticipated by Wahi '005, Wahi '005 renders claim 2 obvious because all of the claim elements are taught or suggested by Wahi '005 and the claimed combination of the elements would be obvious to a POSITA at the Critical Date.

2. Claim 3

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

314. In my opinion, Wahi '005 discloses this element. Claim 3 depends from claim 2, and the discussion of claim 2 is incorporated herein by reference.

315. Wahi '005 discloses Celquat SC-240C and Agequat 400. (Ex. 1007 4:32-35.) Each of these is a polymeric quaternary ammonium compound.

316. In my opinion, Wahi '005 teaches each element of claim 3 of the '802 Patent and therefore anticipates claim 3 of the '802 Patent.

317. In the event that claim 3 is not found anticipated by Wahi '005, Wahi '005 renders claim 3 obvious because all of the claim elements are taught or

suggested by Wahi '005 and the claimed combination of the elements would be obvious to a POSITA at the Critical Date.

3. Claim 1

a. **“A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”**

318. In my opinion, Wahi '005 discloses this element.

319. Claim 1 is identical to claim 2 except that 1) it claims a method rather than a formulation, 2) it does not include the following additional element: “said formulation comprising at least one cationic agent and at least one biocidal agent,” and 3) parts a, b, and c are method steps, rather than descriptions of the formulation. (See Section VI.)

320. The discussion of claim 2 is incorporated herein.

321. Wahi '005 discloses “products for restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage. This prevents or reduces the inflow of airborne contaminants to the nasal passage.” (Ex. 1007 1:22-26.)

322. Therefore, Wahi '005 teaches, like the '802 Patent, formulations to inhibit harmful particulate matter (airborne contaminants) from infecting an individual via inhalation.

b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:”

323. In my opinion, Wahi '005 discloses this element. Refer to Section IX.C.1.b.

324. Wahi '005 discloses that the “nasal application product” may be an ointment, paste, cream, or gel. (Ex. 1007 2:22-26.)

325. As discussed in Section VIII.C., these formulations are applied to the skin or tissue of nasal passages in a thin film.

326. Thus, Wahi '005 discloses this element.

327. In the event that it were found that this element is not expressly taught, a POSITA would understand that Wahi '005 discloses formulations with a cationic agent for restricting the flow of airborne negatively-charged contaminants into a nasal passage inherently creates an electrostatic field of increased charge in an area about the nasal passage, which prevents or reduces the inflow of airborne contaminants to the nasal passage. Alternatively, a POSITA would understand that Wahi '005 teaches or suggests that the formulations are applied in a thin film in or near nasal passages and would have a reasonable expectation of success in doing so.

c. “a) electrostatically attracting the particulate matter to the thin film”

328. Wahi '005 discloses this element. Refer to Section IX.C.1.e.

329. Wahi '005 discloses a nasal topical application product for creating an

“artificial electrostatic field near the human nose.” (Ex. 1007 5:39-53.)

330. Wahi '005 teaches numerous forms of the nasal composition such as “topical solutions, semisolids, ... vaporizable solutions ... ointments, pastes, creams and gels.” (Ex. 1007 2:22-26.)

331. A POSITA would understand at the Critical Date that the nasal compositions in Wahi '005 would coat the skin, tissue, or mucosa of the nasal passages with a thin film.

332. Wahi '005's thin film with the cationic agent(s) would electrostatically attract the airborne contaminants.

333. In the event that it were found that this element is not expressly taught, a POSITA would understand that cationic agent(s) in the thin film inherently electrostatically attract the airborne contaminants. Alternatively, a POSITA would be motivated to use cationic agents in a thin film for restricting the flow of airborne negatively-charged contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage, which prevents or reduces the inflow of airborne contaminants to the nasal passage per Wahi's '005's teachings and suggestions, and would have a reasonable expectation of success in doing so.

- d. **“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”**

334. In my opinion, Wahi '005 discloses this element. Refer to Section IX.C.1.f.

335. Wahi '005's formulation discloses attracting and holding particulate matter to the thin film because Wahi '005's formulations include a cationic agent, which attracts and holds the particulate matter. (Ex. 1007 2:9-12.)

336. The topical compositions in Wahi '005 may be in the form of ointments, pastes, creams, and gels. (*Id.* 2:25-26.)

337. Wahi '005 discloses multiple examples showing different formulations that “vary the concentration of ingredients.” (Ex. 1007 3:45-4:63.)

338. For instance, Example 1 has 5 wt. % of Agequat 400 and Example 4 has 11 wt. %. Agequat is a polymer. (*Id.*)

339. Changing the amount of cationic polymer in a formulation, for example, will change the adhesion and cohesion of a formulation applied in a thin film.

340. 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.”

341. Therefore, Wahi '005 discloses adjusting the adhesion and cohesion of the formulation to provide adequate impermeability to the thin film.

342. In the event that it were found that this element is not expressly taught, a POSITA would understand that Wahi '005 teaches formulations with a cationic agent and that cationic agents inherently attract and hold negatively-charged particulate matter. Alternatively, a POSITA would be motivated to use Wahi '005's formulations in this manner per Wahi's '005's teachings and suggestions because Wahi's purpose is restricting the flow of airborne negatively-charged contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage, which prevents or reduces the inflow of airborne contaminants to the nasal passage and would have a reasonable expectation of success in doing so.

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

343. In my opinion, Wahi '005 discloses this element. Refer to Section IX.C.1.g.

344. Wahi '005 discloses biocidal agents such as TWEEN 60, Celquat SC-240C, and Agequat 400. By definition, each of these biocidal agents would inactivate and render harmless the particulate matter.

345. In the event that this element is not taught, a POSITA would find it obvious that Wahi's formulations comprising a biocidal agent inactivate and render harmless the particulate matter.

346. In my opinion, Wahi '005 teaches each element of claim 1 of the '802 Patent and therefore anticipates claim 1 of the '802 Patent.

347. In the event that claim 1 is not found anticipated by Wahi '005, Wahi '005 renders claim 1 obvious because all of the claim elements are taught or suggested by Wahi '005 and the claimed combination of the elements would be obvious to a POSITA at the Critical Date.

4. Claim 8

- a. **“A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:
a) at least one biocidal agent, and
b) at least one quaternary thickener.”**

348. In my opinion, Wahi '005 discloses claim 8.

349. Wahi '005 discloses “[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. Refer to Section IX.C.1.a.

350. Wahi '005 discloses “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film.” (Section IX.C.1.b.)

351. Wahi '005 discloses “at least one biocidal agent,” TWEEN 60. (Section IX.C.1.d.)

352. Wahi '005 discloses Celquat SC-240C, which is a “polyquaternary [sic] anionium [sic] cellulose.” (Ex. 1007 4:32-33.)

353. Wahi '005 states that the formulation “thickens” after the addition of Celquat SC-240C. (*Id.* 5:1-7.) Thus, Celquat SC-240C is a quaternary thickener.

354. In my opinion, Wahi '005 teaches each element of claim 8 of the '802 Patent and therefore anticipates claim 8 of the '802 Patent.

355. In the event that claim 8 is not found anticipated by Wahi '005, a POSITA would find it obvious to modify Wahi '005's formulations per Wahi '005's teaching and suggestions to arrive at the formulation of claim 8 and would have a reasonable expectation of success in doing so.

D. Detailed Analysis of Ground 4: Claims 1, 2 and 8 Are Anticipated or Rendered Obvious by Rolf.

1. Claim 2

a. “A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”

356. In my opinion, Rolf discloses this element.

357. Rolf addresses the problem of how to prevent respiratory infection. (Ex. 1006 Abstract).

358. Rolf teaches a device with an ointment or gel on a backing, which may

be applied “in the vicinity of the nasal passageway.” (Ex. 1008 at FIG. 9; [0018]; [0021]; and [0042].) Therefore Rolf is teaching inhibiting harmful particulate matter from infecting an individual via inhalation.

359. Rolf discloses a formulation comprising a cationic agent – including quat-15. (Ex. 1008 at [0148].)

360. As discussed earlier, cationic agents electrostatically attract particulate matter, electrostatically inhibiting particulate matter from nasal inhalation, when placed in or near nasal passages.

361. Rolf further states that its composition includes an essential oil that may be used in a method of “contacting a live respiratory pathogen with a therapeutically effective amount of an essential oil, such that the live respiratory pathogen is inactivated upon contact with the essential oil.” (Ex. 1008 at [0024].)

362. Because Rolf’s composition inactivates the respiratory pathogen upon contact with the essential oil in the composition, the composition inhibits “harmful particulate matter from infecting an individual.”

363. In the event that this element is not taught, the element is obvious as of the Critical Date because Rolf discloses formulations of cationic agents for the purpose of “contacting a live respiratory pathogen with a therapeutically effective amount of an essential oil, such that the live respiratory pathogen is inactivated upon contact with the essential oil.” (Ex. 1008 at [0024].)

b. “wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film”

364. In my opinion, Rolf discloses this element.

365. Rolf discloses that “[t]he adhesive patch 1 includes a formulation 5 located on ... the front side 3 of the backing 2” (Ex. 1008 at [0045].)

366. Rolf further states that the “[t]he backing 2 is define[d] by a front side 3 (the side exposed to the skin during use) (*Id.* at [0047].)

367. Rolf discloses that adhesive skin patch 1, which includes formulation 5, “can be applied to the region between the upper lip and the nose of a patient.” (*Id.* at [0147].)

368. Therefore, the formulation 5 is applied to front side 3, and front side 3 is exposed to the skin during use, therefore the formulation is applied to the skin or tissue of the nasal passages, including the area around the nasal passages. A POSITA would understand that these formulations are applied in a thin film.

369. In the event that this element is not taught, the element is obvious as of the Critical Date because Rolf discloses a thin film applied to the skin or tissue of the nasal passages for the purpose of “contacting a live respiratory pathogen [which] ... is inactivated upon contact.” (Ex. 1008 at [0024].)

c. “said formulation comprising at least one cationic agent and”

370. In my opinion, Rolf discloses this element.

371. Rolf discloses a formulation comprising a cationic agent such as quat-15. (Ex. 1008 ¶¶ [0148], [0268]-[0283].)

d. “at least one biocidic agent”

372. In my opinion, Rolf discloses this element.

373. Rolf’s formulations include essential oils. For example, formulation 5 comprises essential oil 15. (*Id.* at [0065].)

374. Rolf discloses essential oils to deactivate “live respiratory pathogens.” (*Id.* at [0020].)

375. For example, Rolf discloses eucalyptus oil and states that it can “kill[] or inactivate[] an airborne pathogen[] [or] a respiratory tract pathogen. (*Id.* at [0071] (kill or inactivate) and [0073] (listing eucalyptus oil.) Therefore, eucalyptus oil is a biocidic agent because it can deactivate viruses.

376. Virucidal effects are encompassed in the definition of the capacity of a biocidic agent (having the capacity to neutralize, inactive, render harmless, or kill airborne particles such as viruses). Refer to Section VII. (“biocidic agent.”)

**e. “and wherein said formulation, once applied:
a) electrostatically attracts the particulate matter to the thin film;”**

377. In my opinion, Rolf discloses this element.

378. As discussed above, Rolf discloses applying a composition with at least one cationic agent, such as quat-15 (Ex. 1008 at [0148]), which electrostatically attracts the particulate matter.

379. As discussed in Section IX.D.1.b., when Rolf's formulation 5 is applied to skin, it is applied in a thin film.

380. Therefore, in my opinion, Rolf discloses a formulation that when applied "electrostatically attracts the particulate matter to the thin film."

381. In the event that it were found that this element is not expressly taught, a POSITA would understand that Rolf's thin film with the cationic agent(s) "contact[s] a live respiratory pathogen [which] ... is inactivated upon contact" and inherently electrostatically attracts the particulate matter. (Ex. 1008 at [0024].) Alternatively, a POSITA would be motivated per Rolf's teachings and suggestions to use Rolf's thin film to electrostatically attract the particulate matter and would have a reasonable expectation of success in doing so.

- f. "b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film"**

382. In my opinion, Rolf discloses this element.

383. Rolf's formulation, which includes cationic agents such as quat-15, discloses holding particulate matter to the thin film.

384. Rolf's formulation can be an ointment or a gel. (Ex. 1008 at [0041].)

385. As discussed earlier, an ointment or gel can be applied to the skin or tissue and sticks to the skin or tissue in a thin film.

386. 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."

387. Rolf's thin films can comprise cationic agents such as quat-15, which will then attract and hold the particulate matter in the thin film. (*Id.* at [0148].)

388. Rolf discloses several forms of compositions, including ointments and gels, which are known to have varying viscosities. (*Id.* at [0042].) As discussed in Section VII. ¶ 76, modifying viscosities allows adjustment to the adhesion and cohesion of the formulation to provide adequate impermeability to the thin film.

389. Rolf discloses 16 examples that "vary[] the concentration of ingredients," and "thereby adjust[] the adhesion and cohesion of the thin film." (Ex. 1008 at [0268]-[0283].)

390. Each of the examples states that the formulation may comprise a percentage range of an ingredient and then lists a "typical" (*i.e.*, preferred) percentage.

391. For instance, Example 6 in paragraph [0273] has a range percentage of 10% to 50% polyvinyl alcohol; Example 8 in paragraph [0275] has a range percentage of 10% to 40%.

392. In my opinion, varying the concentration of polyvinyl alcohol in a formulation by up to 40% will adjust the adhesion and cohesion of the thin film.

393. Therefore, Rolf teaches this element.

394. In the event that it were found that this element is not expressly taught, a POSITA would understand that Rolf's formulations with a cationic agent inherently attract and hold negatively-charged particulate matter. Alternatively, a POSITA would be motivated to use Rolf's formulations in this manner because Rolf's purpose is "contacting a live respiratory pathogen [which] ... is inactivated upon contact" and would have a reasonable expectation of success in doing so. (Ex. 1008 at [0024].)

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

395. In my opinion, Rolf discloses this element.

396. Rolf discloses compounds to deactivate virus cells by membrane disruption, such as essential oils. (Ex. 1008 at [0070]-[0073] and [0020].)

397. Rolf discloses that the formulations comprise essential oil in any suitable amount, and specifically, an amount of essential oil to "effectively kill[] or inactivate[] an airborne pathogen, respiratory tract pathogen, or a combination

thereof).” (Ex. 1008 at [0076]-[0077].)

398. In the event that this element is not taught, a POSITA would find it obvious that Rolf’s formulations comprising a biocidal agent inactivate and render harmless the particulate matter.

399. In my opinion, Rolf teaches each element of claim 2 of the ’802 Patent and therefore anticipates claim 2 of the ’802 Patent.

400. In the event that claim 2 is not found anticipated by Rolf, Rolf renders claim 2 obvious because all of the claim elements are taught or suggested by Rolf and the claimed combination of the elements would be obvious to a POSITA at the Critical Date.

2. Claim 1

a. “A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation”

401. In my opinion, Rolf discloses this element.

402. Claim 1 is identical to claim 2 except that 1) it claims a method rather than a formulation, 2) it does not include the following additional element: “said formulation comprising at least one cationic agent and at least one biocidal agent,” and 3) parts a, b, and c are method steps, rather than descriptions of the formulation. (See Section VI.)

403. The discussion of claim 2 is incorporated herein.

404. Rolf discloses a formulation that performs all the steps required by claim 2. (Section IX.D.1.)

405. Rolf discloses a gel or ointment. (Ex. 1008 at [0042].)

406. Rolf discloses that the composition is used in “a method for inhibiting a respiratory pathogen.” (*Id.* at [0024].) *See also* Section IX.D.1.a.

b. “wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:”

407. In my opinion, Rolf discloses this element. Refer to Sections IX.D.1.b.

408. Rolf discloses, for example, that the formulation 5 is applied to front side 3, and front side 3 is “exposed to the skin during use.” (Ex. 1008 at [0045]-[0047].)

409. The front side 3 is applied to the skin during use. (*Id.* at [0047].) Therefore formulation 5 is located on the skin.

410. As discussed in Section VIII.D., Rolf’s ointments or gels, when applied to skin or tissue, will be on the skin in a thin film.

411. In the event that it were found that this element is not taught, a POSITA would be motivated to use the thin film of Rolf’s formulations for application to the skin or tissue of the nasal passages for the purpose of “contacting a live respiratory pathogen [which]... is inactivated upon contact” per Rolf’s teachings and

suggestions and would have a reasonable expectation of success in doing so. (Ex. 1008 at [0024].)

c. “a) electrostatically attracting the particulate matter to the thin film”

412. In my opinion, Rolf discloses this element. Refer to Section IX.D.1.e.

413. Rolf discloses a thin film of a formulation including at least one cationic agent. (Ex. 1008 at [0148].)

414. The cationic agent would electrostatically attract the particulate matter, as discussed in Section IX.D.1.e.

415. In the event that it were found that this element is not expressly taught, a POSITA would understand that Rolf’s thin film with the cationic agent(s) for the purpose of “contacting a live respiratory pathogen [which]... is inactivated upon contact” would inherently electrostatically attract the particulate matter. (Ex. 1008 at [0024].) Alternatively, a POSITA would be motivated to use Rolf’s thin film to electrostatically attract the particulate matter per Rolf’s teachings and suggestions and would have a reasonable expectation of success in doing so.

d. “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”

416. In my opinion, Rolf discloses this element. Refer to Section IX.D.1.f.

417. Rolf’s formulation with a cationic agent holds the particulate matter in

the thin film, and the adhesion and cohesion of the thin film can be adjusted via varying the concentration of ingredients.

418. In the event that it were found that this element is not expressly taught, a POSITA would understand that Rolf's formulations with a cationic agents inherently attract and hold negatively-charged particulate matter. Alternatively, a POSITA would be motivated to use Rolf's formulations in this manner because Rolf's purpose is "contacting a live respiratory pathogen [which]... is inactivated upon contact" and would have a reasonable expectation of success in doing so. (Ex. 1008 at [0024].)

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

419. In my opinion, Rolf discloses this element. Refer to Section IX.D.1.g.

420. The "at least one ingredient that would render said particulate matter harmless" is the essential oil, which is a biocidal agent in Section IX.D.1.d.

421. In the event that this element is not taught, a POSITA would find it obvious that Rolf's formulations comprising a biocidal agent inactivate and render harmless the particulate matter.

422. In my opinion, Rolf teaches each element of claim 1 of the '802 Patent and therefore anticipates claim 1 of the '802 Patent.

423. In the event that claim 1 is not found anticipated by Rolf, Rolf renders claim 1 obvious because all of the claim elements are taught or suggested by Rolf and the claimed combination of the elements would be obvious to a POSITA at the Critical Date.

3. Claim 8

- a. **“A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:

a) at least one biocidal agent, and

b) at least one quaternary thickener.”**

424. In my opinion, Rolf discloses this claim.

425. Rolf discloses “[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.” Refer to Section IX.D.1.a.

426. Rolf discloses “wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film.” Refer to Section IX.D.1.b.

427. Rolf discloses “at least one biocidal agent.” Refer to Section IX.D.1.d.

428. In regard to the quaternary thickener, Rolf discloses quat-15. (Ex. 1008 at [0148].) Thus, Rolf discloses a quaternary thickener.

429. In my opinion, Rolf teaches each element of claim 8 of the '802 Patent and therefore anticipates claim 8 of the '802 Patent.

430. In the event that claim 8 is not found anticipated by Rolf, a POSITA would find it obvious to modify Rolf's formulations per Rolf's teaching and suggestions to arrive at the formulation of claim 8 and would have a reasonable expectation of success in doing so.

E. Detailed Analysis of Ground 5: Claims 3 is Rendered Obvious by Rolf in view of Wahi '005.

1. Claim 3

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

431. In my opinion, Rolf in view of Wahi '005 discloses this claim.

432. Claim 3 depends from claim 2, and therefore incorporates all of claim 2's elements, and the discussion of claim 2 is incorporated herein by reference. (Section IX.D.1.)

433. Rolf's formulations may include a cationic agent, for example quat-15. (Ex. 1008 at [0148].)

434. Wahi '005 discloses Celquat SC-240C, which is a polymeric quaternary ammonium compound. (Ex. 1007 4:46-63.).

435. Wahi '005 states that "Celquat SC-240C is a polyquaternary [sic] ammonium [sic] cellulose." (*Id.* 6:31.)

436. Celquat SC-240C is also known as polyquaternium-10. (Ex. 1021.)

437. A POSITA would have been motivated to combine Rolf with Wahi

'005 because they are both directed to methods of preventing respiratory infection via the function of the compositions and would have a reasonable expectation of success in doing so. (Ex. 1008 at [0020] and Ex. 1007 at Abstract.)

438. Further, Rolf discloses quaternary ammonium compounds, and in fact, prefers quat-15. (Ex. 1008. at [0148].)

439. A POSITA would find it obvious to modify Rolf with a different quaternary ammonium compound: Celquat SC-240C as taught in Wahi '005.

440. In my opinion, a POSITA would find claim 3 of the '802 Patent obvious over Rolf in view of Wahi '005.

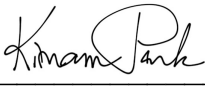
X. JURAT

441. I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in this case and that said cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

442. I hereby declare that all statements made in this Declaration of my own knowledge are true, that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful

false statements and the like are punishable by fine or imprisonment, or both, under
Section 1001 of Title 18 of the United States Code.

Dated: March 13, 2024

By: 
Kinam Park, Ph.D.