

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SALVACION USA, INC.,
Petitioner,

v.

TRUTEK CORP.,
Patent Owner.

IPR2024-00711
Patent 8,163,802

Record of Oral Hearing
Held: September 8, 2025

Before: ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and
SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

APPEARANCES:

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The above-entitled matter came on for hearing on September 8, 2025,
commencing at 1:00 p.m., via video teleconference.

P R O C E E D I N G S

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JUDGE MITCHELL: So, good afternoon, everyone. We have a final hearing this afternoon in IPR2024-00711. I am Judge Mitchell, and with me by video conference are Judges Snedden and Jenks. And also of course, we have Patent Owner's Counsel by video conference as well. So I did want to acknowledge -- oh, I'm sorry. Oh, I thought you had something to say. I did want to acknowledge Patent Owner's request for leave to submit supplemental information. And we will issue an order after this hearing addressing that request. So first, I would like to get appearances for the parties on the record. So who do we have for Petitioners?

MR. OLDACH: Thank you, Your Honor. This is William Oldach. William, lead Counsel for Petitioner Salvacion USA, Inc. With me are backup Counsel Maryellen Feury Hank, who will be doing a portion of the argument today.

JUDGE MITCHELL: Okay.

MR. OLDACH: And our other backup Counsel, Bradley Hough, who is manning our tech station this afternoon.

JUDGE MITCHELL: Great. Thank you and welcome. And who do we have for Patent Owner?

MR. KREMEN: Stanley Kremen, lead Counsel for the Patent Owner Trutek Corp.

JUDGE MITCHELL: Great. Thank you and welcome. So, as set forth in our oral hearing order, each side has 60 minutes to present its case. So just a reminder to assist us in following along with your argument here

1 today. And for the clarity of the record, it is important that if you refer to an
2 exhibit, that you state the exhibit and page number to which you're referring.
3 And when you're referring to a demonstrative, that you state the slide
4 number. Petitioner will present its arguments first as it bears the burden of
5 showing unpatentability of the challenge claims. Petitioner, would you like
6 to reserve any time for rebuttal?

7 MR. OLDACH: Thank you, Your Honor. We would like to
8 reserve 10 minutes.

9 JUDGE MITCHELL: Ten minutes? Great. And Patent Owner,
10 would you like -- you will have the last word certainly, if you wish. And
11 would you like to reserve any of your time?

12 MR. KREMEN: Yes. I would also like to reserve 10 minutes.

13 JUDGE MITCHELL: Great. Thank you. So with that, Petitioner,
14 you may begin when you're ready.

15 MR. OLDACH: Thank you, Your Honor. Again, William
16 Oldach, Counsel for Petitioner Salvacion USA. First, Your Honor, we did
17 bring additional hard copies of both parties' slides if Your Honor would care
18 to have --

19 JUDGE MITCHELL: I would --

20 MR. OLDACH: -- copy.

21 JUDGE MITCHELL: -- like hard copies. I'm still old school, so
22 that would be great. Thank you.

23 UNKNOWN SPEAKER: I think that's the marked up copy for
24 (INDISCERNIBLE).

25 JUDGE MITCHELL: Sorry.

1 UNKNOWN SPEAKER: There you go. Sorry about that.

2 JUDGE MITCHELL: Thank you. Awesome. Thank you. Well,
3 just one moment. I'm sorry. I'm going to set your time. When you're ready.

4 MR. OLDACH: Thank you. So again, lead Counsel here for
5 Petitioner Salvacion USA. Mr. Hough, if you would put up Slide 2, we have
6 an overview of our argument today. I will be going through outline items A
7 through F, the claim construction, our anticipation grounds, and the motions
8 to strike and exclude. Ms. Hank will then be covering the obviousness
9 grounds, including the Rolf in view of Wahi and then the other references.
10 And she will also address the -- while I will address the motion to strike or
11 exclude the evidence, Ms. Hank will address the evidence for its own weight
12 in the context of the obviousness grounds.

13 So at the outset I want to direct the panel's attention to a passage in
14 the '802 Patent that I don't think has been fully appreciated. And I'm going
15 to be reading from the bottom of column 1 of the '802 Patent starting at line
16 62 where it reads, "The present invention also relates to antiviral,
17 antibacterial, and antimicrobial products and methods that involve the use of
18 products heretofore developed for restricting the flow of airborne
19 contaminants into the nasal passages by creating an electrostatic field." And
20 the term heretofore means before this point in time or previously. In other
21 words, it seems to be an admission that the type of compositions disclosed
22 and claimed in the '802 Patent pre-existed the patent and as set forth in our
23 anticipation grounds, we think that is exactly right.

24 Now to be clear, we are not arguing in the petition or today that
25 any of these compositions comprise applicant admitted prior art, a concept

1 that has gotten a lot of recent attention. Our grounds are based on the prior
2 art patents that we have cited. But I think it gives a framework to
3 understand why so many of the Patent Owner's positions in this proceeding
4 seem to come from a view that appreciating properties that are inherent to
5 one degree or another in these prior art compositions amount to a novel or a
6 non-obvious invention.

7 Turning to the claim construction, I want to address the level of
8 ordinary skill in the art which, as the Board stated in the institution decision
9 and as Dr. Park has testified and in fact Patent Owner I don't believe has
10 specifically contested the level of ordinary skill in the art, which is again
11 from Dr. Park's declaration Exhibit 1002 at paragraphs 38 and 39. It's an
12 undergraduate degree in pharmacy, chemistry, biochemistry, biomedical
13 engineering, or a closely related field such that the POSITA generally
14 understands pharmaceutical formulation. Now the Patent Owner has
15 specifically stated at page 4 of its response that it does not challenge Dr.
16 Park's statements on the qualifications of a POSITA, but that it challenges
17 Dr. Park's ability to assess the technology from that point of view. Now as
18 we set out in our reply, Federal Circuit case law such as the Norgren and the
19 Endress+Hauser cases specifically rejects that sort of argument. But I think
20 it speaks to an issue that underlies a lot of the positions that Patent Owner
21 has taken with respect to issues such as inherency and the recognition of
22 properties that we'll be discussing this afternoon.

23 What we don't have in the record of this proceeding is any
24 evidence regarding the level of skill of Trutek's named inventor Mr. Wahi
25 according to the unrebutted definition that Dr. Park has testified to. And I

1 think that may explain how it is that a POSITA, in whose shoes Dr. Park can
2 put himself, would recognize the properties that are inherent in the prior art
3 references that form the basis of the grounds in the petitions. Whereas a
4 person such as Mr. Wahi, whose POSITA status is not established, might
5 find them novel and non-obvious.

6 So turning to the specific claim construction issues that are -- if
7 you would like to go to our Slide number 4 where the header is the, "Patent
8 Owner does not challenge Petitioners claim construction," this is what
9 Patent Owner stated at page 2 of its sur-reply paper 13. However, with
10 respect to a couple of terms such as adequate impermeability, we see that
11 this is not quite correct. I'd like to have Mr. Hough go ahead to Slide
12 number 10 where we are citing Exhibit 1010, the Michigan claim
13 construction ruling. And there, as we have argued, the Board should apply
14 the construction used by the district court in the Michigan litigation. And
15 that was a construction that was proposed by Patent Owner in that litigation,
16 which that court adopted and which we have proposed here, in which the
17 Board largely applied in the institution decision, namely that there is
18 sufficient cohesion to inhibit harmful particles from penetrating the thin film
19 and contacting the skin or tissue to which it is applied.

20 Now, the use of the term inhibit is significant here. And this goes
21 back to something that Patent Owner had pointed out in pages 8 and 9 of its
22 Patent Owner preliminary response. The claims of the '802 Patent as
23 originally filed read, "a method for electrostatically preventing harmful
24 particulate matter from infecting an individual." But the language was
25 amended to "electrostatically inhibiting." And Patent Owner directly states

1 at page 9 of its preliminary response that this change allowed for a few
2 active particles to be inhaled by the individual.

3 So when we apply the claim construction for adequate
4 impermeability that the Board used in its institution decision at page 9,
5 which is similar to what we proposed here and that Patent Owner proposed
6 in the Michigan litigation, adequate impermeability requires sufficient
7 cohesion of the formulation to inhibit, not to prevent, but to inhibit harmful
8 particles from penetrating the thin film and contacting the skin or tissue on
9 which the film is applied.

10 Mr. Hough would go back one to Slide 9. Now here we're quoting,
11 however, from Patent Owner's sur-reply at page 10, where Patent Owner
12 states that "the cohesion of the formulation is adjusted to have adequate
13 impermeability so that the harmful particles will have no contact with the
14 skin or tissue of the nasal passages." And this is not a correct application of
15 the Board's claim construction, which only requires contact to be inhibited,
16 not prevented, just as Patent Owner stated in its preliminary response.

17 Now, if we go back up to Slide 10, it's also significant that the
18 court in the Michigan litigation said, as we quote here from Exhibit 1010,
19 that adequate impermeability "is an expression of the qualities inherent in
20 the thin film." And in fact, the Board, Your Honors, at page 10 of your
21 institution decision stated, "It is reasonable to consider the recited
22 impermeability is a function of the cohesive properties of the thin film and
23 that such impermeability refers to a property of the thin film." But Patent
24 Owner also seems to be adding a limitation to the claim element when it
25 advances the concept of a purposeful adjustment. This is the other claim

1 term we want to emphasize.

2 If Mr. Hough would go back to our Slide 8. And looking at Slide
3 8, Patent Owner has asserted in its sur-reply at page 7 that the electrostatic
4 attraction limitation A in Claims 1 and 2 requires, quote, "a purposeful
5 adjustment of the electrostatic field," which is language that does not appear
6 anywhere in the claims. The adjustment term that is in the claims of the
7 patent by its terms applies to the adhesion and cohesion of the formulation,
8 not directly to the electrostatic field. So Patent Owner then seems to be
9 using the term purposeful adjustment to imply that the prior art would have
10 to recognize the impermeability property in order to satisfy the claim. But
11 that is not the law of inherency for anticipation, as we have set out in our
12 briefing. We have several references in our reply brief in pages 11 through
13 20, for example, including the King Pharmaceuticals case and the Bristol-
14 Myers Squibb case.

15 So as we'll discuss in more detail with particular grounds, Dr. Park
16 has testified that each of the prior art references discloses formulations that
17 inherently possess this property, and that testimony has gone un rebutted.
18 There is no evidence in the form of cross examination of Dr. Park or
19 countervailing testimony as to these points.

20 To that end, I'd like to ask Mr. Hough to put up Patent Owner's
21 Slide 21, which is captioned as, "the '802 versus patent versus Wahi '005."
22 And the last bullet point there reads, "Implementation requires inventor
23 awareness of the problem." That is simply not the law of inherency as it
24 applies to anticipation as we have cited the numerous cases in our reply brief
25 at pages 11 to 20. With that -- is somebody I don't know that meant --

1 JUDGE MITCHELL: Yeah --

2 MR. OLDACH: -- somebody is lost.

3 JUDGE MITCHELL: -- let me pause you because I think I might
4 have lost Judge Snedden. Hang on. Have we lost Judge Snedden?

5 UNKNOWN SPEAKER: (INDISCERNIBLE - TECHNICAL
6 DIFFICULTY) --

7 JUDGE MITCHELL: Okay. Sorry about that. Yeah. He is
8 calling back in.

9 JUDGE SNEDDEN: I'm back.

10 JUDGE MITCHELL: Great. Thank you.

11 JUDGE SNEDDEN: Thank you.

12 MR. OLDACH: Ready?

13 JUDGE MITCHELL: Sorry for interrupting. Yes.

14 MR. OLDACH: Okay.

15 JUDGE MITCHELL: When you're ready.

16 MR. OLDACH: Thank you, Your Honor. So now I'd like to
17 proceed to discuss the grounds, specific grounds that we've asserted.

18 MR. HOUGH: Sorry.

19 MR. OLDACH: It's not Slide 14, Mr. Hough. Please put up Slide
20 13. So in Slide 13, we have broken down the elements of Claim 2, which
21 again, we have used as the base claim to begin our analysis of the grounds
22 for patent invalidity. And we have them broken down into elements A
23 through G. We do include in our elements the portions of the preamble.
24 The Board in the institution decision did determine in this case that the
25 preamble was limiting. We do not necessarily concede that point, but we

1 certainly have analyzed all the claims with the eye toward the preamble
2 potentially being limiting. And so we have found where the prior art does
3 disclose all of the elements. So we have the elements A through G.

4 So, moving ahead to Slide 14, where we're first looking at the
5 Chen reference. Chen does disclose the preamble because the composition
6 is applied to the skin or nasal membrane as set forth in Chen paragraph 44,
7 and the composition includes cationic polymers such as those listed in Chen
8 paragraph 78. And Dr. Park addresses this at paragraphs 108 to 112 of his
9 declaration.

10 Moving ahead to Slide 15, Chen discloses element 2[b], the second
11 part of the preamble. Chen states that it is applied to the skin or nasal
12 membrane. And Chen paragraph 111 states that the composition may be in
13 the form of a lotion, cream, gel, et cetera. Chen discloses that it provides a
14 physical barrier. And Dr. Park has testified that compositions in the forms
15 of lotions, creams, and gels, when applied, would form a thin film, such as at
16 paragraph 115 of his declaration, which we cite there at Slide 15.

17 Moving ahead to Slide 16, we see that Chen discloses cationic
18 agents at paragraph 78, and the Patent Owner has conceded this in its sur-
19 reply at page 16. Moving ahead to Slide 17, similarly, Chen discloses
20 biocidal agents at paragraph 86. And similarly, Patent Owner has conceded
21 this again in the sur-reply at page 16. Moving ahead to Slide 18, as we've
22 established, the formulation does include a cationic agent which, as Dr. Park
23 has testified, electrostatically attracts negatively charged bacteria and
24 viruses. Dr. Park has said this at paragraphs 134, 111 -- oh, it's going to be
25 111 and 44 from Chen.

1 Moving ahead to Slide 19, it is disclosed that Chen will hold the
2 particulate matter in place. And the key to this, as we cited to Dr. Park's
3 declaration in Slide 19, is paragraph 134 of Dr. Park's declaration, where he
4 states that Chen discloses different formulations with varying concentrations
5 of the cationic ingredients and states that, quote, "changing the amount of
6 cationic polymer will change the adhesion and cohesion of the formulation."
7 And then the next sentence, quote, "cationic agents attract particulate matter
8 and hold particulate matter in place," unquote. Again, this is unrebutted
9 expert testimony from Dr. Park. If we move ahead to Slide 21, Chen -- for
10 element G, Chen clearly discloses a germicide such as BAC, and the Patent
11 Owner concedes that this is a biocidic agent.

12 And moving ahead to Slide 23. So we've now established -- I'm
13 sorry. Go back to Slide 22, please. So through that walkthrough, we see
14 that Petitioner has established that Chen anticipates Claim 2. The next slide,
15 Slide 23, addressing Claim 3. This is the dependent claim on Claim 2, and
16 it's a formulation of Claim 2 wherein the at least one cationic agent is a
17 polymeric quaternary ammonium compound. And in paragraph 78 of Chen,
18 as Dr. Park testifies at paragraph 149, we have highlighted a few of the
19 products here, including Eudragit, that he confirms is a polymeric quaternary
20 ammonium compound. Therefore, Claim 3 is anticipated by Chen.

21 So if we go ahead to the next Slide 24, and we're looking at Claim
22 1, when we compare Claim 1 to Claim 2, we see that Claim 1 is essentially
23 identical to Claim 2, but is expressing the product -- the use of the product in
24 a method claim. And it merely omits the requirement that there be the
25 cationic agent and the biocidic agent. But otherwise, the claim language

1 tracks such that Claim 1 is basically Claim 2 in method form. And as we
2 know, a prior art patent disclosing a product anticipates the method claim
3 when that product is used as intended. That is set out in MPEP 2112.02.
4 The quote from there is, "Under the principles of inherency, if a prior art
5 device in its normal and usual operation would necessarily perform the
6 method claimed, then the method claimed will be considered to be
7 anticipated by the prior art device." And there are several cases I believe we
8 cited in our brief. But a host of cases going back to, I think, In re King in
9 the '80s or '90s has repeatedly endorsed that proposition.

10 So if we go ahead then to Claim 8, this is also an -- this is an
11 independent formulation claim. We've addressed every element in Claim 8
12 as applied in Chen other than the one that is phrased here on Slide 25, which
13 is the at least one quaternary thickener. But Dr. Park has testified at
14 paragraph 184 of his declaration that BAC is a thickener. And we note here,
15 of course, that Claim 8, unlike Claim 2 or Claim 1, does not include the
16 language regarding adjustment of the adhesion and cohesion of the thin film.
17 So if I would ask Mr. Hough to put up Patent Owner's Slide 24 where he
18 states that Claim 8 implements the functionality of Claim 1. This is
19 incorrect as Claim 8, as we have noted, lacks the limitations regarding
20 adhesion and cohesion.

21 So we'll move ahead to Ground 2, again, anticipation as a result of
22 Baker. And going up now to Slide 27, Baker states that a goal is to prevent
23 infection through nasal inhalation, among other modalities. Baker says this
24 at claim, excuse me, column 2, line 64 to 66 and column 5 at the top. Baker
25 states that this is achieved through one of a variety of polymeric quaternary

1 ammonium composition, excuse me, compounds listed through his column
2 6. And I will confess, I'm going to try to pronounce this for the benefit of
3 the record one time and then I won't again. NN Dimethyl-2-
4 hydroxypropylammonium Chloride polymer. Dr. Park testifies that this
5 creates an electrostatic field to inhibit harmful matter. Dr. Park testifies that
6 at pages, excuse me, paragraphs 193 to 197 in his declaration.

7 On our next Slide 28, Baker's compositions can be applied to the
8 skin or tissue of nasal passages and that it forms a film. In fact, Dr. Park
9 points out in paragraph 201 of his declaration that Baker specifically states
10 that his compositions, quote, "have good film forming properties," unquote.
11 And that's citing Baker at column 39. Now I'd like to ask Mr. Hough
12 actually to put up Patent Owner Slide number 40. And the reason for that is
13 one of -- to rebut what Patent Owner is saying here about Baker not
14 anticipating.

15 Now, what Patent Owner seems to be arguing here is that in order
16 to satisfy the claims of the '802 Patent, we have to inhibit particles from
17 entering the nasal passages. But this is not correct. The claim language says
18 -- so for example, where it says he's saying Baker is not an external
19 application. Baker does not teach the electrostatic attraction element. The
20 harmful particles are already inside the nose. Attraction outside the nasal
21 passages is not taught either expressly or inherently. So what Patent Owner
22 seems to be arguing from this slide is if the particles get into the nose at all,
23 we can't be anticipating with Baker.

24 But the claim language says we need to inhibit harmful particulate
25 matter from infecting an individual, wherein a film is applied to skin or

1 tissue of the nasal passages. So one can meet this claim by placing the film
2 into the nasal passage tissue, i.e. inside the nose, as long as it
3 electrostatically inhibits the particulate matter from infecting the individual.
4 So there's nothing in the claims that says the matter can never enter the nasal
5 passageway. In fact, it specifically -- the claim language specifically says
6 that the film can be applied to the skin or tissue of the nasal passage. So this
7 distinction that Patent Owner is trying to make with respect to Baker is
8 incorrect.

9 So going back to our slide deck on Slide 29, we have the cationic
10 agent disclosed in Baker. The CPC is cited here and the NN compound, as
11 Dr. Park has testified in his declaration paragraphs 204 to 206. In Slide 30,
12 we see that Baker discloses various biocidal agents disclosed as shown in
13 that slide, including TWEEN 60. Dr. Park testifies to that in his declaration.
14 If we move now to Slide 31, again, Baker discloses that his compositions
15 include cationic agents which a POSITA would understand will attract
16 negatively charged microbes. We also know that the composition can be
17 applied as a thin film. Dr. Park has testified to that previously with respect
18 to Chen in terms of the cationic agent inherently attracting negatively
19 charged microbes. He testifies at paragraphs 220 to 222 of his declaration
20 regarding these disclosures in Baker.

21 So in Slide 32, we know we have a thin film from columns 36 of
22 Baker, as Dr. Park testifies. And Baker discloses adjusting the formulations
23 such as shown in his Figure 29. And Dr. Park testifies that this will adjust
24 the adhesion and cohesion of the thin film. And that's also in Slide 33,
25 where we see the various compositions that Baker has listed which Dr. Park

1 testifies meet this limitation.

2 We go to Slide 34. We know the TWEEN compounds are stated
3 by Baker to have viricidal effects as stated here, column 16 of Baker. There
4 are also numerous compositions disclosed in columns 47 to 69 of Baker that
5 have these effects. Dr. Park testifies to that in his declaration. There's also
6 Baker Figure 29A, which we had looked at in the previous slide that was
7 particularly, I think, noted as an effective one that met the limitations of this
8 claim. So again, Baker does disclose and thus anticipate Claim 2 of the
9 patent.

10 If we move to the next Slide 34, excuse me, 37. I'm sorry, 36. I'm
11 sorry, 36. Claim 3, again, this is the dependent claim from Claim 2. Baker
12 literally states it is disclosing a quaternary ammonium compound. It's right
13 there in Baker, the NN compound being one such compound. And Dr. Park
14 testifies at paragraph 239 that that compound NN is in fact polymeric
15 quaternary ammonium compound.

16 So moving up to Slide 7, again we have Claim 1. I'm sorry, 37.
17 My mistake. Slide 37, we have again the comparison between Claim 1 and
18 Claim 2, Claim 2 minus the requirement for a cationic and biocidal
19 ingredient. Dr. Park testifies that all the elements are meant -- and again, a
20 prior art patent disclosing a product anticipates the method claim if used as
21 intended, as we've discussed in our brief. And that applies here to Baker,
22 and it applies equally, frankly, to all the grounds. And then Claim 8, Slide
23 38 for Baker, just as with the Chen reference, again, Claim 8 is an
24 independent claim but does -- omits some of the functional language in the
25 other claims but does include the "at least one quaternary thickener." And

1 Dr. Park testifies that the quaternary thickener NN Dimethyl disclosed in
2 Baker does serve that purpose. So again, we've shown -- Petitioner's shown
3 by preponderance of the evidence that Baker also anticipates the claims
4 under review in this proceeding.

5 For Ground 3, Wahi '005, and again, this is interesting because it is
6 Mr. Wahi's own prior patent but not part of the chain, not part of the family.
7 So it's prior art. This is where I reflect back on the heretofore developed
8 language that we saw in column one of the '802 Patent. The compounds, or
9 excuse me, the compositions that we see in Wahi '005 -- and we will go
10 through to show why they anticipate the claims here. We're really just
11 dealing with a situation where the Patent Owner, or, yeah, Patent Owner did
12 not realize that the type of compounds they were working with had these
13 other inherent properties. And that's why they filed for this patent.

14 So it's no surprise that Wahi's own earlier patent expresses the very
15 same purpose that the '802 Patent has. In fact, if you could put up our Slide
16 40. So the field of the invention here in Wahi '005 is exactly what we see in
17 '802. "The present invention relates to products for restricting the flow of
18 airborne contaminants into a nasal passage by creating electrostatic field."
19 Go to Slide 41. We see that Wahi specifically discloses that the formulation
20 is applied in a thin film around the nostril as stated in his '481 Patent. The
21 '481 Patent is our Exhibit 1009, and it is incorporated by reference into the
22 '005 Patent as stated at column 1, lines 10 to 15. Pardon me, Your Honor, if
23 we could pause. It looks like Judge Snedden has been lost again.

24 JUDGE MITCHELL: Did we lose him again?

25 JUDGE JENKS: Did we?

1 JUDGE MITCHELL: There he is. I apologize for the technical
2 difficulties.

3 JUDGE SNEDDEN: Yeah. I'm going to turn off my video and
4 see if that doesn't help. And sorry about that.

5 JUDGE MITCHELL: Great.

6 JUDGE SNEDDEN: I'm here.

7 JUDGE MITCHELL: Thanks. You may go ahead.

8 MR. OLDACH: Just wait a moment. Make sure that when his
9 picture goes away, his name should appear, and that'll show that he's --

10 JUDGE MITCHELL: All good.

11 MR. OLDACH: See, it looks like his picture's frozen --

12 JUDGE MITCHELL: (CROSSTALK) --

13 MR. OLDACH: -- and I don't know that that's correct.

14 JUDGE SNEDDEN: No. I'm still here.

15 MR. OLDACH: Oh, okay. Thank you, Your Honor. As I was
16 saying, the '481Wahi Patent is incorporated by reference into the '005 Patent.
17 So everything disclosed in either of those is relevant for our anticipation
18 ground on Wahi '005. In the interest of time, Your Honor, I'll refrain from
19 going through each and every element of Claim 2 here for Wahi '005. But
20 there are certain different polymers that are incorporated in Wahi '005,
21 Agequat and Celquat, which Dr. Park testifies meet the cationic and/or
22 biocidic agents. TWEEN is also disclosed in Wahi '005. So for all the same
23 reasons that we've shown that Chen and Baker anticipate Claims 1, 2, 3 and
24 8, we contend and have established by preponderance of the evidence that
25 Wahi '005 does so as well.

1 But I do want to move ahead to Ground 4 before I pass things over
2 to Ms. Hank. Going up to Slide 53 of our presentation, and there again the
3 purpose that we have here for Claim 2[a], "present invention provides a
4 method for preventing a respiratory infection in a mammal at risk thereof."
5 We have the same purpose. One ingredient that he lists is quat-15, which
6 Dr. Park testifies as a cationic agent at paragraph 359. So again, inherently
7 that will electrostatically provide a field of -- an electrostatic field that will
8 attract the particulate matter. Dr. Park testifies to that.

9 Now, the difference in Rolf from some of the others -- go to Slide
10 54 -- is that the formulation is applied to the area near the nose through an
11 adhesive patch. And Rolf at paragraph 42, states that there is an ointment or
12 a gel on a backing. And Dr. Park testifies at paragraph 368 that a POSITA
13 would understand that the ointment or gel is therefore contacting the skin in
14 a thin film. So if you imagine, for example, a Band-Aid, and I have the
15 composition on the -- what you would think of kind of as the underside of
16 the Band-Aid that contacts the skin, I would put it on there. And therefore a
17 thin film is going to be disposed on that area of the skin, as Dr. Park has
18 testified.

19 And the other interesting thing about Rolf is that what Rolf uses is
20 a -- is what he calls an essential oil. But Rolf states that that essential oil is
21 present in an amount sufficient to kill or inactivate the pathogen. That's our
22 Slide 60, if you would go ahead to that, Mr. Hough. So, yeah, in Rolf
23 paragraphs 76 and 77, we have an "essential oil can be present in any
24 appropriate and suitable amount, provided" that it "effectively kills or
25 inactivates an airborne pathogen, respiratory tract pathogen, or combination

1 thereof."

2 Now, I also want to address here and ask Mr. Hough to put up
3 Patent Owner's Slide 34. And this is one way that Patent Owner says Rolf
4 does not anticipate. And the argument he's making is that because Rolf's
5 claims were rejected under section 112, Rolf's disclosure is not enabling.
6 Now, obviously that conclusion does not necessarily follow. A does not
7 necessarily lead to B. But if we looked back at Exhibit 2001 that Patent
8 Owner had submitted, in fact, the term that the examiner in Rolf was
9 concerned with, and that was the claim that Rolf's composition would
10 prevent respiratory infection. And this is the very same term that the Patent
11 Owner amended to substitute inhibiting in the '802 Patent. So to distinguish
12 Rolf on this basis, we believe is completely unavailing.

13 In the couple of moments I have left before I'm going to turn over
14 to Ms. Hank, I do want to touch on the motions to strike and exclude the
15 evidence submitted with Patent Owner's sur-reply which was in violation of
16 rule 42.23(b) And as I said, Ms. Hank will address the substance of the
17 evidence itself in the context of the obviousness grounds that she will be
18 addressing.

19 As Your Honors well know, it's very common for a panel of the
20 Board to allow evidence to come in or not to exclude it, even if there are
21 questions about whether it should be admitted, and may then often dismiss a
22 motion to strike or exclude the evidence as moot if it would not alter the
23 panel's decision otherwise. And I can tell you we certainly are of the view
24 that this evidence would not in fact have any impact on the panel's decision.

25 But I respectfully submit that the violation in this proceeding was

1 so stark as to justify the rare remedy of striking the evidence. The proper
2 method to introduce supplemental information would have been a motion
3 under rule 42.123(b), as Judge Mitchell referred to earlier this afternoon.
4 The Patent Owner did not attempt to do this until after it had already
5 improperly submitted the evidence with the sur-reply. And most tellingly, in
6 response to Petitioner's motion to strike, the Patent Owner admitted that it
7 could have introduced the evidence earlier, which is of course the opposite
8 of what one must show in order to justify a motion to file late supplemental
9 information.

10 If the bar to filing evidence with a sur-reply is to have any
11 meaning, respectfully, we'd suggest that this is the case where that motion to
12 strike should be granted. And with respect to the evidentiary objections
13 which bear on the motion to exclude more so than the motion to strike, the
14 Wahi declaration again gave us no meaningful opportunity to depose Mr.
15 Wahi because of the time frame, no window for us to present any brief. It
16 looks like Judge Jenks may have left us.

17 JUDGE MITCHELL: Yes, she did. I apologize.

18 JUDGE JENKS: I'm back.

19 JUDGE MITCHELL: Great.

20 JUDGE JENKS: I apologize. This has been going on all morning,
21 and we have no idea what's going -- why. So I might do -- I might end up
22 doing the same as Judge Snedden because -- maybe we're using too much
23 bandwidth by having streaming the video alongside. So I will turn my video
24 off and listen. Hopefully we will not be disconnected again. I apologize.

25 MR. OLDACH: Thank you. Shall I resume?

1 JUDGE MITCHELL: Yes.

2 JUDGE JENKS: Please do.

3 MR. OLDACH: And again, as to the merits of what was said in
4 Mr. Wahi's declaration, it did not sufficiently authenticate or refer to the
5 other exhibits that it seemed to try to reference and introduce. It didn't
6 reference the product packaging, Exhibit 2005, or the instructions, I think
7 that was Exhibit 2004, the study which was 2006, or the website list which
8 was 2007. There's simply no basis provided on which any of this material
9 could be admitted. And again, Ms. Hank will talk about some of those other
10 aspects of that evidence in a little more detail as I hand this over to her to
11 address the obviousness grounds. Thank you very much.

12 JUDGE MITCHELL: Thank you.

13 MS. HANK: Thanks, Bill. I'm Maryellen Feury Hank for the
14 Petitioner. Could we turn to Slide 68, please? I'm here to talk about Ground
15 5 to begin with. And then I'll turn to Grounds 4 -- 1 to 4 as they refer to
16 obviousness. Under Ground 5, we've established that Claim 3 is rendered
17 obvious by Rolf in view of Wahi '005. And we heard Mr. Oldach talk about
18 Rolf by itself and talk about Wahi '005 by itself as well. One the things that
19 was mentioned was whether Rolf was enabled. That has been raised by the
20 Patent Owner. And what we'd like to note is that while Rolf is a U.S.
21 printed patent application, it's available for all the things that are taught
22 within that printed publication. And whether or not it was under a 112
23 rejection may or may not be the reason why it was abandoned and did not go
24 forward as a patent. So we can't say for certain that this was held enabled as
25 it will. So we're offering Rolf for everything it was offered and all the

1 teachings that are within that printed publication.

2 And we turn to obviousness, which we note -- and if we go to
3 Patent Owner Slide 33, please, we note that the Patent Owner side, they talk
4 repeatedly about whether one needed to be aware of the problem. And a
5 POSITA must recognize the problem that particles dislodge before arriving
6 at the invention. But let's think about it this way.

7 Obviousness requires motivation to combine with a reasonable
8 likelihood of success. And what is known or recognized in the art might be
9 very different. For instance, for example, if a reference were to teach water
10 at negative 5 degrees Fahrenheit, but never mentions that that is actually ice,
11 the reference still teaches ice because necessarily water at negative 5 degrees
12 Fahrenheit is in the form of ice, whether or not it was in the four corners of
13 the document, one of ordinary skill in the art would recognize that that
14 reference teaches ice.

15 Similarly, we have references here that, if the panel should not
16 reach anticipation, could each be offered and establish by themselves and
17 here with Rolf and Wahi together establish that the claims are rendered
18 obvious.

19 If we turn to our Slide 71, we see that Rolf teaches a method for
20 preventing respiratory infection. And that is very relevant and on point to
21 what the '802 Patent is claiming. Again, as we talked about with Mr.
22 Oldach, it's irrelevant, even though the Patent Owner keeps referring to this,
23 that some particles might be inhaled because the '802 Patent -- the claims are
24 very clear that it is inhibiting. And as the Patent Owner reminded us, it's not
25 preventing. Preventing would be 100 percent. Inhibiting is something less

1 than 100 percent. So if some particles are inhaled, that's okay because we're
2 inhibiting the particles from being inhaled.

3 So we see that Rolf is on point with regard to the motivation, the
4 method for preventing respiratory infection. We also see that Wahi is on
5 point because Wahi talks about restricting the flow of airborne contaminants
6 into the nasal passage. Again, the idea is that you don't want to be
7 contaminating a person. And so both of these are on point for what is being
8 claimed in the '802 Patent with the upshot that it would have had a
9 reasonable expectation of success. So you combine Rolf with Wahi '005,
10 you would have a reasonable expectation of success, as was discussed by our
11 expert witness, Dr. Park, declaration paragraph 437.

12 We talk about several different points of these claim language.
13 And one of the things that keeps coming up is this claim language element
14 B, holding the particulate matter in place by adjusting the thin film to stick
15 to the skin or tissue and provide adequate impermeability of the thin tissue.
16 What's interesting is that nothing here requires that it's external. It requires
17 that this is applied to the skin or tissue of the nasal passage. So that could be
18 internal or external.

19 And unlike what the Patent Owner would like to argue, Rolf at
20 Figure 1 and also at paragraph 47 discusses the fact that there is a backing
21 and that the formulation is on the backing and is on the front side of the
22 backing. And the front side is actually exposed to the skin. And we hear
23 also from Dr. Park supporting that interpretation of the Rolf reference at
24 paragraphs I think it's 430 to 437. We also see in the Wahi reference that
25 Wahi teaches a nasal application product for restricting the airflow -- the

1 flow of airborne contaminants into a human nasal passage, combining
2 together to render this claim obvious.

3 The Patent Owner offers secondary considerations of non-
4 obviousness. While we certainly do not concede that this evidence should
5 be part of the record, we're going to argue it in the event that this does need
6 to be addressed. So if we go to Slide 74, what the Patent Owner has not
7 established, if this is evidence that will be part of the record, has not
8 established that there's any nexus between the evidence of this alleged
9 commercial success and the patented claimed invention. For instance, if you
10 look on Slide 74, you'll see that the Wahi declaration at page 2 lists a
11 number of things and establishes a number of or tries to establish a number
12 of things such as "the '802 Patent number is marked on every tube of product
13 sold in the United States."

14 However, then we turn to Slide 75 and 76, and we see that not
15 every one of those references or those pictures of products offered have the
16 '802 Patent listed. And that begs the question, were they covered by the '802
17 Patent. There's nothing to establish that the products and/or the methods that
18 were used with the products read on Claims 1 to 3 and 8 of the '802 Patent.
19 It's talked all around, but it's never established by evidence that these
20 actually read on these claims. And supposedly they were all sold in the
21 United States. We have no support to show that. We have no evidence that
22 establishes that.

23 In fact, if you look on Slide 76, you'll see on the right side -- this is
24 Exhibit 2004, page 4. You'll see that it's manufactured for and distributed by
25 Trutek Europe. Again, begging the question, was this a product that was

1 sold in the United States and covered by the claims in the '802 Patent? And
2 then the question becomes well, was the fact that this, if it were -- if these
3 products were covered by the '802 Patent, is that the reason for this alleged
4 commercial success? I mean, or could it be many other reasons? For
5 instance, perhaps people like their labeling. Maybe they have great ads.
6 There could be many other reasons where there might not be a nexus
7 between this alleged commercial success and the actual claimed patented
8 invention.

9 Looking at what the Patent Owner has attempted to offer for
10 secondary considerations. Really, even if these were accepted as evidence
11 into the record, there's no evidence to overcome our prima facie case
12 obviousness.

13 Turn to Slide 77, please. Now I'll talk about grounds. In the
14 interest of time, I'm going to move to actually Slide 84. We have Grounds 1
15 and 2 obvious over each Chen and Baker. But in the interest of time, I'll just
16 move to Grounds 3, which is the claims being obvious over Wahi '005.
17 Again, as we heard from Mr. Oldach talking about the anticipation, Wahi
18 '005 is incorporated by reference into the '802 Patent. Wahi '481 is
19 incorporated by reference into the '005 Patent.

20 All of these are in the record and all talk about the same thing,
21 restricting flow of airborne contaminants into a nasal passage by creating an
22 electrostatic field in an area about the nasal passage with a reasonable
23 expectation of success. And so, even though it may be that Mr. Wahi would
24 like us to believe that no one understood what he was doing until the '802
25 Patent, what we realize is that if you look at the Wahi '005, it in fact does

1 what needs to be done.

2 For instance, if you look at our Slide 85, 2[b], which is our element
3 wherein a formulation is applied to skin or tissue of nasal passages in a thin
4 film, we definitely have that. Within the Wahi '005 we have ointments,
5 pastes, creams, and gels, Wahi column 2:22-26. And also Wahi '481 talks
6 about the patient provided with the gel with a very thin film should be
7 applied with the finger outside the nostril and above the lip. That's external
8 to the nasal passages.

9 Again we see the other elements that were established in the '102
10 argument. But in the event that you need to reach 103, we look at element
11 2[e] as well. And that's Slide 86. Here we talk, and Dr. Park offers in his
12 declaration that "a POSITA would understand that Wahi's '005 thin film with
13 the cationic agent(s) for restricting the flow of airborne negatively-charged
14 contaminants into a nasal passage inherently creates an electrostatic field of
15 increased charge in an area about the nasal passage." And "alternatively, a
16 POSITA would be motivated to use Wahi '005's thin film to electrostatically
17 attract particulate matter." This has not been refuted with any evidence.

18 Again, we call attention to the beginning of the '802 Patent which,
19 as Mr. Oldach started out with, mentioned, and I quote -- this is column 1,
20 lines 62 to 65, quote, "the present invention also relates to an antiviral,
21 antibacterial, and antimicrobial products and methods that involve the use of
22 products heretofore developed for restricting the flow of airborne
23 contaminants into the nasal passages by creating an electrostatic field in an
24 area near about the nasal passages. This is Wahi '005 and Wahi '481. These
25 are prior art products that the exact inventor developed. This is what he's

1 talking about, in essence saying Wahi '005 and Wahi '481 have these
2 heretofore developed products.

3 Turning to Ground 4, Wahi -- I'm sorry, Rolf, as Rolf renders
4 obvious Claims 1 to 2 and 8 by itself. And what we're kind of dealing with,
5 with regard to the Patent Owner, is that he is raising some issues about
6 whether the essential oil is in a vapor. Really, if you track the claim
7 language, you'll hear him argue that the essential oil is a vapor and that that
8 matters. But reality is, Rolf teaches that we have a cationic agent with an
9 essential oil in a thin film, and it inactivates the particles. That happens in a
10 formulation below a patch put on the skin. Whether or not essential oil
11 vaporizes at some point is irrelevant to the analysis that Rolf actually does
12 render Claims 1, 2 and 8 obvious. And in the interest of time, I will just
13 leave it at that.

14 JUDGE MITCHELL: Thank you. Ms. Hank.

15 MS. HANK: Thank you.

16 JUDGE MITCHELL: And Mr. Kerman, you can begin --

17 MR. KREMEN: Would it be --

18 JUDGE MITCHELL: --- whenever you want.

19 MR. KREMEN: -- possible to take a momentary break?

20 JUDGE MITCHELL: Sure.

21 MR. KREMEN: I'd say just about two minutes. That's all I need.

22 JUDGE MITCHELL: Okay. Sure. You can take a break.

23 (Whereupon, the above-entitled matter went off the record at 1:57
24 p.m. and resumed at 1:59 p.m.)

25 MR. KREMEN: Thank you for that.

1 JUDGE MITCHELL: Great. You can begin when you're ready.

2 MR. KREMEN: Okay. Do you have my slides?

3 JUDGE MITCHELL: I do. We do. We all have your slides. Yes.

4 MR. KREMEN: Okay. Thank you. Okay. In Slide 1, essentially
5 what we're dealing with, the universe that we're dealing with is Claims 1, 2,
6 3 and 8. And those are the only claims which are in contest. The rest of the
7 patent is not in contest here. Claim 1 is an independent claim, so is Claim 2.
8 Difference is that 1 is a method claim, 2 is a formulation claim. Claim 3
9 depends from Claim 2, and it incorporates all of the features of Claim 2.
10 And Claim 8 is also an independent formulation claim.

11 Now, the preamble has been ruled as being limiting. And
12 essentially the important thing that we're talking about, electrostatically
13 inhibiting from harmful particulate matter, which is any kind of viruses or
14 pollen or dust or anything like that, from nasal inhalation through a
15 formulation that's applied with thin film. And essentially what happens is
16 that the -- by applying an electrostatic material, it can either be cationic or
17 anionic. It doesn't matter for Claim 1. For Claim 2, it's cationic. And what
18 you're doing is you are supplying -- applying the preparation, in this case it's
19 a gel, to the exterior of the nostrils. And that establishes an electrostatic
20 field which surrounds the nasal area. So essentially what it's doing is it has
21 its effect beyond where the application is.

22 The Patent Owner has used a shorthand notation called catch to
23 mean electrostatically attracting the particulate matter to the thin film. So
24 essentially that's element A is the catch function. Now, we know that
25 opposites attract, and similar charges repel. So in this case, what we're

1 trying to do is we're trying to attract the oppositely-charged particles. Now,
2 we do know that most harmful particles are negatively charged. So
3 essentially what we're doing is we are putting a positive charge to create an
4 electrostatic field in and around the nose. And the harmful particles, the
5 viruses, bacteria, any kind of pollutants, dust, pollen, anything like that -- in
6 fact the product that was protected by the '802 Patent and the '005 Patent was
7 originally used for allergies. And essentially what it does is it catches -- the
8 cationic positive charge catches the negative harmful particle and repels
9 anything which is positively charged.

10 So now the Petitioner claims logically that the formulation is
11 applied and a thin film must be on the exterior region of the nostril, that's the
12 skin and/or slightly inside the edge of the nostril, in order to prevent nasal
13 infection. That is actually agreed to by Judge Franklin in her paper 7, page
14 10. So basically what we're looking at here is that the -- and the patent
15 agrees with this -- that it is not applied internally. It's applied to the external
16 region of the nose.

17 Now, essentially what that means is just to show how the
18 application is done -- and incidentally the words that are in step one, step
19 two and step three are in the photographs, but they're not really legible.
20 That's why I included the text of them over here. So the first thing that you
21 do is you put a little drop of the gel on your finger. You smear it around
22 between the pointer finger and the thumb, and then you apply to the nose
23 -- nostril above the upper lip. In other words, you don't actually apply it
24 inside the nostril. Now the -- okay. Oh, okay. Sorry.

25 JUDGE JENKS: I have a question. If you happen --

1 MR. KREMEN: Sure.

2 JUDGE JENKS: -- to apply this inside the nostril, would it still
3 -- why would it not work there?

4 MR. KREMEN: Well, because what you're not trying to do is
5 you're not trying to apply it to the nasal mucosa because already once you
6 apply it to the inside of it -- what you're trying to do by applying it to the
7 outside of the nostril is to try to prevent the particles from going into the
8 nose. You want to inhibit the harmful particles from being breathed in
9 because once it's inside the nostril, there's a good chance that it will be
10 inhaled. What we're trying to do is we're trying to collect the -- what you're
11 trying to do is you're trying to attract the particles from the air. In other
12 words, you're not trying to eliminate them. You're trying to attract them, and
13 you want them to be together on the skin surrounding the nose. And this
14 way you won't breathe it in. And we found that it's quite successful doing
15 that.

16 Now, a second feature is holding the particulate matter in place by
17 adjusting the adhesion of the thin film to the -- so that it should stick to the
18 skin and by adjusting the cohesion of the formulation to provide adequate
19 impermeability to the thin film. Now, the adequate impermeability does not
20 mean that it -- you can't contact the skin. The size of the harmful particles
21 are minuscule compared to the thickness of the thin film. The thin film is
22 not completely continuous at that scale, and those harmful particles enter the
23 film to some depth. The coherence is adjusted to bind the particle to the film
24 to prevent it from dislodging. And adequate permeability is not necessarily
25 implemented to prevent contact with the skin. It's done to constrict the film

1 to hold the particles to prevent dislodging. Now, essentially, this is showing
2 how the particles will be attracted to the exterior part of the nostril.

3 Now, Wahi '005 was a similar product, and it existed before the
4 product of the '802 Patent. And it also was applied to the external region of
5 the nose as shown in the drawing. And it created the electrostatic field
6 surrounding the nose. So in other words, it was used to attract harmful
7 particles to the skin surrounding the nose -- surrounding the nostrils. Now,
8 the '802 Patent in 2:52-58 discusses Wahi '005, and it says, "furthermore,
9 actions by the person having those electrostatic compositions in the vicinity
10 of the nostrils can sufficiently displace the offending particle or organism,
11 especially in such instances as blowing or wiping the nose, that those
12 particles that were held captive by the former compositions could become
13 dislodged again and set free and be inhaled." What we're trying to do is
14 we're trying to avoid the particles from being inhaled into the nose. Now
15 this demonstrates what happens that you can see that a particle got dislodged
16 and this had been determined experimentally. Now --

17 JUDGE JENKS: I'm sorry, what slide are you on, on your deck?

18 MR. KREMEN: I'm sorry. I'm now on Slide 14. But one of the
19 things, going back to Slide 13. Wait a second. Excuse me. Going back to
20 Slide 13, that passage was in -- right at the bottom of column 2. But then
21 when you look at column 3, the hold function is defined in the '802 Patent at
22 3:1-3. And it says, "it is further an object of this invention to have the
23 capability to hold it for a duration from being dislodged into the airstream
24 again." That is the definition that the '802 Patent gives for the hold function.

25 In other words, it describes the problem. It says that experiments

1 have shown the Wahi '005 that the particles get dislodged. And then
2 defining the concept of a hold function, it's further the object of the
3 invention to have the capability to hold it for a duration from being enlarged
4 into the airstream again.

5 Now, I don't know whether this is what one would consider the
6 plain and ordinary definition of the hold function of the concept of holding.
7 But in this particular case the applicant may be his own lexicographer as in
8 MPEP 2111.01. And here the applicant is acting as his own lexicographer.
9 That hold function is the important thing. And it is the difference between
10 Wahi '005 and '802. Otherwise, Wahi '005 does the same thing as the '802
11 Patent. The main difference, the primary difference is the hold function.
12 And the first time that this problem of dislodging has ever been expressed
13 has been in the '802 Patent in -- let me see. It was 2:52-58.

14 Now the kill function is inactivating the particulate matter by
15 adding at least one ingredient that would renders it particulate matter
16 harmless. And we know that both Wahi and the '802 Patent do two of the
17 -- they both do two of the things. They do the catch and the kill. But only
18 the '802 Patent does the hold function. And the hold function is the unique
19 part of what differentiates Wahi '005 to Wahi '802.

20 Now Claim 2 is an independent claim. And what it does, Claim 1
21 was the method claim. Claim 2 recites the formulation of Claim 1. And the
22 formulation implements the method of Claim 1 which is catch, hold, and
23 kill. It has to do all three. Now the functions of the formulation, it contains
24 a cationic agent that electrostatically attracts negatively charged harmful
25 particles. That's called the catch function. The formulation deliberately

1 adjusts the adhesion and the cohesion to hold harmful particles in place.
2 That's the hold function. And the formulation contains a biocide to render
3 the particles harmless. That's the kill function. Wahi '005 did the catch
4 function and the kill function but not the hold function. And that is specific
5 -- that is specifically stated, expressly stated in the '802 Patent. And I've
6 done pretty much said this already.

7 Now looking at the '802 Patent versus Wahi '005, Ashok Wahi is
8 the sole inventor of both patents. It wasn't confusing. He wasn't confused
9 when he indicated that it was used heretofore prior substances. Both the
10 '802 Patent and Wahi '005 contain a cationic agent and a biocidic agent.
11 And both the '802 Patent and Wahi '005 implement the catch and kill
12 function, but they do not implement the hold function. Now the
13 methodology and formulation of the '802 Patent represents a significant
14 improvement of a Wahi '005.

15 And the first time in the prior art that the hold function appears is
16 in the '802 Patent's criticism of Wahi '005. It never appears in any other
17 prior art. The implementation of the hold function is a deliberate
18 improvement. Implementation requires the inventor awareness of the
19 problem which was first pointed out in the '802 Patent. If you didn't know
20 the problem, maybe you could create a product that would hold. But there's
21 no purposeful implementation of that product, and it's not adherent in the
22 claims. The whole --

23 JUDGE SNEDDEN: Mr. Kremen, I have a question. This is
24 Judge Snedden. With regard to these other patents that Dr. Wahi or Mr.
25 Wahi has, do any of these patents also cover that product that you reference

1 in your brief?

2 MR. KREMEN: In other words, the -- well, you'll notice that the
3 '005 Patent is listed on the product packaging of the gel. That's because it
4 did -- it was effective in terms of allergies and things like that. But we found
5 that the '802 Patent was very effective in terms of being able to attack
6 viruses and bacteria and microorganisms. So essentially both product, the
7 '005 Patent, which is a 1995 patent, and the '802 Patent, which is a 2012
8 patent, are listed on some of the earlier products which were sold that were
9 protected by the '802 Patent. Does that answer your question?

10 JUDGE SNEDDEN: It does. Thank you. Thank you.

11 MR. KREMEN: Okay. Thank you. Okay. Now, essentially
12 Claim 3 is dependent from Claim 2, and it incorporates all, by reference, all
13 of the limitations of Claim 2. So in other words, Claim 3 has to exhibit the
14 hold function -- it has to exhibit the catch, hold, and kill function. It has to
15 do all three. Plus the cationic agent has to be a polymeric quaternary
16 ammonium compound. So if Claim 2 is patentable, then Claim 3 must also
17 be patentable because it contains all of the limitations of Claim 2.

18 Claim 8 is an independent formulation that implements the
19 functionality of Claim 1. Essentially, electrostatically inhibiting is
20 something that the examiner understood it, and he defined what it meant by
21 inhibiting. But he also understood the fact that it does create the
22 electrostatic field. And that is the main thing that is attracting the harmful
23 particles to the point of application. Now, electrostatically inhibiting must
24 be interpreted as inhibiting using electrostatic means. There's no other
25 reasonable interpretation as a statement of use for the method of Claim 1 and

1 the formulation of Claims 2 and Claim 8. The difference between Claim 8
2 and Claim 2 is the fact that you're using a quaternary thickener, and that is
3 being used to adjust the cohesion of the product.

4 Now the prior art that was asserted against the '802 Patent is Chen,
5 Baker, Wahi '005, and Rolf. And I'm going to take them in a sort of a
6 different order than -- because obviously Chen is the important one, and I
7 want to eliminate the others before getting to Chen. Now, essentially for
8 anticipation, you need a single prior art reference. Every element of the
9 claim must be disclosed either expressly or inherently. And the prior art
10 reference must be enabled and operative. That's in MPEP 2121.01. For
11 obviousness, you have to determine the scope and context of the prior art,
12 ascertain the differences, determine the level of skill. And that's the
13 POSITA, P-O-S-I-T-A, and a person of ordinary skill. And you have to
14 have a reason or rationale for combining the prior art references by a person
15 of ordinary skill.

16 Now, the combined prior art must teach and suggest every element
17 of the claim. You can't have any elements missing. And the person of
18 ordinary skill must have a rationale for combining the multiple references to
19 foresee every element in the claim. If he can't foresee it, he's not going to
20 combine it. For a determination of obvious of a claim based on a single
21 reference, the person of ordinary skill must have a rationale to foresee every
22 element of the claim.

23 Now, Wahi '005 fails to anticipate the '802 Patent. It is a gel that is
24 applied externally to the nasal region, which is what the '802 Patent
25 specifies. It creates an electrostatic field that attracts harmful particles.

1 However, the Wahi '005 formulation does not exhibit the hold function.
2 Very specifically, the '802 Patent very much states that the particles
3 dislodge, and the whole purpose of the hold function is to prevent the
4 dislodging of the particles.

5 And the Examiner Henley was aware, and he took Wahi '005 into
6 consideration when he issued the notice of allowance. And that is Exhibit
7 1004, which is the office action. Or it's actually the image file wrapper,
8 page 40, number 16, in which he put his initial next to the '005 Patent. So
9 the examiner did not see '005 anticipating the '802 Patent, and he understood
10 that it was the difference of the hold function which made the difference
11 between the '802 and the '005.

12 Now, the '802 Patent claims are not obvious over Wahi '005 under
13 section 103. The Petitioner alleges obviousness using a single reference.
14 Now, that's a very difficult bar to overcome. Wahi '005 does not teach and
15 suggest every element of the claim. The hold function is absent. A person
16 of ordinary -- now, a person of ordinary skill must recognize the problem
17 that particles dislodge before arriving at a solution that includes the hold.
18 There's no motivation to -- for him to actually do that because he doesn't
19 know that's needed to be done. The dislodging problem is disclosed for the
20 first time in the '802 Patent. If he would refer to the '802 Patent and learn it,
21 it's impermissible hindsight. Rolf --

22 JUDGE MITCHELL: Mr. Kremen, can I --

23 MR. KREMEN: Sure.

24 JUDGE MITCHELL: -- ask you a question? We're talking about,
25 I guess, the recognition by a POSA that the '802 would teach a hold

1 function versus the Wahi '005. Can you tell me, though, what the difference
2 in the formulations are between the Wahi '005 -- what's taught in the Wahi
3 '005 reference and what's taught in the '802 Patent that would provide that
4 difference where the '802 teaches the hold function because of the
5 formulation and the Wahi '005 does not?

6 MR. KREMEN: Now, one thing which helps you to implement
7 the hold function is the quaternary thickener of Claim 8. But that's
8 implemented in all of the formulations which are shown in a table. Now,
9 essentially what you do is you change the concentration of water. You
10 change the concentration of the quaternary compounds. And all of the
11 formulations that were implemented in Tables 1 through 10 exhibit that hold
12 function experimentally. And now one of the things about the formulations
13 in Tables 1 and 10, they're all indicated by ranges. And one of the things
14 which we did when we had the Markman hearing in the Michigan Court is I
15 showed that you can pick any -- as long as it meets those ranges, all of the
16 functions will be exhibited. And you could actually come up with a
17 formulation from that which would have definite concentrations. The claims
18 are not definite because of the ranges. And all of those formulations in
19 Tables 1 through 10 exhibit the catch, hold, and kill functions. Does that
20 answer your question?

21 JUDGE MITCHELL: Yeah. I think it does. So is the quaternary
22 thickener not disclosed or not used in the Wahi '005 reference formulations?

23 MR. KREMEN: No, it's not. Well, it depends because you have
24 to do it for adequate -- it's not the existence of the quaternary thickener. It's
25 the amount of the quaternary thickener because you have to adjust the

1 adhesion and cohesion. Now, the purpose of the adhesion is to stick to the
2 skin. That is its main function, although some particles can stick to the
3 adhesive portion of it. But the cohesion is the important part because
4 essentially what happens is the particles -- there are gaps in the thin film
5 because the particles are minuscule compared to the thin film. And so
6 essentially consider them to be interstices. And essentially what happens is
7 that the particles, they don't stick to the surface. They penetrate into the
8 composition. And the more cohesive that composition is, the more
9 restricting it will be to prevent the product from dislodging. The cohesion is
10 a very important thing.

11 And also one of the things which is very important to understand
12 -- one of the things that Dr. Park said, and I don't remember exactly where
13 he said it, but he said that Chen modifies the cohesion because he puts in a
14 viscosity modifier. Viscosity and cohesion are two different things. You
15 can, for example, take a fluid and put sand into the fluid or some sort of a
16 gum into the fluid and -- to slow down the fluid flow. But that doesn't
17 increase the cohesion of the product.

18 JUDGE MITCHELL: Thank you.

19 MR. KREMEN: Okay. Now, Rolf --

20 JUDGE JENKS: Hold on. Let me just go back. So you were
21 saying it was -- was it the polyquat that makes the difference between the --

22 MR. KREMEN: Yes. Because --

23 JUDGE JENKS: --- '005? Okay.

24 MR. KREMEN: Yeah.

25 JUDGE JENKS: So is there any evidence --

1 MR. KREMEN: It's --

2 JUDGE JENKS: -- in the record? Because I'm looking at -- hold
3 on. I'm looking at the '005 in column 4 where they're telling me that they're
4 using Celquat, which is a polyquat in those formulations. Is there any
5 evidence that the Celquat -- you've compared it to your -- the various
6 polyquats you used in your formulation --that the Celquat does not work?

7 MR. KREMEN: Well, it's not that it doesn't work. It's the
8 question of -- when '005 composition was first marketed in 1995, it was not
9 known that the particles would dislodge from it. And it probably wasn't
10 important because it was an -- it was sold mainly to alleviate allergies, and it
11 worked for that. But you still --

12 JUDGE JENKS: I --

13 MR. KREMEN: -- had allergic reactions.

14 JUDGE JENKS: I appreciate that your product that you started
15 selling would dislodge. But the teaching in the '005 is much broader than
16 your product.

17 MR. KREMEN: That's correct. But the --

18 JUDGE JENKS: So --

19 MR. KREMEN: But the thing as far as -- the thing which
20 distinguishes what -- the way to modify the cohesion is not only to have the
21 correct substance in there, but also to adjust the concentrations so that you
22 achieve your -- in other words, the formulator takes that into account to
23 develop those formulations. And any formulation that is in Tables 1 through
24 10 will actually exhibit the hold function.

25 JUDGE JENKS: That's Table 1 through 10 of the --

1 MR. KREMEN: '802 Patent. Yes.

2 JUDGE JENKS: '802 Patent.

3 MR. KREMEN: Yes. All those exhibit the hold function,
4 provided that the concentration ranges are kept within the ranges that are
5 given. And the product which actually was first issued as protected by the
6 '802 Patent was a derivative of Table 10. But all of those products will -- as
7 long as the ranges are kept, they will exhibit the hold function.

8 JUDGE JENKS: Okay. Continue on.

9 MR. KREMEN: Okay. Now we're talking about Rolf right now.
10 And Rolf does not anticipate the -- well, not only were all claims rejected,
11 but the disclosure was indicated by the examiner as being inoperable. And if
12 you take a look at Exhibit 2001, pages 7 to 8, and on page 8, he specifically
13 -- the examiner said that disclosure is inoperable. And to anticipate a prior
14 art reference must be enabled and operative. And that's MPEP 2121.01.
15 Now that doesn't apply to obviousness. It only applies to anticipation.

16 For obviousness, the exhibit -- the reference can be used for what it
17 teaches rather than which -- but it has to be enabled for it to be able to
18 anticipate. Now when we look at Rolf, and Rolf was a -- there was an
19 Exhibit 202 is Block's patent, Block '403. And what he does, he uses the
20 same type of patch. He applies it to the person's chest, and the essential oils
21 evaporate into -- evaporate from the patch and go into the nasal region. Now
22 the adhesive that Block uses is on the side of the patch that contacts the skin.
23 I'm sorry. I lost video on everybody. Can you still hear me?

24 JUDGE MITCHELL: We can hear you.

25 JUDGE JENKS: We can hear you.

1 MR. KREMEN: Okay. So --

2 JUDGE SNEDDEN: I can hear you.

3 MR. KREMEN: Okay. So now the adhesive portion is on the skin
4 side of the patch rather than the side facing air. Similarly, the Rolf patch is
5 the same patch as the Block patch because Rolf is a co-inventor of the Block
6 Patent. So the one thing which we have over here is that -- the one thing that
7 Rolf does not do is it doesn't indicate the catch function because it's not
8 attracting the particles to the patch. And even if it does, it certainly doesn't
9 exhibit the hold function. Admittedly, some of the essential oils might be
10 biocidal. There is benzalkonium chloride in the Rolf, which he uses as a
11 preservative, not as a biocide. Whatever happens, the particles go into the
12 nose rather than being attracted to the patch. And there's no hold function.
13 There's nothing --

14 JUDGE SNEDDEN: He's lost his microphone --

15 JUDGE MITCHELL: Yeah.

16 JUDGE MITCHELL: Mr. Kremen. Yeah. Mr. Kremen, I think
17 we all of a sudden couldn't hear you. I don't know if you went on mute. I'm
18 still not hearing you. I cannot hear you now. Pardon?

19 UNKNOWN SPEAKER: I know (INDISCERNIBLE PHRASE).

20 JUDGE MITCHELL: Okay. Great. Thank you. We still cannot
21 hear you. So we've contacted our IT folks.

22 MR. KREMEN: Really. And the (INDISCERNIBLE -
23 TECHNICAL DIFFICULTY) --

24 JUDGE MITCHELL: There we go.

25 MR. KREMEN: For the essential oils go into the --

1 JUDGE MITCHELL: We can hear you now. Go ahead.

2 MR. KREMEN: Oh, I'm sorry. The Rolf Patent essentially wants
3 the essential oils to go into the nose. And essentially it will -- it may drag
4 some harmful particles in it. Some of them maybe -- we're hoping that a lot
5 of them are going to be killed. There's no assurance that many of them will
6 be killed. It's a very ineffective invention, and certainly it does not exhibit
7 the hold function.

8 Both Rolf and Block use the same patch. Block affixes the patch
9 to the chest. It's more like Vicks VapoRub, where you get the essential oils
10 going up to the -- to alleviate any infection. Rolf attaches it to the upper lip.
11 Both patches emit vapors of essential oil that are toxic to microbes. But the
12 hold element is not taught either expressly or even inherently. Particles still
13 dislodge and float free in the air. And the live particles that are not affected
14 by the essential oil vapors can be inhaled.

15 The '802 Patent is not obvious over Rolf because in an obviousness
16 determination, a person of ordinary skill must foresee every element of the
17 claim. Now this is true especially when the prior art is a single prior art
18 reference rather than a combination of references. A person of ordinary skill
19 must be -- is one who is aware of all prior art. That's one of the things. So
20 to foresee an element, the person of ordinary skill must see a solution to a
21 problem. Without awareness of a problem, he can't foresee a solution. The
22 only prior art where the problem of this large particle appears is in the '802
23 Patent. Therefore, a person of ordinary skill cannot foresee the hold element
24 without reading the '802 Patent.

25 Now the '802 Patent claims are not obvious over Rolf in view of

1 Wahi '005. Why? The hold function is a critical element of the '802 Patent
2 claims. Neither Rolf nor Wahi '005 exhibit the hold element. And that was
3 specifically disclaimed in the '802 Patent. And it's impossible for the
4 combination of Rolf and Wahi to exhibit -- together to exhibit the hold
5 element. Therefore, they can't possibly be combined to produce all the other
6 elements.

7 Now that leaves two grounds left: Ground 1 Chen and Ground 2
8 Baker. And now let's take a look at Baker first, and then we'll get to the one
9 which Judge Franklin was mostly interested in, which is Chen. Now, Baker
10 uses an oil and water liquid nanoemulsion that's applied inside the nasal
11 passages. It's not an external application. In other words, it doesn't go to the
12 skin or tissue of the nasal passages.

13 Baker doesn't teach the electrostatic attraction of the catch
14 function. The harmful particles are already inside the nose. Electrostatic
15 attraction, the catch function outside the nasal passages stationary is not
16 taught either expressly or inherently. Remember, this was the construction
17 -- the claim construction that Petitioner himself indicated, that it was that it
18 is an external application.

19 Baker does not teach us to just a hold element either expressly or
20 inherently. In other words, he doesn't even approach the problem of
21 dislodging. He doesn't teach or suggest holding the microorganism in place.
22 There is no mention of adjusting the adhesion and cohesion of the
23 nanoemulsion to achieve impermeability.

24 And the '802 Patent claims are not obvious over Baker because a
25 person of ordinary skill -- now here is a situation. Person of ordinary skill

1 could possibly foresee the catch and kill function in Baker's nanoemulsion
2 compositions. However, the problem of the microorganism dislodging
3 would be unknown to the person of ordinary skill. It is not either taught or
4 suggested by Baker. It is also not inherent. A person of ordinary skill could
5 not foresee the hold element without first reading the '802 Patent. And that's
6 impermissible hindsight.

7 So now we're going to Chen, which is the most important reference
8 that we're speaking about. Now first of all, Chen does not disclose or teach
9 the hold element. Dr. Park, Petitioner's expert, makes the following
10 statement several times; "Cationic agents attract particulate matter and hold
11 particulate matter in place." And he says this -- the first place he puts it is in
12 paragraph 134. But he has paragraphs throughout his disclosure in which he
13 says that essentially that because you have a cationic agent, it necessarily
14 will attract and hold. And he does that without even -- without setting any
15 basis for his opinion. It does not hold. It attracts it, but it doesn't hold it
16 according to the definition that is provided by the '802 Patent.

17 Now, in anticipation, the hold element is discussed in the '802
18 Patent specification as a solution to a problem of the captured particles
19 dislodging from the applied formulation only to be inhaled. Dr. Park's
20 conclusion is an opinion without providing a basis. Dr. Park's opinion
21 ignores the '802 Patent's use of the hold function to -- the hold element to
22 prevent particles from being dislodged and inhaled. And the hold element is
23 the primary improvement of the '802 Patent. And when you see an element
24 in a claim, it has to be interpreted according to the specification. In other
25 words, you have to consider the specification in interpreting the hold

1 element.

2 Now, Chen does anticipate a viscosity modifier in its composition.

3 And Dr. Park said (INDISCERNIBLE) in the art can adjust the adhesion or
4 cohesion of the composition by adjusting the viscosity. But adjusting
5 viscosity and cohesion are two different things. Viscosity is related to fluid
6 flow. Cohesion is forming a bond between the same or similar material.
7 They're two different things. And while Chen modifies the viscosity of the
8 composition, he does not adjust his cohesion. In Claim 8, addition of a
9 quaternary thickener increases the cohesion by bonding to other ingredients
10 in the formulation. It is not merely viscosity.

11 Now, in Paper 7, Judge Franklin wrote, "The '802 Patent
12 recognizes that other patents have described electrostatically charged
13 compositions that may have been applied externally in the vicinity of the
14 nostril and attract oppositely charged materials that would otherwise be
15 inhaled. However, those patents were all prior inventions by Ashok Wahi.
16 The '802 Patent distinguished from and improved upon these prior patents.
17 It is an improvement patent over the other ones."

18 Now, Judge Franklin also -- I'm in Slide number 50 now. I'm sorry
19 for not giving the slide number as I spoke. Judge Franklin next wrote,
20 "Petitioner contends that logically, the formulations applied to thin film must
21 be on the interior -- exterior region around the nostril, that is the skin, and/or
22 slightly inside the edge of the nostril, which is the tissue of the nasal
23 passages, in order to prevent nasal inhalation. However, Chen does not
24 contemplate this applied to the to the exterior region of the nostril."

25 Slide 51. Chen does not expressly teach electrostatic attraction of

1 harmful particles. That is inherent from his from his from his cationic
2 agents. Chen incorporates several cationic ingredients into his antiviral
3 composition that will establish a positively charged electrostatic field that
4 inherently attracts negatively charged harmful particles. If his composition
5 is applied inside the nostril, it will increase the probability of those harmful
6 particles -- that the harmful particles will be inhaled into the respiratory
7 system. He doesn't teach or suggest or even contemplate external
8 application into the exterior skin or tissue of the nasal passages. And one of
9 the things that Chen does mention is he does mention that it can be a gel, and
10 it can be applied to the skin. But he doesn't mention external application to
11 the nostrils. He applies his composition to the nasal mucosa. This was not
12 something that Wahi contemplated. Now, Chen --

13 JUDGE MITCHELL: Mr. Kremen --

14 MR. KREMEN: Sure.

15 JUDGE MITCHELL: -- Mr. Kremen, show me in the claim where
16 it talks about or where it's required that it be outside the nasal --

17 MR. KREMEN: It's not --

18 JUDGE MITCHELL: -- passage.

19 MR. KREMEN: -- in the claim. It's in the specification. I don't
20 have --

21 JUDGE MITCHELL: Okay.

22 MR. KREMEN: -- the '802 Patent with me. But it's in the
23 specification rather than the claim. It very specifically says that it has to be
24 applied to the skin or where the skin or tissue is, the skin of the nostril or
25 slight or slightly inside the nostril. But it does not -- the product does not go

1 into the nasal mucosa. That would be very detrimental to the product. Now
2 --

3 JUDGE MITCHELL: Okay. Thank you.

4 MR. KREMEN: Now, Chen 110, paragraph 110, the composition
5 of the present invention may be administered to a subject locally. The term
6 local encompasses application in and around the site of the intended
7 treatment. That excludes per oral, in other words, not through the mouth.
8 Exemplary local administration includes, but is not limited to; one, topical
9 application, including the treatment of the human skin, hair, and nail; and
10 two, mucosal application, including the treatment on the nasal mucosa
11 -- mucous membrane. And I won't read the rest of it.

12 Now from Chen 110, while he anticipates applying his antiviral
13 composition to the human skin and the nasal mucus membrane, he does not
14 contemplate applying the composition to the exterior of the nostril to capture
15 airborne viruses, airborne particles, and prevent it from being inhaled. Chen
16 doesn't anticipate implying his composition to the nasal mucosa. But if he
17 does this, the inherent attraction of the airborne viruses will cause them to be
18 inhaled.

19 In paper 7, Judge Franklin wrote, "Petitioner research that Chen
20 described this formulation as providing micro adhesiveness by forming a
21 physical barrier over the mucous membrane." That's fine. But in the '802
22 Patent, the gel is not applied to the mucous membrane. The application to
23 the mucous membrane causes the virus particles to be inhaled. You're not
24 considering having them go to -- the problem is not so much the particles
25 going to the mucous membrane as being inhaled into the respiratory system.

1 Now, on page 17 of paper 7, which is Judge Franklin wrote, "The
2 Petitioner research that Chen's formulation holds the particulate matter in
3 place by adjusting the adhesion to stick to the skin or tissue and by adjusting
4 the cohesion of the formulation to provide adequate impermeability to the
5 thin film as required by the claim. According to Petitioner and Dr. Park,
6 Chen's formulation functions in this way because Chen's cationic age in the
7 formulation attracts particulate matter. And the thin film comprising the
8 cationic agent formulated as a gel, lotion, cream, or ointment holds a
9 particular matter in the film. And it doesn't because there is nothing
10 preventing it from dislodging it, which is the main definition of the hold
11 function.

12 The primary difference between the composition of the '802 Patent
13 and the Wahi '005 is the hold element. Both patents electrostatically catch
14 harmful particles due to their cationic agents attracting these later thin
15 -- their thin films. However, the hold element prevents captured particles
16 from being later dislodged. Petitioner and Dr. Park failed to show how Chen
17 prevents captured particles from being later dislodged. Chen does not
18 implement the hold function of the '802 Patent claims.

19 So therefore the '802 -- the claims in the '802 Patent, each recite
20 the three elements catch, hold, and kill. Without all three elements, there
21 can be no anticipation. Now, Chen employs cationic agents to his
22 formulations. While his formulations attract harmful particles, he does not
23 contemplate external application to the exterior region around the nostril or
24 slightly inside the edge of the nostril. If Chen's liquid gel lotion or cream is
25 applied to the nasal mucosa, the individual would be inhaling the virus

1 particles. Chen is mainly interested in destroying viruses already infecting
2 an individual rather than electrostatically attracting live viruses to its
3 formulation. Without proper application, Chen's formulation will not
4 inherently electrostatically inhibit infection.

5 Chen does not expressly teach electrostatic attraction of viruses.
6 For the catch element to function, the cationic agent must create an
7 electrostatic field that surrounds the person's nose. That requires exterior
8 application to the skin in the vicinity of the nose. Application of Chen's
9 formulation to the mucosa will only perform the kill element on those
10 viruses already inhaled. Chen does not expressly or inherently teach the
11 hold element. No prior art earlier than the '802 Patent expressly or
12 inherently teaches the hold element that prevents captured harmful particles
13 from dislodging and from being inhaled into the individual's respiratory
14 system.

15 The problem was first recognized by Ashok Wahi, and that led to
16 inventing the formulation of the '802 Patent. Claims 1 and 2 expressively
17 recite the catch, hold, and kill function. Claim 3 simply -- implicitly recites
18 the catch, hold, and kill elements. Claim 8 is a formulation claim. The
19 preamble reads license into the claim and is limiting. In Claim 8, the term
20 electrostatically inhibited takes on the same meaning as it does in preamble
21 of Claim 1 and 2 and 3. In Claim 8, the inclusion of the quaternary
22 thickener ingredient is done to adjust the cohesion of the formulation for
23 adequate impermeability.

24 Obviousness. I'm now on Slide 63. A person of ordinary skill -- a
25 fictional individual of ordinary skill who is aware of all prior art in his field

1 and all analogous art. Chen does not expressly or inherently teach
2 anticipation -- application of his composition to the exterior region in the
3 vicinity of the nostril. However, Ashok Wahi's prior patents, notably Wahi
4 '005, do expressly teach this application as well as the catch function. A
5 person of ordinary skill would understand that Wahi '005 already taught the
6 catch function and that Chen could be modified to incorporate it.

7 However, no published art prior to the '802 Patent teaches the
8 either expressly or inherently or even discusses the problem of captured
9 virus particles dislodging from the gel and being inhaled into the respiratory
10 system. Without an understanding of this problem, a person of ordinary skill
11 would not be motivated to modify Chen to include the hold element in its
12 disclosure. Therefore, the claims of the '802 Patent are not obvious over
13 Chen. Patent Owner Trutek has held significant -- now we're getting to the
14 issue of the motion that that Petitioner has filed. Now, one of the things
15 from a factual (CROSSTALK) --

16 JUDGE MITCHELL: Mr. Kremen.

17 MR. KREMEN: Sure.

18 JUDGE MITCHELL: Mr. Kremen, I just wanted to let you know
19 you're going into your rebuttal time and that's fine. I just wanted to let you
20 know you are.

21 MR. KREMEN: Okay. Well, specifically the Patent Owner has
22 had significant commercial success in setting the product protected by the
23 '802 Patent in the United States and worldwide. The secondary
24 consideration should mitigate against obviousness of the '802 Patent claims.
25 And the evidence of commercial success presented to the Board is currently

1 in dispute between the parties and is awaiting the ruling.

2 But the point is that unfortunately I have no excuse for this. This
3 was my first trial, and the submission of evidence was not explained to me.
4 And it's not an excuse. But I presented the evidence of the commercial
5 success in Wahi's declaration in the -- when it was pointed out to me that it
6 was not done in my reply. And I presented the -- to show that factually there
7 was significant commercial success. The '802 Patent product has been sold
8 since 2012, and it has been very successful. Over 15 million tubes of the
9 product have been sold, and it's been sold worldwide. And most of those
10 tubes are not new customers. In other words, there's no 15 million
11 customers for the product. Most of it is repeat business. And the fact is that
12 to overlook this issue of commercial success would not be in the interest of
13 justice.

14 Yes, I could have -- had I realized that it was an issue to provide
15 the evidence rather than just the argument, I would have provided Mr.
16 Wahi's declaration earlier. But there was no intention to waive the issue.
17 That issue was brought up in the preliminary response, and it was brought up
18 in the response to the petition. That was brought up in both things, but it
19 was brought up as an argument. I did provide a -- something showing that
20 the packaging for the airborne particle blocker, nasal guard airborne particle
21 blocker was included in the response to the petition. But basically to ignore
22 the fact that the product was commercially -- very commercially successful.
23 It's still being sold. It's being sold on Amazon as being widely, widely used.
24 I know I use it myself, and it's very effective.

25 Now I agree that the evidence of the clinical study is hearsay, but it

1 shows that the product was originally developed to be able to fight cold and
2 flu. In fact, in the UK it's actually being used for that purpose. It's not FDA
3 approved for that purpose in the United States. But the product was
4 originally tested to determine whether it will fight cold and flu, and it's been
5 very, very successful throughout the world.

6 Now, some of the products, which is in the exhibit that I showed
7 with the packaging, are products that were exhibited before the '802 Patent.
8 For example, there's a Chloraseptic product which was used for allergies,
9 and that was for the '005 Patent. It was no longer sold when the '802 Patent
10 was issued. All products were sold from -- that were sold in the United
11 States would be -- were marked with the '802 Patent number. And the
12 Patent Owner has filed a number of lawsuits that have been made to protect
13 the product. Okay. I'll hold my rebuttal at this point.

14 JUDGE MITCHELL: Thank you. Mr. Kremen --

15 MR. KREMEN: If I still have time left after Petitioner's rebuttal, I
16 would like to continue.

17 JUDGE MITCHELL: Yes. You will have about five and a half
18 minutes.

19 MR. KREMEN: Okay. Thank you.

20 JUDGE MITCHELL: Whenever you're ready.

21 MR. OLDACH: Thank you, Your Honor. I'll just try to briefly
22 respond to some of the points that Mr. Kremen has made in his argument.
23 Concerning Baker and Rolf and even Chen, there is a, I guess, a key dispute
24 as to whether the formulation must or can only be applied externally versus
25 inside the nose. And again, the claim language of the '802 Patent

1 specifically says that this formulation can be applied to skin or tissue of
2 nasal passages. That certainly includes something that could be skin
3 anywhere. I don't think it would be effective if you put it on your elbow.
4 But certainly the skin between one's nose and one's upper lip would be an
5 area that one could apply it.

6 So when we then add or tissue of nasal passages, that supposedly
7 must mean something other than skin. And when we go inside the nose,
8 whether we reach as far as the mucosa level or not, it can certainly be within
9 the nasal passage. So the '802 Patent claims this very broadly. So any
10 reference that refers to this formulation being applied either to the skin or
11 inside the nostril, whether it's just inside or further up, that is going to be
12 covered by that language.

13 Now, Mr. Kremen did refer in his argument to his Slide 14,
14 something we had not touched upon in our initial presentation, but which
15 was covered in our motion or our objections that we filed to his
16 demonstratives, particularly into -- in his Slide 14, he is referring to these
17 facts not in evidence, such as the amount of product that had been sold. And
18 again, looking at his Slide 14, he referred to a number of 15 million tubes.
19 Again, there's not any -- that they've been selling the product since 1995.
20 That fact isn't even in Mr. Wahi's declaration. He only presumably was
21 talking about the '802 products since 2012. He refers to these experiments.
22 The experiments are not in the record anywhere regarding how particles
23 would allegedly become dislodged after contact with the thin film. So again,
24 for this reason, the specific slides we objected to, we certainly maintain
25 those objections.

1 He talks about the hold function. Again, there are several passages
2 in Dr. Park's declaration where he addresses the -- how the cationic polymer
3 will act. So, for example, at Dr. Park's paragraph 301, he says, "The cationic
4 polymer will continually attract the particulate matter and thus hold the
5 particular matter in place." That only makes sense because as long as that
6 field, the cationic substance is present, that as long as the attraction is
7 continuing, it is then therefore going to be holding it. Think of when you
8 catch a baseball, you have to hold it for a period of time for it even to be
9 determined that it is a catch.

10 But what really points that out, and what Mr. Kremen said that I
11 think is very significant here, he was talking about how the specific
12 formulations in the '802 Patent under experiments perform better than the
13 substances that were in the '005 Patent. And I'm just going to pause --

14 JUDGE MITCHELL: Yeah.

15 MR. OLDACH: -- if I ask we pause. Mr. Kremen has gone away.

16 JUDGE MITCHELL: Yeah. I'm sorry. Hold on. Can we see if
17 Mr. Kremen --

18 MR. KREMEN: I'm back.

19 MR. OLDACH: I think he's -- Okay.

20 JUDGE MITCHELL: Okay. Yeah.

21 MR. OLDACH: So I believe, Your Honor, that what Mr. Kremen
22 had said in his argument was that the '005 formulations performed
23 adequately when it came to allergens but did not perform as well with virus.
24 When I hear that is that, in fact, the '005 formulations were holding. They
25 were enough to hold an allergen. They just weren't sufficient to hold a virus.

1 But either way, they're holding because, again, the claims in the '802 Patent
2 don't specifically address viruses. They just broadly claim that they protect
3 against harmful particulates. Harmful particulate matter can include an
4 allergen, or it can include a virus.

5 So what I hear -- when I hear that, I hear that the '005 compositions
6 were holding the harmful particulate matter. It's just that they were holding
7 allergens. They might not have been formulated strongly enough to hold a
8 virus. But again, that's not in the claim. The claim is just harmful
9 particulate matter. And so when we talk about the adequate amount of
10 adhesion and cohesion, again, Dr. Park testifies that these products will
11 perform those functions. But obviously, if you vary the level of
12 concentration in the formulas, it may hold or it may catch more effectively
13 than another product.

14 But the claims here are not expressed in the context of how
15 effectively they perform. They're not expressed in the context of specific
16 concentrations of compounds in the formulation. So Mr. Kremen refers to
17 the tables, to the specific substances that are identified in the '802 Patent.
18 But any specific targeting of concentration ranges for a quaternary thickener
19 or for a cationic agent or for the biocide, they're not recited in the claims. So
20 these claims are exceptionally broad. And I think that's what, frankly, Mr.
21 Kremen is effectively arguing when he says, yeah, the '005 concentrations
22 were enough to hold an allergen. They just weren't enough to hold a virus.
23 So in the '802 Patent, I've increased one thing or another according to the
24 tables that are laid out. But again, the claim doesn't speak to that. The claim
25 just says it performs a hold function. But obviously -- I shouldn't say

1 obviously. It's disclosed in terms of the '005 as Mr. Kremen admits that they
2 were holding allergens. They maybe just weren't strong enough to hold a
3 virus. Should I pause again to see if Mr. Kremen is --

4 JUDGE MITCHELL: Mr. Kremen, can you hear us?

5 MR. KREMEN: I can hear you, and I see myself also.

6 JUDGE MITCHELL: Okay. We just don't want (CROSSTALK)

7 --

8 MR. KREMEN: I don't see the video from anybody else, though.

9 JUDGE MITCHELL: Okay. Proceed, Mr. Oldach.

10 MR. OLDACH: Okay. Thank you. So again, I think that's one of
11 the critical issues. Particularly when you compare the Wahi '005 to the
12 Wahi '802. He also made the point about the examiner during the
13 prosecution history of the '802 Patent, that he initialed the '005 Patent and
14 considered it and did not see the hold function reflected there. But all that
15 does is it speaks to what I said, I think, at the very outset of the argument,
16 which is that Mr. Wahi may not have recognized that his '005 Patent was
17 performing a hold function. And so because the '005 Patent didn't talk about
18 the hold function, when the examiner would review the '005 Patent, he
19 would not see the hold function expressed because it's an inherent property,
20 as Dr. Park has testified. So that explains why the examiner may have
21 allowed the '802 Patent over the '005 Patent. Even though again, inherently
22 those '005 compounds are performing all of those functions.

23 And then just one last note on the business. There's first time we're
24 hearing about the repeat business as being relevant to this commercial
25 success. And the lawsuits, the only one that's in the record here, of course,

1 is the Michigan case with the claim construction ruling. With that, Your
2 Honor, unless the panel has any questions for me, I will yield my time.

3 JUDGE MITCHELL: Thank you.

4 JUDGE JENKS: I do not have any questions.

5 MR. OLDACH: Thank you.

6 JUDGE SNEDDEN: Yeah, none for me either.

7 JUDGE MITCHELL: Thank you.

8 JUDGE JENKS: Thank you.

9 MR. KREMEN: Do I have some rebuttal time?

10 JUDGE MITCHELL: Yes. I'm trying to figure out how to do that.
11 You may begin when you're ready.

12 MR. KREMEN: Thank you. Let's for the moment speak about the
13 Petitioner's objection to Slide 14. And my apologies to the Board. These
14 first statements saying that Trutek has been selling electrostatically charged
15 gel products since 1995, that specifically referred to the '005 Patent. I wasn't
16 trying to use that for commercial -- to demonstration commercial success.
17 But now it is true that the '005 Patent was used primarily for allergens.

18 But the fact that some of the products dislodged and were re-
19 inhaled are not an important thing. Essentially what it does is it alleviates
20 allergies. It doesn't completely prevent them. But one of the things that was
21 found was that particles were being dislodged from the use of the '005. And
22 there was a number of experiments that were performed on that. And the
23 '802 Patent very specifically -- it wasn't that he didn't recognize that there
24 was a hold function. There was no hold function.

25 And the only thing that was there was the fact that the cationic

1 agent attracted the particles to it. But it was the fact that they could not be
2 -- that they could be dislodged was not a factor. In fact very specifically, the
3 fact that they couldn't be -- that the particles were dislodging was very
4 specifically mentioned in the '802 Patent, that that had happened. And that
5 was done -- the only way that Wahi would have known that was
6 experimentally.

7 Now the claim, I agree that the claim did not mention specific
8 concentrations. Claims have to be read in light of the specification. And the
9 claims were -- claims are generally read a little bit broader than you disclose.
10 So essentially the claim -- the hold function in the claim must be read in
11 light of the specification. And it was absolutely defined in the specification
12 on column 3 in the further objects of -- the objects of the invention, saying
13 that it had to be held long so it would not dislodge. Wahi '005 definitely did
14 not exhibit the hold function because -- not even for the allergens.

15 But in the allergens you could tolerate the dislodging and re-
16 inhaling because essentially for allergies, it's a question of the quantity of
17 pollen that's -- or dust that's inhaled. One or two particles is not going to
18 really create that much of a problem. But when you start looking at more
19 infectious materials, it is -- it does create a real problem. I guess that's my
20 entire rebuttal.

21 JUDGE MITCHELL: Great. Thank you so much, Mr. Kremen.
22 And I want to thank you all. This has been very, very helpful. We so
23 appreciate oral argument. We love to be able to ask you questions and sort
24 of kick the tires on things. So we really appreciate your time. And with that
25 we will take the case under advisement.

IPR2024-00711
Patent 8,163,802

1 (Whereupon, the above-entitled matter went off the record at 3:09
2 p.m.)

IPR2024-00711
Patent 8,163,802

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