

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SALVACION USA, INC.,
Petitioner,

v.

TRUTEK CORP.,
Patent Owner

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

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

Inter Partes Review No. IPR2024-00711

PETITIONER'S REPLY

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I. INTRODUCTION

The '802 Patent's claims are anticipated and/or rendered obvious for the reasons set forth in Grounds 1-5 in the Petition (Paper 2). Patent Owner's Response to the Petition (Paper 9) ("Response") fails to fully respond to the Petition and is ineffective at rebutting Grounds 1-5.

Patent Owner has refused to accept Petitioner's claim construction, but instead has offered a claim construction that is incorrect and unsupported by any evidence of record. Similarly, Patent Owner's argument against Ground 1 also lacks any evidence for support.

Notably, Patent Owner has failed to respond to Grounds 2-5 at all in its Response. Instead, rather than arguing against Grounds 2-5 in the body of the Response, Patent Owner has impermissibly attempted to incorporate by reference its Preliminary Response to the Petition (Paper 6) into the Response as its sole effort to rebut Grounds 2-5. Thus, Patent Owner has effectively not rebutted Grounds 2-5.

Patent Owner's Response is wholly ineffective to rebut Petitioner's Grounds, and therefore the Board should find the challenged claims (1- 3 and 8) unpatentable.

II. PETITIONER'S CLAIM CONSTRUCTION IS CORRECT

A. No Evidence Was Offered To Rebut Petitioner's Claim Construction

Petitioner has offered a claim construction for certain terms in the Petition. In its Response, Patent Owner offers no evidence in the record to rebut Petitioner's proposed claim construction, nor to support its own proposed claim construction.

1. Petitioner's Claim Construction

Petitioner's claim construction set forth in the Petition is the same as that adopted by the court in *Trutek Corp. v. Bluewillow Biologics, Inc.*, Case No. 2:21-cv-10312 (E.D. Mich. Feb. 10, 2021) (the "Michigan Litigation") (Ex. 1010 at 22). This IPR and the Michigan Litigation are both subject to the claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

While the full claim construction was set forth in the Petition, the construction of certain claim elements is worth reiterating here as relevant to responding to Patent Owner's arguments.

Biocidic agent. As used in the '802 Patent claims, "biocidic agent" means an agent which has the capacity to neutralize, inactivate, render harmless or kill airborne particles, including microorganisms, for example viruses and/or bacteria. This meaning is consistent with the '802 Patent specification which states:

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

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

(Ex. 1001 at 3:32-40.)

Adequate Impermeability. As proposed by Patent Owner and accepted by the court in the Michigan Litigation:

“Adequate impermeability” refers to the “thin film holding harmful particles in place and inhibiting them from penetrating the thin film and contacting the skin or tissue of an individual’s nasal passages. This is done by varying the concentration of ingredients . . . [,] thereby adjusting the adhesion and cohesion of the thin film.”

(Ex. 1010 at 17.)

In the '802 Patent, the phrase “skin or tissue of nasal passages” means skin in or near the area of the nasal passages or tissue of the nasal passages. The term “skin” itself refers specifically to skin near the nasal passages, because independent claims 1, 2, and 8 all recite that the formulations and method are “for electrostatically inhibiting harmful particulate matter from infecting an individual through *nasal inhalation*.” (Ex. 1001 10:19-21, 10:34-36, 11:1-3 (emphasis added).) Therefore, the formulations must be in or near the nasal passages in order to prevent nasal inhalation.

The object of the invention disclosed in the '802 Patent states that a composition can be readily applied to “the exterior region around the nostril and/or slightly inside the edge of the nostril.” (Ex. 1001 2:62-65, 3:6-7, 3:15-16.) Logically, the formulations applied in a thin film must be positioned on the exterior region around the nostril (*i.e.*, skin) and/or slightly inside the edge of the nostril, which is the tissue of nasal passages, in order to prevent nasal inhalation. (Ex. 1002 ¶71.)

The specification of the '802 Patent provides multiple instances of support for placing the formulation in or near the nasal passages. (*See* Ex. 1001 Abstract (“in close proximity of one or more nostrils”), 1:66-67 (“creating an electrostatic field in an area near about the nasal passages”), 2:63-65 (“applied to the exterior region around the nostril”), 3:47-48 (“creating an electrostatic field in an area near about the nasal passages”).)

Because this claim construction is fully consistent with the specification and the Michigan Litigation, and because, as discussed below, Patent Owner has failed to submit any evidence to the contrary, the Board should adopt Petitioner’s proposed claim construction as set forth in the Petition.

2. Dr. Park, as an Expert, Can Testify as to How the Claims Would Be Construed by a Person of Ordinary Skill

Petitioner has submitted evidence in support of its claim construction and each ground of patentability, including the expert testimony of Dr. Park. As established in the Petition, Dr. Park qualifies as an expert, who by definition has greater than

ordinary skill in the art and can opine on how a person of ordinary skill in the art (“POSITA”) would interpret the claims.

Patent Owner has not disputed that Dr. Park meets or exceeds the qualifications of a POSITA. Indeed, Patent Owner has expressly stated that it “did [not] challenge his qualification of a POSITA” (Response at 4), but instead “challenge[d] Dr. Park’s ability to view Trutek’s technology from the point of view of a POSITA.” *Id.* This challenge must fail under the law.

There is no requirement that an expert match the skill level of a POSITA. “Because the person having ordinary skill in the art is a ‘theoretical construct’ and is ‘not descriptive of some particular individual,’ ‘a person of *exceptional* skill in the art’ should not be disqualified because he or she is ‘not ordinary enough.’” *Norgren Inc. v. Int’l Trade Comm’n*, 699 F.3d 1317, 1325 (Fed. Cir. 2012) (quoting *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997) (emphasis in original)).

Accordingly, Petitioner’s expert Dr. Park, who possesses skills well in excess of the minimum required, is fully qualified to opine on how a POSITA would interpret the claims.

B. The Board Only Needs To Address The Response, And Not Arguments Patent Owner Unsuccessfully Attempted To Incorporate By Reference

Patent Owner improperly attempts to incorporate by reference its Preliminary Response into its Response.¹ *E.g.*, Response at 3 (“Said preliminary response is incorporated by reference in its entirety herein”), 22.

A party is not permitted to incorporate a document by reference in an *inter partes* review. 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document. Combined motions, oppositions, replies, or other combined documents are not permitted.”) This rule was upheld in *Parus Holdings, Inc. v. Google LLC*, 70 F.4th 1365, 1373 (Fed. Cir. 2023).

Thus, the Board should disregard any arguments Patent Owner seeks to incorporate from its Preliminary Response (as Petitioner will do) and confine its consideration to the arguments presented in the Response.

¹ If the Preliminary Response were permitted to be incorporated by reference, this would add 12,247 words to the Response’s 4,368 words totaling 16,615, which exceeds the 14,000 words permitted. 37 C.F.R. § 42.24.

C. The Record Lacks Any Evidence Supporting Patent Owner's Attempt At Claim Construction

Patent Owner attempts to offer an alternative claim construction to Petitioner's but poses only attorney argument, unsupported by any evidence in the record. The Board should therefore disregard Patent Owner's proposed construction.

Patent Owner states on pages 7 and 8 of its Response that "[t]he mechanism used by the '802 Patent's formulations to inhibit infection of individuals due to nasal inhalation utilizes a three step process:...CATCH ... HOLD ...[and] KILL." However, this language does not appear in any of the claims. Moreover, Patent Owner improperly seeks to import limitations from alleged mechanisms of action into the claims limitations that are unsupported and unfounded. For example, Patent Owner's claim construction would require that "[t]he thin film is both sticky and impermeable" and further asserts that "[i]t is important that the harmful particles do not dislodge to be inhaled, but also that they remain in contact with the formulation long enough for the biocidal agent to KILL any living particles." Response at 11. These are invented requirements, not grounded in the claim language, not supported by intrinsic or extrinsic evidence, and unsupported by any expert declaration, technical reference or experimental data in the record.

In the absence of such support, the Board should give no weight to Patent Owner's arguments. The Board should reject Patent Owner's proposed construction

and adopt Petitioner’s construction, which is grounded in the claim language, the specification, and evidence, including expert testimony.

1. No Evidence for Patent Owner’s Proposed Claim Construction for “Catch” Was Provided

Patent Owner contends that “a) electrostatically attracting the particulate matter to the thin film” (Ex. 1001 10:24-25) (referred to as “Claim Element a)”) in claims 1 and 2 should be construed as “catch,” while pointing to no supporting evidence. Further, Patent Owner further attempts to rewrite Claim Element a) by introducing a series of requirements not present in the claims. Specifically on page 10 of the Response, Patent Owner alleges that the claims require: “a *purposeful adjustment* of the positive charge so as to *effectively create* an *electrostatic field surrounding the user’s nose and face that would attract airborne particles that float in the vicinity of the nostrils*.” Response at 10 (emphasis added).

None of these concepts appear in the claim language. Patent Owner’s claim construction would necessitate the addition of at least three new terms to Claim Element a) of claims 1 and 2, even though these terms are absent from the claims. None of the terms “purposeful adjustment of a positive charge,” “electrostatic field” and “surrounding the user’s nose and face that would attract airborne particles that float in the vicinity of the nostrils” is found in the claims. (Ex. 1001 10:24-25, 40-41.) Patent Owner does not provide any evidence – expert declaration, scientific

proof or otherwise – that would justify importing these limitations into Claim Element a) of claims 1 and 2. Response at 7-8.²

In contrast, Petitioner’s expert, Dr. Park, has opined that a POSITA would not interpret Claim Element a) of claims 1 and 2 as requiring “a purposeful adjustment of the positive charge so as to effectively create an electrostatic field surrounding the user’s nose and face that would attract airborne particles that float in the vicinity of the nostrils.” (*See e.g.*, Ex. 1002 ¶¶ 126-130 (discussing how Chen meets the limitation “a) electrostatically attracts the particulate matter to the thin film”).) Dr Park’s testimony is unchallenged by any competing expert declaration, and his interpretation is consistent with the plain claim language and the teachings of the prior art.

- a. The ’802 Patent and the undefined earlier Wahi patents do not require a “purposeful adjustment of the positive charge”

Patent Owner argues that Claim Element a) “electrostatically attracting the particulate matter to the thin film” should be construed to require a “purposeful adjustment of the positive charge ... to create an electrostatic field.” Response at 10.

² In any case, Patent Owner on page 10 of the Response concedes that Chen attracts negatively charged viruses inherently, thus meeting this alleged requirement of “catch.”

In support of this construction, Patent Owner relies not on intrinsic evidence or expert testimony, but vaguely argues that the term has a certain meaning because “Wahi’s earlier patents clearly recite this feature, and the examiner of the ‘271 Application was aware of these patents.” *Id.*

This argument fails for several reasons. First, even if the proposed construction were correct (and Petitioner does not concede that it is), Patent Owner’s own comment that “Wahi’s earlier patents clearly recite this feature” is an admission that this alleged feature of Claim Element a) is anticipated by the prior art. *Id.* By asserting that this element is disclosed in earlier Wahi patents, Patent Owner concedes that the feature is not novel, undercutting any argument that Claim Element a) should be construed to exclude the prior art.

Second, Patent Owner provides no specific citation to support the sweeping statement about some vague earlier Wahi patents. It does not identify the patents to which it refers, nor does it cite any passage within those patents showing the alleged “purposeful adjustment” of charge or the claimed electrostatic effect.

Although Patent Owner references U.S. Patent Nos. 5,468,488; 5,674,481 (“Wahi ’481”); and 6,844,005 (“Wahi ’005”) in an unrelated argument earlier in its Response (Response at 5), if these are the earlier Wahi patents being relied upon, only two of the three patents (Wahi ’005 and ’481) are in the record: Ex. 1007 (Wahi ’005) and Ex. 1009 (Wahi ’481). Neither Wahi ’005 nor Wahi ’481 defines the term

“electrostatically attracting” to mean that an electrostatic field must be “purposefully adjusted,” nor do they ascribe any field strength or effect as required by Patent Owner’s construction. Wahi ’005 and Wahi ’481 do not explicitly define the term “electrostatically attracting,” as used in Claim Element a). Nor does Wahi ’005 or Wahi ’481 discuss a “purposeful adjustment” of an electrostatic field. (*See e.g.*, Ex. 1007 FIG. 2 and 5:39-53; Ex. 1009 FIG. 2 and 6:57-67 (discussing electrostatic fields, but not “purposeful adjustment.”).) Wahi ’005 and Wahi ’481 only generally discuss electrostatic fields and charge density, not Patent Owner’s assertions about electrostatic fields and charge density. (*See, e.g.*, Ex. 1007 FIG. 2 and 5:39-53; Ex. 1009 FIG. 2 and 6:57-67.)

In contrast, Petitioner has offered ample evidence for the construction of Claim Element a). (*See* Petition at 19-20; Ex. 1002 ¶¶ 126-130.)

2. No Evidence for Patent Owner’s Proposed Claim Construction for “HOLD” Was Provided

Claims 1 and 2 of the ’802 Patent include “b) holding[/holds] the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film” (“Claim Element b”).

Patent Owner contends that Claim Element b) requires that “the harmful particles do not dislodge to be inhaled, but also that they remain in contact with the formulation long enough for the biocidal agent to KILL any living particles,” and

that “[t]he HOLD element attribute of the formulation cannot be achieved accidentally.” Response at 11-12. These assertions are nothing more than attorney argument—they are entirely unsupported by any intrinsic or extrinsic evidence. Patent Owner cites no expert testimony, no experimental data, and no specification language that imposes these alleged temporal or intent-based requirements on Claim Element b).

In contrast, Petitioner has offered ample evidence for the construction of Claim Element b).

- a. Inherent properties of compositions may be achieved accidentally (and may or may not be recognized)

Patent Owner’s claim construction argument that the “HOLD” element of the formulation cannot be achieved accidentally is factually flawed. It ignores the well-established principle that inherent properties of compositions exist regardless of whether they are recognized or intentionally designed.³

Patent Owner argues that Claim Element b) requires purposeful intent to achieve the “HOLD” function—in other words, that a person must design or engineer the formulation to “hold” particulate matter in place. However, this is incorrect.

³ Full discussion of inherency is below at Section III.C.

Claims 1 and 2 have a formulation that is applied, and that inherently either “hold[s or does not hold] the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film.” (Ex. 1001 10:26-30 (claim 1) and 10:42-46 (claim 2).) The claim is directed to what the formulation does, not how or why it was intended to do it. No purposeful performance or intent by the inventor is required by Claim Element b) because the formulation either necessarily holds or does not hold the particulate matter; it is an inherent property. The “HOLD” of the formulation exists whether or not the inventor recognizes this. Therefore, Claim Element b) cannot be construed to require that someone intentionally desires the formulation to hold the particulate matter. A formulation’s (inherent) “HOLD” property would fulfill Claim Element b) whether by accident or intent. The relevant question is whether the formulation, once applied, inherently exhibits the claimed functional properties—not whether the formulator subjectively intended to achieve those properties.

The Federal Circuit has consistently held that a product possessing a claimed function or property satisfies a claim limitation, even if the property was unknown or unintended by the inventor or alleged infringer. *See, e.g., In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002) (“[I]f a product, sometimes but not always, possesses a property, that property is inherent.”); *Atlas Powder Co. v.*

IRECO Inc., 190 F.3d 1342, 1348 (Fed. Cir. 1999) (“Inherency may be established even though the property is not appreciated.”).

Thus, Claim Element b) cannot be construed to require that the formulation’s ability to “HOLD” be the result of purposeful intent or design. If the formulation, by its physical properties, inherently adheres to the skin or tissue and provides sufficient cohesion to be impermeable to particulates, then it satisfies the limitation—regardless of whether that result was intended. Accordingly, Patent Owner’s argument should be rejected. The proper construction of Claim Element b) does not include any element of intentionality or purposeful formulation. The Board should accept Petitioner’s construction, which correctly interprets the claim language in light of the inherent nature of physical properties.

3. Patent Owner Did Not Contest Petitioner’s Claim Construction of Claim Element c)

Claims 1 and 2 include, “c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.” (“Claim Element c).”) Patent Owner does not contest Petitioner’s claim construction of Claim Element c). Response at 10-11.

D. Petitioner’s Claim Construction Should Be Adopted By The Board

Patent Owner offers no evidence to support an alleged “CATCH, HOLD, KILL” claim construction requiring a made-up set of add-on requirements including “purposeful adjustment of the positive charge so as to effectively create an

electrostatic field surrounding the user's nose and face that would attract airborne particles that float in the vicinity of the nostrils," Response at 10, and intentionally (not accidentally) having the formulation hold the particulate matter, and "remain in contact ...long enough for the biocidal agent to KILL any living particles." Response at 11-12.

Petitioner has offered more than sufficient evidence cited in the Petition and this reply for Petitioner's claim construction. The Board should therefore adopt Petitioner's claim construction.

III. CHEN ANTICIPATES OR RENDERS THE CLAIMS OBVIOUS, AND NO EVIDENCE HAS BEEN PROVIDED TO REBUT THIS

A. Claims 1-3 And 8 Are Anticipated Or Rendered Obvious By Chen

Chen anticipates claims 1-3 and 8 of the '802 Patent on the grounds set forth in the Petition. In the event that the Board determines that one or more of claims 1-3 or 8 are not anticipated by Chen, then those claims are nevertheless unpatentable as obvious over Chen, as understood by a POSITA as of the Critical Date.⁴

B. Patent Owner Admitted That "Chen's Positively Charged Composition Would Inherently Attract Negatively Charged Viruses"

Patent Owner expressly admits that Chen's formulations are "positively charged" and that this would result in "attraction" to "negatively charged particles."

⁴ Petitioner defines the Critical Date as July 7, 2007, in the Petition. Petition at 6.

Response at 10. This admission confirms that Chen’s formulation “electrostatically attracts the particulate matter to the thin film.” Therefore, Claim Element a) of the claims is met by Chen, and Patent Owner’s argument to the contrary must be rejected.

Patent Owner nonetheless contends that Chen’s formulation does not meet Claim Element a) because there is no “purposeful adjustment of the positive charge so as to effectively create an electrostatic field.” Response at 10. This is irrelevant.⁵ As discussed above, claims 1 and 2 neither recite nor require a “purposeful adjustment of the positive charge so as to effectively create an electrostatic field.” Claim Element a) requires only that the formulation “electrostatically attract the particulate matter to the thin film”—a requirement that, by Patent Owner’s own admission, is satisfied by Chen’s positively charged formulation. The attempt to import subjective intent or design is improper and unsupported.

⁵ While irrelevant, Petitioner notes that Chen disclosed adjustment of the positive charge of the electrostatic field by adjusting the polyelectrolyte concentration. For example, “the concentration of the cationic polymer component (w/w/) may be about 0.001% to about 20%.” (Ex. 1005 at [0037], [0092] and claim 14).

C. Patent Owner’s Argument That Chen Would Not Provide The So-Called “HOLD” Function Is Without Evidence

Patent Owner contends that there is “no indication” that Chen would provide the “HOLD” function of Claim Element b). However, this contention is merely attorney argument, unsupported by any evidence. Patent Owner has not provided any evidence as to why Chen’s formulation would not provide the “HOLD” function. In contrast, Petitioner has provided ample evidence that Chen’s formulation inherently performs the “HOLD” function. Under well-established Federal Circuit precedent, inherent properties of a chemical composition are present regardless of whether they are known or intended.

As discussed in the Manual for Patent Examining Procedure § 2112.01.II:

Products of identical chemical composition can not[sic] have mutually exclusive properties. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

See Southwire Co. v. Cerro Wire LLC, 870 F.3d 1306, 1311-12 (Fed. Cir. 2017); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) (inherent properties of a chemical composition do not require recognition by the inventor). In general, a limitation or the entire invention is inherent and in the public domain if it is the “‘natural result flowing from’ the explicit disclosure of the prior art.” *Id.* at

1377 (quoting *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003)). Here, Chen’s disclosed film necessarily performs Claim Element b), and whether Chen recognized this function or not is irrelevant. (Ex. 1002 ¶¶ 165-169 (claim 1), 131-140 (claim 2).) Chen’s formulation necessarily performs “holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film.” *Id.* Thus, this limitation is met.

Patent Owner’s argument that the ’802 Patent “solved a previously unrecognized problem” and that Chen does not anticipate it because it does not identify or address the problem, Response at 12-13, is legally incorrect. The “new realization” of a previously unappreciated benefit does not confer patentability on an otherwise known composition. *Perricone*, 432 F.3d at 1377; *see Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) (emphasis added).

Petitioner has provided evidence that Chen’s formulation inherently provides “holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film.” (Ex. 1002 ¶¶ 165-169 (claim 1), 131-140 (claim 2).) Accordingly, Chen anticipates Claim Element b), and Patent Owner has failed to provide any evidence to rebut this conclusion.

D. Patent Owner Conceded That Chen Includes A Biocidal Agent Which Deactivates Harmful Particles

Patent Owner admits that Chen anticipates Claim Element c). Response 10-11. Thus, this element is met.

E. Patent Owner's Arguments Regarding Chen Are Not Sufficient To Rebut Ground 1

1. Patent Owner Has Attempted to Confuse the Analysis of Chen by Raising Irrelevant Questions

Patent Owner contends that Chen does not meet the elements of the challenged claims due to FDA approval status, a lack of human testing, Chen's alleged absence of knowledge about whether virus particles would remain lodged on the skin during breathing, and Chen's alleged absence of knowledge of the problem of virus particles dislodging from the composition. Response at 12-13. However, these considerations are irrelevant.

FDA approval and human trials⁶ are not required to establish that a reference is enabling prior art. *See Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1310 (Fed. Cir. 2012) (holding that human testing was not necessary to show that a product was effective as to be an enabling prior art reference); *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326 (Fed. Cir. 2005) (holding that

⁶ Notably the '802 Patent itself does not include FDA approval information or details about human trials.

“proof of efficacy” for a reference is not required for anticipation); *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) (“Title 35 does not demand that such human testing occur.”). Neither FDA approval nor human testing is needed for a POSITA to interpret a prior art reference and recognize any inherent properties of the invention. *King Pharms., Inc. v. Eon Labs., Inc.*, 616 F.3d 1267, 1275-76 (Fed. Cir. 2010) (holding that the benefit of a claimed invention is not patentable if the prior art also inherently provides that benefit—whether or not the prior art recognized that benefit); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (stating that the “results of known processes directed to the same purpose are not patentable because such results are inherent”).

The only evidence offered by either party is Dr. Park’s Declaration, which states that Chen’s invention inherently (accidentally or intentionally, but necessarily) performs all the elements of the challenged claims. (Ex. 1002 ¶¶ 131-140.).

Patent Owner did not rebut Petitioner’s contention or support its own argument with evidence.

2. Merely Stating That Chen’s Gel “Would Have Been Too Dilute to Produce the Effects Presented in ...His Specification,” Is Only Argument, not Evidence

Patent Owner contends that Chen’s gel “would have been too dilute to produce the effects presented in ...his specification.”⁷ Response at 15.

Again, Patent Owner’s contention is merely argument; Patent Owner has not provided any evidence that Chen’s gel would have been too diluted to achieve the results set forth in Chen. To the contrary, Chen expressly teaches that the gels were designed to be viscous. (Ex. 1005 at [0115].) In further contrast to Patent Owner’s unsupported argument, Petitioner has offered evidence that Chen meets each of the claim elements of the challenged claims. (Ex. 1002 ¶¶ 165-169 (claim 1), 131-140 (claim 2).)

3. Stating That Chen Is a Person of Extraordinary Skill in the Art Is not Evidence

Patent Owner contends that Chen “is a person of extraordinary skill in the art” and that even he was unaware of the problem (whether virus particles dislodge from Chen’s gel product) allegedly solved by the ’802 Patent. Response at 16.

⁷ Further, Patent Owner contends that “[w]hile increased cohesion will increase viscosity, the converse is not necessarily true.” Response at 13-14. Again, there is no evidence to support this contention.

This argument fails for the reason that no evidence is offered to support the assertion that Chen is a person of extraordinary skill in the art, nor that Chen, as a person of extraordinary skill in the art, was not aware of the potential issue of virus particles becoming dislodged from a gel. This is just another example of Patent Owner's irrelevant and unsupported attorney argument.

4. A POSITA Would Read Chen and Understand That Adequate Impermeability Was Necessary to Achieve the Antiviral Activity

Patent Owner contends that Chen's formulations do not meet Claim Element b), "holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film," because Chen "would not have been motivated to develop a formulation that would hold the virus particles in place." Response at 15-16. No evidence is offered to support this statement.

In contrast, Petitioner has provided evidence that Chen's teachings included adequate impermeability to achieve antiviral activity. (Ex. 1002 ¶¶ 165-169 (claim 1), 131-140 (claim 2).)

Patent Owner contends that "the only way that a POSITA would envisage the HOLD function [Claim Element b)] is if he or she recognized the necessity of that function." Response at 19. Further, Patent Owner contends (without evidence) that a POSITA would not be motivated to solve the problem allegedly solved by the '802

Patent because Chen supposedly did not know about the problem of virus particles dislodging from a gel. The test is not whether a POSITA envisages the “HOLD” function, but whether the “HOLD” function is necessarily performed. Even if it were true, and substantiated by evidence, that Chen did not recognize that adequate impermeability was required for antiviral activity, this is irrelevant because the inherent properties of Chen’s formulations would solve the problem of “hold[ing] the virus particles in place.” Response at 15-16.

Even if, for the sake of argument, the ’802 Patent were construed to require Chen to know that the “HOLD” function was provided, the ’802 Patent and Chen are directed to the same problem—“preventing or treating virus infection through nasal passages.” (Ex. 1005 at [0111].) Therefore, Chen understood the problem stated in the ’802 Patent, and his invention solved it. Thus, Patent Owner cannot contend that the inventor of the ’802 Patent first recognized the necessity of the “HOLD” function and that therefore Chen did not anticipate it.

Thus, the claims should be found unpatentable as either anticipated or obvious over Chen based on at least Ground 1.

IV. LACK OF EVIDENCE OF SECONDARY CONSIDERATIONS

A. No Evidence Has Been Introduced To Overcome Obviousness With Commercial Success

Patent Owner’s Response includes photographs of an alleged product (never introduced to the record as evidence) purportedly sold since 2012 and states that the

sales of the product “have been very successful.” Response at 21-22. However, these photographs and statements were never introduced as evidence, nor were they accompanied by any sworn declaration, sales data or supporting documentation.

Patent Owner has not submitted any evidence of secondary considerations. Mere attorney arguments and generalized assertions of allegedly successful sales do not constitute evidence of commercial success. Accordingly, there is no evidence that any secondary considerations weigh towards finding the challenged claims of the '802 Patent nonobvious.

Moreover, even if these photographs and assertions were considered, Patent Owner has failed to establish the required nexus between the alleged success and the alleged invention in the '802 Patent. *See Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1363 (Fed. Cir. 2023) (requiring that secondary consideration evidence “must have a ‘legally and factually sufficient connection’ (nexus) to the claimed invention” (quoting *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019))). Here, Patent Owner has not argued, let alone demonstrated, any such nexus exists. Without any evidence of any nexus between the alleged success and the '802 Patent, Patent Owner cannot argue that secondary considerations overcome the obviousness grounds established by Petitioner in the Petition.

V. PATENT OWNER'S RESPONSE HAS NOT PROVIDED ANY ARGUMENTS ADDRESSING GROUNDS 2-5

In addition to Ground 1, Petitioner contends that the challenged claims are unpatentable over Baker (Ground 2), Wahi '005 (Ground 3), Rolf (Ground 4), and Rolf in view of Wahi '005 (Ground 5). Petition at 13. The Board instituted review on all these Grounds, which remain pending. Petitioner has supported each ground with detailed analysis and substantial evidence, including Dr. Park's expert testimony and other exhibits submitted with the Petition.

Patent Owner has failed to refute Grounds 2-5 in its Response, which includes no arguments or evidence contesting Petitioner's Grounds 2-5. Patent Owner has instead improperly attempted to incorporate by reference its Preliminary Response, which is not permitted. However, to the extent that the Board considers Patent Owner's arguments as to Grounds 2-5 presented in its Preliminary Response, Petitioner notes that each of those arguments depends on the same erroneous claim constructions with respect to its so-called "CATCH" and "HOLD" limitations discussed above. Accordingly, Patent Owner's rebutting of these grounds is incorrect, and the Board should hold claims 1-3 and 8 unpatentable on each of these grounds as well.

Accordingly, Petitioner requests that the challenged claims be found unpatentable in light of Grounds 2-5 as well as Ground 1.

VI. CONCLUSION

For all the foregoing reasons, Petitioner respectfully requests that the Board enter a Final Written Decision finding claims 1-3 and 8 of the '802 Patent unpatentable.

Respectfully submitted,

Dated: May 27, 2025

/s/William H. Oldach III

Reg. No. 42,048

Lead Counsel for Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I hereby certify that the foregoing “Petitioner’s Reply” contains 5,525 words as measured by the word processing software used to prepare the document, excluding the parts of the document exempted by 37 C.F.R. § 42.24(a)(1).

/s/William H. Oldach III
Reg. No. 42,048
Lead Counsel for Petitioner

CERTIFICATION OF SERVICE

The undersigned hereby certifies that the above-captioned “Petitioner’s Reply” was served on May 27, 2025, upon the following via email:

uspto@patentsgroup.com
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As well as a courtesy copy to the patent owner’s litigation counsel, by email:

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