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Paper 25
Entered: April 6, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBAL HEALTH SOLUTIONS LLC,
Petitioner Application 15/672,197,[1]
Petitioner,

v.

MARC SELNER,
Respondent Application 15/549,111,[2]
Respondent.

DER2017-00031

Before JAMESON LEE, JAMES T. MOORE, and JONI Y. CHANG, *Administrative Patent Judges*.

LEE, *Administrative Patent Judge.*

DECISION
Institution of Derivation Proceeding
35 U.S.C. § 135(a)

I. INTRODUCTION

A petition alleging derivation of invention was filed on August 11, 2017. Paper 3. Both parties' application claims changed during the course of examination. On January 28, 2022, with authorization from the Board,

[1] Bradley Burnham is the sole named inventor on Petitioner's Application.
[2] Marc Selner is the sole named inventor on Respondent's Application.

and without objection from Respondent, Petitioner filed a "Supplemental Brief." Paper 19. The Supplemental Brief is a "Supplemental Petition" that replaces the initially filed petition in its entirety, such that the petition as originally filed need not be considered in any respect. Paper 18, 2. Hereinafter, we refer to Petitioner's Supplemental Brief/Supplemental Petition simply as "Petition" and cite to it as "Pet."[3]

The parties jointly filed a listing of both parties' pending claims. Paper 17. The list identifies claims 1–10 in Petitioner's Application 15/672,197. *Id.* at 2. It also identifies claims 24–38 in Respondent's Application 15/549, 111. *Id.* at 7–9. However, Respondent's claims 37 and 38 have been cancelled by the Examiner. Ex. 3001. Thus, Respondent has only claims 24–36.

35 U.S.C. § 135(a)(1) reads as follows:

> **(a) Institution of Proceeding.–**
>
> **(1) In General.–**An applicant for patent may file a petition with respect to an invention to institute a derivation proceeding in the Office. The petition shall set forth with particularity the basis for finding that an individual named in an earlier application as the inventor or joint inventor derived such invention from an individual named in the petitioner's application as the inventor or a joint inventor and, without authorization, the earlier application claiming such invention was filed. Whenever the Director determines that a petition filed under this subsection demonstrates that the standards for instituting a derivation proceeding are met, the Director may institute a derivation proceeding.

[3] Petitioner relies on three Declarations, one from inventor Bradley Burnham (Ex. 1011), one from attorney Todd M. Malynn (Ex. 1012), and one from Dr. Eric C. Luo (Ex. 1013).

This panel has authority to institute a derivation proceeding on behalf of the Director. *See* 37 C.F.R. § 42.408(a). The threshold showing for institution of a derivation proceeding is whether the petition demonstrates substantial evidence that, if unrebutted, would support a determination of derivation. 37 C.F.R. § 42.405(c). For reasons that follow, we conclude that Petitioner has made a sufficient showing as to the requirements of 37 C.F.R. § 42.405(b) to warrant institution. Accordingly, pursuant to 35 U.S.C. § 135(a) and 37 C.F.R. § 42.408(a), we institute a derivation proceeding.

II. DISCUSSION

A. Principles of Law

Although a derivation proceeding is a creation of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, § 3(i), 125 Stat. 284 (September 16, 2011),[4] the charge of derivation of invention as a basis for finally refusing application claims and cancelling patent claims had been adjudicated under 35 U.S.C § 135(a) as it existed prior to the enactment of AIA. On the substantive law of derivation of invention, the Board applies the jurisprudence which developed in that context, including the case law of the United States Court of Appeals for the Federal Circuit and the United States Court of Customs and Patent Appeals. *Catapult Innovations Pty Ltd. v. Adidas AG.*, DER2014-00002, Paper 19 at 3 (PTAB July 18, 2014).

[4] Leahy-Smith America Invents Technical Corrections Act, Pub. L. No. 112-274, § 1(e)(1), (k)(1), 126 Stat. 2456 (Jan. 14, 2013).

The threshold showing for institution of a derivation proceeding is whether the petition demonstrates substantial evidence, which if unrebutted, would support the assertion of derivation.[5] 35 U.S.C. § 135(a); 37 C.F.R. § 42.405(c). For establishing derivation, a petitioner must show that the respondent, without authorization, filed an application claiming a derived invention. 35 U.S.C. § 135(a); 37 C.F.R. § 42.405(b)(2). The party asserting derivation must establish prior conception of an invention and communication of that conception to an inventor of the other party. *Cooper v. Goldfarb*, 154 F.3d 1321, 1332 (Fed. Cir. 1998); *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993); *Hedgewick v. Akers*, 497 F.2d 905, 908 (CCPA 1974).

"Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his completed thought expressed in such clear terms as to enable those skilled in the art to make the invention." *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985). A rule of reason applies to determining whether the inventor's testimony has been corroborated. *Price*, 988 F.2d at 1195. "The rule of reason, however, does not dispense with the requirement for some evidence of independent corroboration." *Coleman*, 754 F.2d at 360. Also, proof of conception must encompass all limitations of the invention. *See Singh v. Brake*, 222 F.3d 1362, 1367 (Fed. Cir. 2000); *Kridl v. McCormick*, 105 F.3d 1446, 1449

[5] Substantial evidence is defined as that which a reasonable person might accept as adequate to support a conclusion. *Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006); *see also In re Zurko*, 258 F.3d 1379, 1384 (Fed. Cir. 2001).

(Fed. Cir. 1997); *Sewall v. Walter*, 21 F.3d 411, 415 (Fed. Cir. 1994); *Coleman*, 754 F.2d at 359; *Davis v. Reddy*, 620 F.2d 885, 889 (CCPA 1980).

Likewise, communication of the conception to an inventor of the other party must be corroborated. 37 C.F.R. § 42.405(c) ("The showing of communication must be corroborated."). The purpose of the requirement of corroboration is to prevent fraud. *Berry v. Webb*, 412 F.2d 261, 266 (CCPA 1969). An inventor "must provide independent corroborating evidence in addition to his own statements and documents." *Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed. Cir. 1989); *Reese v. Hurst*, 661 F.2d 1222, 1225 (CCPA 1981).

Also applicable to derivation proceedings are regulations in Subpart E of Part 42 of Title 37, Code of Federal Regulations. 37 C.F.R. §§ 42.400–412. In particular, as noted above, under 37 C.F.R. § 42.405(b)(3), a petitioner has to show that each challenged claim is the same or substantially the same as the invention disclosed by petitioner to the respondent. And under 37 C.F.R. § 42.405(a)(2), a petitioner has to show that it has at least one claim that is (i) the same or substantially the same as the respondent's claimed invention, and (ii) the same or substantially the same as the invention disclosed to the respondent.

Assuming that corroborated conception and communication both are established, and that the regulatory requirements are met, a petitioner would be able to regard as a derived invention those challenged claims of the respondent which are shown by the petitioner to be "same or substantially the same" as petitioner's disclosed invention, i.e., that which was conceived

by petitioner's inventor and communicated to the respondent.[6] *See* 37 C.F.R. § 42.405(b)(3).

B. The Invention Allegedly Conceived and Disclosed by Bradley Burnham

The Petition specifically identifies the invention allegedly conceived by Bradley Burnham and disclosed to Marc Selner as:

> *a stable suspension composition comprising an aqueous phase containing at least one ionic biocide compound dissolved in water in particular amounts, with the aqueous phase suspended as nanodroplets in a petrolatum carrier, and without the composition containing an emulsifier to stabilize the ionic biocide aqueous phase in the hydrophobic petrolatum carrier*.

Pet. 5 (emphasis added). According to Petitioner, this stated invention encompasses a method Bradley Burnham conceived and disclosed to Marc Selner, because "it was not known prior to Burnham's conception and the February 14, 2014 communication of specific method steps whether the stable suspension could be prepared at all." *Id.* at 6. The Petition states: "Since Burnham conceived of the first method of preparing the stable suspension, Burnham is the inventor of the stable suspension as well as the communicated method of preparing the stable suspension." *Id.* at 7.

On the present record, and for purposes of determining whether a derivation proceeding should be instituted, we accept that prior to Petitioner's conception of a method of preparing the suspension, it was not known how such a stable suspension could be made. Specifically, that

[6] "Same or substantially the same" means patentably indistinct, 37 C.F.R. § 42.401, and in this specific context, patentably indistinct is evaluated one-way in the direction from the invention disclosed to the respondent to each challenged claim.

method, as identified by Petitioner (Pet. 6), is the one described in an email sent by Bradley Burnham on February 14, 2014 (Ex. 1028):

> *Place the petrolatum in ingredients of 1kg in a clean stainless steel container. Heat the petrolatum until semi-solid which will appear white not clear (40-45 c). The consistency will be of an almost liquid. Stir constantly if possible once this state is achieved.*
>
> > *1. Add heated (50 c): 25 gm of preservative with 25gm of USP water. *Add the heated liquid slowly while mixing into the petrolatum. 50gm liquid/1kg petrolatum*
> >
> > *2. Mix while cooling slowly until the mixture has reached a solid state. As it cools the mixture will get more solid and whiter.*
> >
> > *3. Fill vessels with mixture immediately above solidified temperature of mixture.*
> >
> > **The liquid is heavier than the petrolatum so it will always go to the bottom. Make sure you continue stirring all the way to the bottom until the mixture has congealed.*
> >
> > *4. Wait 4-6 hours until sealing vessel.*

Ex. 1028, 2 (emphasis added).[7]

Petitioner also identifies an email communication, dated February 7, 2014, which more generally describes the method without any specific temperature or temperature range. Pet. 5. Because Petitioner relies on the specifics of the steps in the email communication of February 14, 2014, in performing its analysis under 37 C.F.R. § 42.405(b)(3), we understand and

[7] Petitioner explains that Burnham's conceived and disclosed method differed from prior unsuccessful attempts to produce the stable suspension in at least two ways: "First, it called for heating the petrolatum to 40–45ºC prior to mixing with the aqueous phase. . . . Second, it called for heating the aqueous phase slightly hotter, to 50ºC, just before adding the aqueous phase to the petrolatum." Pet. 7.

take the method described in the email communication of February 14, 2014, as Petitioner's identification of the method that was conceived by Bradley Burnham and communicated to Marc Seller. Pet. 40–45. However, the email of February 7, 2014, is useful in indicating that the "preservative" mentioned in the email of February 14, 2014, is "PHMB." Exs. 1026, 1028.

Thus, Petitioner identifies the invention Bradley Burnham conceived and communicated to Marc Selner as both the stable suspension and the method reproduced in italics above.

1. Conception

A known ionic biocide liquid, polyhexanide, is referred to as "PHMB." Pet. 13. Petitioner acknowledges that an emulsion comprising PHMB in a petrolatum carrier was not novel. *Id.* Petitioner's invention, however, as stated above, is a "*stable suspension composition comprising an aqueous phase containing at least one ionic biocide compound dissolved in water in particular amounts, with the aqueous phase suspended as nanodroplets in a petrolatum carrier, and without the composition containing an emulsifier to stabilize the ionic biocide aqueous phase in the hydrophobic petrolatum carrier*."

Petitioner relies on Exhibits 1026, 1028, 1041, and 1042 to prove conception of the disclosed invention. *Id.* at 5. Exhibit 1026 purportedly is an email, dated February 7, 2014, sent by Bradley Burnham to a company "Pro-Tech," which would make the suspension according to his instructions, and Marc Selner allegedly was copied on that email. *Id.* Exhibit 1028 purportedly is an email, dated February 14, 2014, sent by Bradley Burnham to Pro-Tech, and, again, Marc Selner allegedly was copied on that email. *Id.*

at 6. Exhibit 1041 purportedly is an email from Bradley Burnham, dated February 28, 2014, to Marc Selner to report the successful production of a stable suspension at Pro-Tech following Bradley Burnham's instructions. *Id.* Exhibit 1042 purportedly is a manufacturing outline from Pro-Tech which Bradley Burnham signed and returned to Pro-Tech to confirm the manufacturing steps carried out by Pro-Tech to make the stable suspension. *Id,*

Exhibits 1026, 1028, 1041, and 1042, constitute sufficient evidence, under the substantial evidence standard, to support Petitioner's assertion of conception, except for the requirement of independent corroboration. For instance, there is no declaration testimony from any of the recipients of the email communications or people who were copied on those email communications to corroborate those email communications. There is no testimony from anyone at Pro-Tech to corroborate the nature and existence of the signed manufacturing outline that is Exhibit 1042.

There is, however, a declaration from Todd M. Malynn, counsel for Petitioner in this proceeding. Ex. 1012. Mr. Malynn represents that he tried to obtain a declaration from Brad Meeuwsen who "was the sales representative at Pro-Tech Design and Manufacturer, Inc. ('Pro-Tech') that interfaced with Bradley Burnham ('Burnham') in connection with Burnham's efforts to manufacture novel antimicrobial gel." *Id.* ¶ 2. Mr. Malynn explained that he was unable to obtain a declaration from Brad Meeuwsen because he was informed by an attorney at Pro-Tech that "Pro-Tech, as a business matter, did not want to divert resources away from its

business, and we would need a subpoena to obtain any documents or testimony from Meeuwsen." *Id.* ¶¶ 3–4.

Mr. Malynn, however, was able to interview Mr. Meeuwsen and learned from Mr. Meeuswen what Mr. Meeuswen would testify to and what documents he would produce in response to a subpoena. *Id.* ¶ 8. Among the things Mr. Meeuswen would testify to is authenticating "his email correspondence with Burnham and other documents related to the project." *Id.* ¶ 8e. Also among the things Mr. Meeuswen would testify to is "[t]o his surprise and relief, Meeuswen recalled that the new production protocol [from Bradley Burnham] seemed to work." *Id.* ¶ 8k. Further among the things Mr. Meeuswen would testify to is his recalling "Burnham completing and returning the Pro-Tech manufacturing documents." *Id.* ¶ 8l.

If a derivation proceeding were instituted, given the testimony of Mr. Malynn discussed above, we may authorize Petitioner to file a motion seeking authorization to apply to a U.S. District Court for a subpoena for Mr. Meeuswen to provide testimony and documents. *See* 35 U.S.C. § 24. Thus, under this unique factual situation, the lack of independent corroboration at this time for the alleged conception of the disclosed invention does not render the Petition insufficient to support institution of a derivation proceeding.

2. Communication

The circumstance with regard to communication of the conception to Marc Seller is essentially the same as that regarding conception as discussed above. Petitioner likewise depends on Exhibits 1026, 1028, 1041, and 1042. Pet. 2, 5, 6. Similar to the circumstance regarding conception, Exhibits

1026, 1028, 1041, and 1042 constitute sufficient evidence, under the substantial evidence standard, to support Petitioner's assertion of communication to Marc Selner of Bradley Burnham's conceived invention, except for the requirement of independent corroboration. However, Mr. Malynn's testimony concerning what Mr. Meeuswen would testify to in response to a subpoena, e.g., authenticating the email correspondences with Bradley Burnham, makes the lack of corroboration at this time not a critical deficiency for the Petition.

C. Petitioner Having at Least One Claim Satisfying 37 C.F.R. § 42.405(a)(2)(i)

Per 37 C.F.R. § 42.405(a)(2)(i), Petitioner must have at least one claim that is "[t]he same or substantially the same as the respondent's claimed invention." Specifically, Petitioner identifies Petitioner's claim 1 and Respondent's claim 36. Pet. 9. In an order dated December 17, 2021, we explained that for this determination under 37 C.F.R. § 42.405(a)(2)(i), "Petitioner need only show one claim in its application that is same or substantially the same as one claim of Respondent, and that the determination is made one-way in the direction from the Petitioner claim to the Respondent claim." Paper 18, 2–3. "Same or substantially the same" means patentably indistinct, 37 C.F.R. § 42.401.

Petitioner's claim 1 reads as follows:

> 1. A stable suspension, comprising water, greater than about 80% by weight petrolatum, and at least one ionic biocide compound, wherein the suspension contains no emulsifier, and all ionic biocide compounds present are either all cationic or all anionic, wherein the at least one ionic biocide is contained within nanodroplets having a diameter of from about 10 nm to about 10,000 nm.

Paper 17, 1.

Respondent's claim 36 reads as follows:

> 36. A non-separating, non-coalescing, non-flocculating stable suspension essentially consisting of water, petrolatum and at least one cationic biocide; and optionally mineral oil, where the at least one ionic biocide is contained within nanovescicles having a diameter of 100 microns or less.

Id. at 9.

A "stable suspension" is "non-separating, non-coalescing, non-flocculating." A suspension "comprising water, greater than about 80% by weight petrolatum, and at least one ionic biocide," and not reciting any other component is one that is "essentially consisting of water, petrolatum and at least one cationic biocide" or at least would have rendered the latter obvious. The phrase "consistently essentially of" permits inclusion of components not listed in the claim, provided that they do not materially affect the basic and novel properties of the invention." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Although Petitioner's claim 1 uses the more open-ended phrase "comprising," it would have been obvious to one with ordinary skill in the art to exclude the presence of materials that would materially affect the basic and novel properties of the stable suspension invention.

Claim 1 recites that all ionic biocide compounds present are either all cationic or all anionic, which would have suggested the at least one cationic biocide of claim 36. The recitation in claim 36 of mineral oil is expressly stated as optional and thus need not be met. The diameter of the nanodroplets of claim 1 ranges from $1x10^{-5}$ to $1x10^{-8}$ meters, which is

completely within the range of the diameter of the nanovescicles of claim 36, i.e., less than $1x10^{-4}$ meters. The former anticipates the latter.

For the foregoing reasons, Petitioner's claim 1 would have rendered obvious Respondent's claim 36. The requirement of 37 C.F.R. § 42.405(a)(2)(i) is met.

D. Petitioner Having at Least One Claim Satisfying 37 C.F.R. § 42.405(a)(2)(ii)

Per 37 C.F.R. § 42.405(a)(2)(ii), Petitioner must have at least one claim that is "[t]he same or substantially the same as the invention disclosed to the respondent." In an order dated December 17, 2021, we explained that for this determination under 37 C.F.R. § 42.405(a)(2)(ii), "Petitioner need show only one claim of Petitioner that is the same or substantially the same as 'the invention disclosed to the respondent,' and that is also a one-way analysis in the direction from Petitioner's claim to 'the invention disclosed to the respondent.'" Paper 18, 3. *See Catapult Innovations Pty Ltd. v. Adidas AG*, DER2014-00002, Paper 19 at 17 (PTAB July 18, 2014). That means the invention disclosed to respondent either must be anticipated by or would have been obvious over a Petitioner claim.

Specifically, Petitioner identifies Petitioner's claim 1. Pet. 39. Petitioner asserts: "all the limitations of Petitioner's Claim 1 are present in Petitioner's invention disclosed to Respondent." *Id.* at 44. Corresponding explanation is provided on pages 39–44 of the Petition. *Id.* at 39–44. For this analysis, Petitioner selected the "method" articulation of the "invention disclosed to the respondent." *Id.*

There are two deficiencies with Petitioner's approach. First, the analysis is in the opposite direction. Petitioner is asserting that the invention

disclosed to the respondent anticipates Petitioner's claim 1, rather than what is required, i.e., the invention disclosed to respondent either must be anticipated by or would have been obvious over a Petitioner claim. Second, it is not true that all the limitations of Petitioner's claim 1 are present in Petitioner's invention disclosed to Respondent. Indeed, Petitioner's claim 1 requires as a component of the suspension "greater than about 80% by weight petrolatum." Petitioner's accounting for that element does not identify anything in the invention disclosed to respondent which satisfies that limitation. *See* Pet. 40–41.

Those deficiencies are inconsequential, because the appropriate analysis is whether claim 1 anticipates or would have rendered obvious the invention disclosed to Respondent. It is manifestly evident, without need of any explanation, that for institution purposes Petitioner's claim 1 anticipates the suspension articulation of the invention disclosed to Respondent:

> *a stable suspension composition comprising an aqueous phase containing at least one ionic biocide compound dissolved in water in particular amounts, with the aqueous phase suspended as nanodroplets in a petrolatum carrier, and without the composition containing an emulsifier to stabilize the ionic biocide aqueous phase in the hydrophobic petrolatum carrier*.

Pet. 5 (emphasis added).

For the foregoing reasons, in this particular situation, the requirement of 37 C.F.R. § 42.405(a)(2)(ii) is met.

E. Showings under 37 C.F.R. § 42.405(b)(3)

Under 37 C.F.R. § 42.405(b)(3), a comparison should be made by Petitioner between each challenged claim and the "invention disclosed to respondent" which in this case has been expressly defined by the Petitioner

in two ways, an articulation in a "suspension" form, and another articulation in a "method" form. Depending on the challenged claim, Petitioner may rely on either articulation. As discussed above, in a derivation proceeding, a challenged claim would be deemed a derived invention under 37 C.F.R. § 42.405(b)(3), if it is the same or substantially the same as the invention Petitioner's inventor conceived and disclosed to a Respondent inventor.[8]

Petitioner asserts that Respondent's claims 24–35 are the same or substantially the same as the invention disclosed to Respondent's inventor Marc Seller. Pet. 50–51. As discussed above in Section B, as identified by Petitioner (Pet. 6), the "method" articulation of the invention disclosed to Respondent is:

> *Place the petrolatum in ingredients of 1kg in a clean stainless steel container. Heat the petrolatum until semi-solid which will appear white not clear (40-45 c). The consistency will be of an almost liquid. Stir constantly if possible once this state is achieved.*
>
> > *1. Add heated (50 c): 25 gm of preservative with 25gm of USP water. *Add the heated liquid slowly while mixing into the petrolatum. 50gm liquid/1kg petrolatum*
> >
> > *2. Mix while cooling slowly until the mixture has reached a solid state. As it cools the mixture will get more solid and whiter.*
> >
> > *3. Fill vessels with mixture immediately above solidified temperature of mixture.*

[8] The Petition makes no showing with respect to Respondent's claim 36 under 37 C.F.R. § 42.405(b)(3). Thus, Petitioner has not, for institution purposes, adequately shown that Respondent's claim 36 is the same or substantially the same as the invention disclosed to Respondent.

> **The liquid is heavier than the petrolatum so it will always go to the bottom. Make sure you continue stirring all the way to the bottom until the mixture has congealed.*
>
> *4. Wait 4-6 hours until sealing vessel.*

And also as discussed above in Section B, the "preservative" is PHMB.

1. Respondent's Claim 24

Respondent's claim 24 reads as follows:

> 24. A method of making a non-separating, non-coalescing, non-flocculating stable suspension comprising combining petrolatum at a temperature about 37ºC to about 45ºC, with a liquid biocide to form nanovesicles of liquid biocide suspended in said petrolatum, said liquid biocide comprising biocide and water mixture, said biocide comprising substantially all cationic molecules or all anionic molecules.

Paper 17, 7–8.

Petitioner explains that a stable suspension is non-separating, non-coalescing, non-flocculating. Pet. 52. The explanation is rational and persuasive at this stage without contrary evidence and argument from Respondent. Thus, the invention disclosed to Respondent is a method of making a non-separating, non-coalescing, non-flocculating stable suspension. The invention disclosed to Respondent includes combining PHMB (a liquid ionic biocide) and water mixture with petrolatum where the petrolatum is at a temperature between 40ºC to 45ºC. The temperature range substantially overlaps with the range recited in claim 24, i.e., 37ºC to about 45ºC. Petitioner explains:

> Because the "about 37ºC to about 45ºC" temperature range recited in Claim 24 overlaps with the optimal 40–45ºC range communicated to Selner, Respondent's claimed range is anticipated by or obvious over Burnham's communicated range and is therefore the same or substantially the same as Burnham's

> communicated heating range, which resulted in the stable suspension composition claimed by Petitioner.

Pet. 51. We agree. Because the 40–45ºC range is completely within the about 37ºC to about 45ºC range, the former anticipates the latter. Further, overlapping range sufficiently supports an obviousness determination, subject to rebuttal. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). Accordingly, the claimed range of about 37ºC to about 45ºC would have been reasonably suggested by the disclosed range of 40–45ºC.

Petitioner explains that PHMB "is a known liquid ionic biocide having a cationic nature" and is the only biocide added in the invention disclosed to the Respondent. Pet. 52 (citing Ex. 1011 ¶ 19). This is sufficient to meet the requirement in claim 24 of "said biocide comprising substantially all cationic molecules or all anionic molecules."

Regarding claim 24's recitation of the intention "to form nanovesicles of liquid biocide suspended in said petrolatum," even assuming that the phrase is limiting, Petitioner makes two contentions both of which we find sufficiently persuasive on the current record. First, Petitioner asserts that to form nanovesicles of liquid biocide suspended in said petrolatum "is inherent to the method communicated to Respondent." Pet. 53. In that regard, Petitioner explains:

> Respondent's application admits that nanovesicles are an inherent feature of the heating method and the use of an ionically charged cationic biocide, stating: "Due to the heat and the ionic charge, these nanovesicles remain separate and do not join or coalesce, due to ionic repulsion forces between neighboring nanovesicles." Ex. 1001, [0009].

Id. Second, Petitioner asserts:

> A POSITA at the time of the invention would understand that a stable suspension would inherently have a vesicle or droplet size of 100 microns or less since that broad range encompasses the entire spectrum of stable suspensions contemplated by a POSITA. Pet., p. 42; Ex. 1013 at ¶¶40–44. As a result, the feature 'to form nanovesicles of liquid biocide suspended in said petrolatum' in Claim 24 is obvious in view of Petitioner's method disclosed to Respondent.

Id. at 54. The assertion is supported by the cited evidence.

For institution purposes, and on the current record, Petitioner has adequately shown that Respondent's claim 24 is the same or substantially the same as the invention disclosed to Respondent.

2. Respondent's Claim 25

Respondent's claim 25 reads as follows: "A method as in claim 24, wherein said petrolatum is at a temperature within the range just above its melting point of approximately 37ºC." Paper 17, 8.

Petitioner explains:

> While Burnham's February 14, 2014 email specified heating the petrolatum to 40–45ºC, Burnham's February 7, 2014 email communicated general information on ointment preparation discussing the use of heat to melt components after which Burnham wrote "[h]eat the PHMB liquid AND the petrolatum . . . [m]ix together at the lowest possible heat to allow complete mixing." Ex. 1026 at 2. Heating at the petrolatum at the lowest possible heat for mixing, at approximately the 37ºC heating range recited in Claim 25, is anticipated by or obvious over the method steps communicated to Respondent. *See Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985). Therefore, Respondent's Claim 25 is the same or substantially the same as Petitioner's communicated invention.

Pet. 55.

We see two problems with Petitioner's approach. First, Petitioner is permitted a coherent and complete articulation of the method disclosed to Respondent, not multiple articulations at different degrees of specificity for Petitioner to switch back and forth as the circumstance requires. It is important to articulate "the invention disclosed to respondent" precisely, to indicate all the specific elements in it, because "the invention disclosed to respondent" is used in multiple analysis of "same or substantially the same" inquiry. Such communication cannot be amorphous and change in the elements encompassed thereby as the need to change arises for Petitioner. Petitioner already identified the specific method described in the email of February 14, 2014, as the invention disclosed to Respondent, and cannot now perform its analysis with a differently stated invention which includes different elements. Second, Petitioner does not adequately explain what is "the lowest possible heat to allow complete mixing." There is no explanation on why that necessarily is just above approximately 37ºC.

Those two problems, however, are inconsequential, because the range specified in the method communicated in the email of February 14, 2014, 40-45ºC reasonably can be deemed as just above approximately 37ºC. Accordingly, for institution purposes, and on the current record, Petitioner has adequately shown that Respondent's claim 25 is the same or substantially the same as the invention disclosed to Respondent.

3. Respondent's Claims 26 and 27

Respondent's claim 26 reads as follows: "A method as in claim 24, wherein said petrolatum is at a temperature within the range of 37ºC to 40ºC." Paper 17, 8. Respondent's claim 27 reads as follows: "A method as

in claim 24, wherein said petrolatum is at about 40ºC." *Id.* The temperature range in the disclosed invention is 40–45ºC, which overlaps the recited range of both claims 26 and 27. The claimed ranges, on this record, would have been obvious over the range disclosed to Respondent. *See Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985). Thus, for institution purposes, and on the current record, Petitioner has adequately shown that Respondent's claims 26 and 27 are the same or substantially the same as the invention disclosed to Respondent.

4. *Respondent's Claim 28*

Respondent's claim 28 reads as follows: "The method of claim 24, wherein all ionic biocide compounds present are all cationic biocides." Paper 17, 8. Petitioner persuasively explains that in the invention disclosed to Respondent, PHMB, a cationic biocide, is the only biocide mixed. Pet. 56 (citing Exs. 1026, 1028–30). For institution purposes, and on the current record, Petitioner has adequately shown that Respondent's claim 28 is the same or substantially the same as the invention disclosed to Respondent.

5. *Respondent's Claim 29*

Respondent's claim 29 reads as follows: "The method of claim 24, wherein all ionic biocide compounds present are all anionic biocides." Paper 17, 8. Petitioner first asserts:

> After disclosing the invention, Burnham shared with Selner the particulars of the FDA monograph and 510(k) systems and discussed with him other ingredients suitable for the invented delivery system, including the use of the anionic biocide sodium hypochlorite that may be used in the stable suspension. Ex. 1011 at ¶49; Ex. 1062; Ex. 1063.

Pet. 56. This assertion, even if true, does not help Petitioner. As we

explained above, the invention disclosed to respondent may not be amorphous, and must be precisely identified by Petitioner with each of its elements such that various analysis of the same or substantially the same invention can be made. Petitioner may not propose a different invention disclosed to respondent when analysis is performed for a different challenged claim like Respondent's claim 29. Petitioner already selected and identified the invention disclosed to Respondent as the method communicated in the email dated February 14, 2014, which does not say anything about using all anionic biocides.

Nevertheless, the above deficiency is inconsequential, because Petitioner, in addition to the above incorrect analysis, still makes the correct analysis. Petitioner explains:

> Further, a POSITA would understand that anionic biocides, as negatively charged compounds, would be just as likely as cationic biocides to form micelles in the petrolatum carrier and just as likely to repulse each other contributing to the stable suspension. Pet., p. 47; Ex. 1013 at ¶55. Additionally, a POSITA would understand that when using ionic biocides in a petrolatum carrier composition, such as the derived composition, the ionic biocides used should be either all anionic or all cationic as using a combination of cationic and anionic biocides could cause the oppositely charged biocides to interact with each other, thereby defeating the repulsion of the miscelles and potentially reducing the stability of the suspension. Pet., p.46–47; Ex. 1013 at ¶56. Therefore, this feature is obvious and not patentably distinct, and Respondent's Claim 29 is the same or substantially the same as Petitioner's communicated invention.

Id. at 57–58. The explanation is supported by the cited evidence.

For institution purposes, and on the current record, Petitioner has adequately shown that Respondent's claim 29 is the same or substantially

the same as the invention disclosed to Respondent.

6. *Respondent's Claim 30*

Respondent's claim 30 reads as follows: "The method of claim 24, wherein the at least one ionic biocide compound is selected from the group consisting of polyhexanide (PHMB), polyaminopropyl biguanide (PAPB), benzalkonium chloride, stearalkonium chloride, and sodium hypochlorite utilizing the salt forms where necessary where necessary to attain an ionic state." Paper 17, 8. PHMB is the ionic biocide used in the method described in the email dated February 14, 2014. Exs. 1026, 1028.

For institution purposes, and on the current record, Petitioner has adequately shown that Respondent's claim 30 is the same or substantially the same as the invention disclosed to Respondent.

7. Respondent's Claim 31

Respondent's claim 31 reads as follows: "The method of claim 30, wherein the at least one ionic biocide compound is a combination of PHMB and benzalkonium chloride, utilizing the salt forms where necessary to obtain an ionic state." Paper 17, 8.

Petitioner explains:

> Additionally, on or before May 2014, to comply with an FDA monograph to commercialize the Disclosed Invention, Burnham conceived of adding benzalkonium chloride (BZK) as a second ionic biocide to the composition, also without an added emulsifier, a composition he shared with Selner, which Selner described as "genius." Pet., p. 48–49; Ex. 1011 at ¶47; Ex. 1032; Ex. 1033. On October 1, 2014, before any dispute arose, Selner admitted that he made the intended commercial embodiment the same way it was disclosed by Burnham (Ex. 1035). Therefore, Respondent's claim 31 is the same or substantially the same as the Disclosed Invention, including its commercial embodiment.

Pet. 59. The above-quoted contention is misplaced. As we explained above in the analysis for claim 25, "the invention disclosed to respondent" is used in multiple analyses of "same or substantially the same" inquiry. It cannot be amorphous and change in the elements encompassed thereby as the need to change arises for Petitioner. Petitioner already selected the specific steps described in the email communication of February 14, 2014, as the invention disclosed to Respondent, and therefore cannot start over with a differently stated set of elements or steps.

What Petitioner should have explained, under 37 C.F.R. § 42.405(b)(3), is how Respondent's claim 31 is either anticipated by or would have been obvious over the method communicated by the email dated February 14, 2014. That analysis, however, has not been provided by Petitioner.

Petitioner has not, for institution purposes, adequately shown that Respondent's claim 31 is the same or substantially the same as the invention disclosed to Respondent.

8. Respondent's Claim 32

Respondent's claim 32 reads as follows: "The method of claim 24, wherein the suspension further comprises at least one nonionic biocide compound. Paper 17, 8.

Petitioner explains: "This dependent claim is likewise derived from Burnham's disclosures to Selner when he was developing products for SteriWeb. *See*, *supra*, Section III, pp. 19–21." Pet. 59. The referenced portion of the Petition cites to paragraph 49 of the Declaration of Bradley Burnham (Ex. 1011). The testimony refers to additional disclosures

subsequent to the email communication dated February 14, 2014. Ex. 1011 ¶ 1049.

As we explained above in the analysis for claims 25, 29, and 31, "the invention disclosed to respondent" is used in multiple analyses of "same or substantially the same" inquiry. The invention disclosed to respondent cannot be amorphous and change in the elements encompassed thereby as the need to change arises for Petitioner. Petitioner already identified as the invention disclosed to Respondent the method described in the email communication of February 14, 2014, and should stay with the particular elements precisely as expressed therein. Accordingly, the above-quoted assertions are unavailing.

This deficiency, however, is inconsequential, because Petitioner, in addition to the above incorrect analysis, still further makes the correct analysis. Petitioner further asserts that it would have been obvious to one with ordinary skill in the art that the invention disclosed to respondent could further include one nonionic biocide. Pet. 59 (citing Ex. 1013 ¶ 58). Petitioner explains: "[C]ompositions of PHMB and other biguanides in petrolatum carrier with surfactants or emulsifiers, were known in the prior art as further including other antibacterial agents, including nonionic biocide compounds such as bacitracin, erythromycin, and others. Pet., pp. 49–50; Ex. 1013 at ¶58; Ex. 1014 at ¶53." *Id.* The assertion is supported by the cited evidence.

For institution purposes, and on the current record, Petitioner has adequately shown that Respondent's claim 32 is the same or substantially the same as the invention disclosed to Respondent.

9. Respondent's Claims 33, 34, and 35

Respondent's claim 33 reads as follows: "The method of claim 24, wherein the suspension further comprises at least one additional medicament." Paper 17, 9. Respondent's claim 34 reads as follows: "The method of claim 33, wherein the at least one additional medicament is a steroid." *Id.* Respondent's claim 35 reads as follows: "The method of claim 34, wherein the steroid is cortisone." *Id.*

Petitioner asserts that it would have been obvious to one with ordinary skill in the art that the method invention disclosed to Respondent "could further include at least one additional medicament, where the medicament is a steroid, and where the steroid is cortisone." Pet. 60 (citing Ex. 1013 ¶¶ 59–60). Petitioner further explains: "For example, compositions of PHMB and other biguanides in petrolatum carrier with surfactants or emulsifiers were known in the prior art as further including other medicaments, such as anti-inflammatory agents, antiviral agents, and antifungal agents, as further including steroidal anti-inflammatory agents, such as cortisone." *Id.* (citing Ex. 1013 ¶¶ 59–60, Ex. 1014 ¶ 53).

The assertions are supported by the cited evidence and we are sufficiently persuaded. For institution purposes, and on the current record, Petitioner has adequately shown that Respondent's claims 33, 34, and 35 are the same or substantially the same as the invention disclosed to Respondent.

III. ORDER

It is

ORDERED that, pursuant to 35 U.S.C. § 135(a), a derivation proceeding is instituted as to claims 24–36 of Respondent's Application 15/549,111;

FURTHER ORDERED that pursuant to 37 C.F.R. § 42.4 (*see* 37 C.F.R. § 42.400(a)), notice is hereby given of the institution of a trial. The trial will commence on the entry date of this Decision; and

FURTHER ORDERED that Petitioner is authorized to obtain a subpoena, pursuant to 35 U.S.C. § 24, from an appropriate United States District Court, to take the testimony of Brad Meeuwsen, where the scope of the testimony to be taken is limited to that proffered in the Declaration of Todd M. Malynn (Ex. 1012).

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Petitioner Application 15/672,197
Respondent Application 15/549,111

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