

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Clean Chemistry, Inc.,
Petitioner,

v.

Enviro Tech Chemical Services, Inc.,
Patent Owner

Review no.: IPR2025-01459

U.S. Patent No. 9,730,443

Issued: August 15, 2017

Filed: March 7, 2016

Inventors: Michael S. Harvey and Jonathan N. Howarth

Title: Methods and Compositions for the Generation of Peracetic Acid on Site
at the Point-of-Use

Petition for *Inter Partes* Review of U.S. Patent No. 9,730,443

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LIST OF EXHIBITS

Exhibit 1001	U.S. Patent No. 9,730,443
Exhibit 1002	Graphical Representation of Priority for U.S. 9,730,443
Exhibit 1003	Complaint in <i>Enviro Tech Chemical Services, Inc. v. Clean Chemistry, Inc.</i>
Exhibit 1004	Service of Complaint
Exhibit 1005	Certified File History of U.S. Patent No. 9,730,443
Exhibit 1006	Claims Pending in U.S. Application No. 15/063,293
Exhibit 1007	U.S. Patent No. 8,546,449
Exhibit 1008	Declaration of Dr. Klibanov in Support of the Petition
Exhibit 1009	U.S. Patent No. 6,387,238
Exhibit 1010	U.S. Patent No. 7,919,122 (“Okano 1”)
Exhibit 1011	EP 0563460
Exhibit 1012	WO 2011/017095
Exhibit 1013	<i>The Condensed Chemical Dictionary</i> , 10th ed., edited by Gessner G. Hawley, Van Nostrand Reinhold Co., New York, 1981.
Exhibit 1014	U.S. 2009/175956 (“Buschmann 1”)
Exhibit 1015	U.S. 2009/314652 (“Buschmann 2”)
Exhibit 1016	U.S. 6,221,341 (“Montgomery”)
Exhibit 1017	EP 1618786 (counterpart to U.S. 7,919,122)
Exhibit 1018	JP 2006-045147 A certified English translation (“Okano 2”)
Exhibit 1019	JP 2006-045147 A Certification of Translation
Exhibit 1020	JP 2006-045147 A (original in Japanese)

I. INTRODUCTION

Clean Chemistry, Inc. (“Petitioner”) petitions for *inter partes* review of all claims (Claims 1-3) of U.S. Patent No. 9,730,443 (“the ‘443 Patent,” Ex. 1001) under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100. The ‘443 Patent lists as the assignee Enviro Tech Chemical Services, Inc. (“Patent Owner”).

This Petition demonstrates that there is a reasonable likelihood that Petitioner will prevail on at least one of the challenged claims. Evidence in this Petition establishes that Claims 1-3 are unpatentable under 35 U.S.C. § 102 and/or §103. Petitioner respectfully requests that this Petition for *inter partes* review be granted and Claims 1-3 of the ‘443 Patent be canceled.

II. MANDATORY NOTICES

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this Petition.

A. Real Party in Interest Under 37 C.F.R. § 42.8(b)(1)

For Petitioner, Black Bay Energy, L.P. is Clean Chemistry, Inc.’s parent, owning 10% or more of Clean Chemistry, Inc.’s stock. There is no publicly held corporation owning 10% or more of Clean Chemistry, Inc.’s stock.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

Regarding related matters under 37 C.F.R. § 42.8(b)(2), Petitioner is concurrently filing or expects to soon file one or more additional petitions for *inter partes* review of three related patents respectively, specifically U.S. Patent Nos.

8,546,449, 9,363,997, and 9,737,072. U.S. 9,363,997 and 9,737,072 are divisionals of the same patent from which the ‘443 Patent is divided, and U.S. 8,546,449 is the grandparent patent. *See* the Graphical Representation of Priority, Exhibit 1002. The Patent Owner has filed a lawsuit alleging that Petitioner infringes the ‘443 Patent, as well as U.S. 8,546,449, U.S. 9,363,997, and U.S. 9,737,072, in *Enviro Tech Chemical Services, Inc. v. Clean Chemistry, Inc.*, Case No. 1:24-cv-1313 (W.D. Tx.), filed on October 29, 2024 (Exhibit 1003, hereinafter the “Parallel Litigation”), and served on January 27, 2025. Exhibit 1004. As already noted, the other patents asserted by the Patent Owner in that lawsuit are related to the ‘443 Patent. *See* Exhibit 1002, the Graphical Representation of Priority.^{1,2}

¹ The four patents in suit are indicated in blue in Exhibit 1002.

² While Petitioner does not believe it relevant to the Petition, for completeness, it is noted that the continuation-in-part, U.S. 10,912,321, is the subject of a lower court invalidity ruling and a pending appeal of that ruling to the Federal Circuit (*Enviro Tech Chemical Services, Inc. v. Safe Foods Corporation*, Appeal No. 2024-2160 (Fed. Cir.)). A declaratory judgment action on the same patent (*Zeco, LLC v. Enviro Tech Chemical Services, Inc.*, Case No. 1:21-cv-00079-CEA-CHS (E.D. Tenn.)) has been administratively closed pending the outcome of the appeal to the Federal Circuit. Three reissue applications (Appln. nos. 18/098,525,

C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner provides the following designation of counsel:

Lead Counsel	Backup Counsel
R. Andrew Patty II (Reg. No. 38,992) drew.patty@phelps.com Phone: 225-376-0284	Mary H. Drabnis (Reg. No. 45,909) mary.drabnis@phelps.com Phone: 225-376-7965
Phelps Dunbar LLP 400 Convention Street, Suite 1100 Baton Rouge, LA 70802 Fax: 225-381-9197	

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service on Petitioner may be made by electronic service by email at ipdocket@phelps.com, or by mail or hand delivery to 400 Convention Street, Suite 1100, Baton Rouge, LA 70802. The fax numbers for lead and backup counsel are shown above. Petitioner also consents to electronic service by email at n.gardiner@cleanchemi.com.

19/239,762 and 19/239,865) with respect to U.S. 10,912,321 have been filed, with 18/098,525 suspended by the Office *sua sponte* on May 8, 2025, for six (6) months, in view of the ongoing appeal to the Federal Circuit.

III. OTHER REQUIREMENTS

A. Payment of Fees Under 37 C.F.R. § 42.103

The undersigned authorizes the Office to charge the total of the fees specified by 37 C.F.R. § 42.15(a)(1) and 42.15(a)(2), to Deposit Account No. 604651.

B. Power of Attorney

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition.

IV. REQUIREMENTS FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.104

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies that the ‘443 Patent is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of the ‘443 Patent on the grounds identified herein. Neither Petitioner, nor any party in privity with Petitioner, (i) has filed a civil action challenging the validity of Claims 1-3 of the ‘443 Patent; (ii) has been served a complaint alleging infringement of the ‘443 Patent more than one year prior to the present date; or (iii) is estopped from challenging the claims on the grounds identified in this Petition.

B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

1. Claims for which *inter partes* review is requested under 37 C.F.R. § 42.104(b)(1)

Petitioner requests *inter partes* review and cancellation of Claims 1-3 of the ‘443 Patent under 37 C.F.R. § 42.104(b)(1).

2. Summary of statutory grounds and prior art on which the challenge is based under 37 C.F.R. § 42.104(b)(2)

All of the claims of the ‘443 Patent are challenged on grounds of 35 U.S.C. § 102 and/or 35 U.S.C. § 103. Petitioner requests cancellation of the challenged claims of the ‘443 Patent on the grounds listed in the table below.

Grounds	Bases	Claim(s)	Prior art
1a-1d	35 U.S.C. §102 and/or §103	1-2	U.S. 2009/175956
2a-2d	35 U.S.C. §102 and/or §103	1-2	U.S. 2009/314652
3	35 U.S.C. §102 and/or §103	1	U.S. 6,221,341
4a-4f	35 U.S.C. §102 and/or §103	1-3	U.S. 7,919,122
5a-5f	35 U.S.C. §102 and/or §103	1-3	JP 2006-045147 A
6a-6c	35 U.S.C. §103	1-3	U.S. 7,919,122 and JP 2006-045147 A

The references deemed to have been cited in the present case were, upon information and belief from the prosecution history, cited in Information Disclosure Statements filed only in the ‘072 Patent’s grandparent, US 8,546,449 (Exhibit 1007).

Although U.S. 2009/175956 was cited to the Office, the Office has not previously considered the arguments presented herein, nor any substantially similar art or arguments, regarding the ‘443 Patent based on this reference.

Although U.S. 7,919,122 was cited to the Office, the Office has not previously considered the arguments presented herein, nor any substantially similar art or arguments, regarding the ‘443 Patent based on this reference.

The Office has not previously considered U.S. 6,221,341 for the ‘443 Patent.

The Office has not previously considered JP 2006-045147 A for the ‘443 Patent.

Each of the specific statutory grounds on which the challenge is based under 37 C.F.R. § 42.104(b)(2) are discussed in detail in Section VI below. This Petition demonstrates at least a reasonable likelihood, based on a preponderance of the evidence (35 U.S.C. § 316(e)), that Petitioner will prevail in establishing that one or more of the claims of the ‘443 Patent are unpatentable.

3. The references on which the challenge is based qualify as prior art

Publication U.S. 2009/175956 is prior art to the 443 Patent. U.S. 2009/175956 was published on July 9, 2009, was filed on January 8, 2009, and claims an earlier priority of January 8, 2008, and qualifies as prior art under 35 U.S.C. § 102. This publication was cited in an Information Disclosure Statement filed in the

grandparent application (now U.S. 8,546,449) on May 10, 2012. This reference was not applied during the pendency of the application that matured into the '443 Patent.

Publication U.S. 2009/314652 is prior art to the 443 Patent. U.S. 2009/314652 was published on December 24, 2009, was filed on March 19, 2009, and claims an earlier priority of March 19, 2008, and qualifies as prior art under 35 U.S.C. § 102. This publication was cited in an Information Disclosure Statement filed in the grandparent application (now U.S. 8,546,449) on May 10, 2012. This reference was not applied during the pendency of the application that matured into the '443 Patent.

Patent U.S. 6,221,341 is prior art to the '443 Patent. U.S. 6,221,341 was filed on November 19, 1998, claims an earlier priority date of November 19, 1997, and issued on April 24, 2001. This reference was not cited or applied during the pendency of the application that matured into the '443 Patent.

Patent U.S. 7,919,122 is prior art to the '443 Patent. U.S. 7,919,122 was filed on July 10, 2006, as a National Stage entry of a PCT application filed on April 1, 2004, claiming a priority date of April 2, 2003. The PCT application was published as WO 2004/08089 on October 21, 2004. U.S. 7,919,122 published on November 29, 2007, as U.S. 2007/274857. This patent was cited in an Information Disclosure Statement filed in the grandparent application (now U.S. 8,546,449) on May 23, 2013. This reference was not applied during the pendency of the application that matured into the '443 Patent.

Publication JP 2006-045147 A is prior art to the ‘443 Patent. JP 2006-045147 A was filed on August 6, 2004, and was published on February 16, 2006. This reference was not cited or applied during the pendency of the application that matured into the ‘443 Patent.

V. SUMMARY OF THE ‘443 PATENT

A. Effective Filing Date of the ‘443 Patent

The ‘443 Patent issued from U.S. Patent Application No. 15/063,306, filed on March 7, 2016. The ‘306 Application is a divisional of U.S. Patent Application No. 14/019,296, filed on September 5, 2013, now U.S. Patent No. 9,370,180, which in turn is a divisional of U.S. Patent Application No. 13/065,553, filed on March 26, 2011, now U.S. Patent No. 8,546,449. As noted above, a Graphical Representation of the relationship of these patents is set forth in Exhibit 1002.

For the purposes of this proceeding, Petitioner has assumed that the earliest effective filing date of the ‘443 Patent is March 26, 2011. Therefore, pre-AIA statutes should apply to this proceeding.

Petitioner notes that although the box on the Application Data Sheet for the “Statement under 37 CFR 1.55 or 1.78 for AIA Transition Application” was not checked, and that the Filing Receipt and both Corrected Filing Receipts indicated “No” for the Statement under 37 CFR 1.55 or 1.78 for AIA Transition Application purposes, the Image File Wrapper and the Office Actions in the application indicate

that the application that matured into the '443 Patent was an AIA application. This was not challenged in the Responses to the Office Actions.

The prior art applied in this Petition qualifies as prior art under both pre-AIA and post-AIA 35 U.S.C. §§ 102 and 103.

B. Summary of the Technology

By way of background, peroxyacetic acid, commonly called peracetic acid, is a known disinfectant with application in many areas, including food processing and medical equipment. Exhibit 1009, col. 1, lines 20-28. Unlike hypochlorite biocides, peracetic acid does not corrode metals. Exhibit 1010, col. 1, lines 23-24.

Peracetic acid can be prepared from acetic acid and hydrogen peroxide. Exhibit 1009, col. 1, lines 29-31. Other preparation methods include oxidation of acetaldehyde. Exhibit 1010, col. 1, lines 47-51. Another method is to react hydrogen peroxide with an organic peracid precursor selected from glycol esters and glycerin esters. *See* Exhibit 1011, Page 2, lines 23-25, wherein triacetin is listed as one of the glycol esters. Exhibit 1011, Page 3, lines 55-56.

C. The '443 Patent

The '443 Patent describes methods for generating peroxyacetic acid from aqueous hydrogen peroxide, triacetin, water, and an aqueous source of an alkali metal hydroxide or earth alkali metal hydroxide. Exhibit 1001, abstract. The claims of the '443 Patent recite a non-equilibrium solution of peracetic acid. Exhibit 1001.

There are three claims in the ‘443 Patent. Claim 1 is the only independent claim. Claims 2 and 3 depend from Claim 1. Exhibit 1001, col. 35, lines 13-25.

D. The ‘443 Patent’s Prosecution History

The ‘443 Patent as originally filed had three claims. Exhibit 1005, Page 82. On January 30, 2017, the Examiner issued a nonfinal Office Action, provisionally rejecting Claims 1-3 for obviousness-type double patenting over Claim 5 or 6 of co-pending Application No. 15/063,293 (now U.S. Patent No. 9,737,072). Exhibit 1005, Pages 120-121; Exhibit 1006.³ Claim 5 of the ‘293 Application was a product-by-process claim directed to a non-equilibrium solution of peracetic acid and Claim 6 of the ‘293 Application was directed to a system for generating non-equilibrium peracetic acid.

The rejection stated that the conflicting claims were not patentably distinct, reasoning that the rejected claims are directed to “a non-equilibrium solution of peracetic acid comprising peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol and alkali metal or earth alkali metal hydroxide,” while Claims 5 and 6 of the ‘293 Application claim “a non-equilibrium solution of peracetic acid or its

³ Claims 5 and 6 of the ‘293 Application were cancelled by an Examiner’s amendment accompanying the Notice of Allowance in the ‘293 Application. See Exhibit 1002 for the relationship between the ‘072 Patent and the ‘443 Patent.

generation system comprising peracetic acid, hydrogen peroxide, triacetin, and alkali metal or earth alkali metal hydroxide.” Exhibit 1005, Page 121.

The Office Action stated that “The difference between instant claims and Harvey et al. ‘293 is that Harvey et al. ‘293 is silent on the instant element 1,2,3-propanetriol, reasoning that “Harvey et al. ‘293 solution or composition inherently overlap with the instant invention.” Exhibit 1005, Page 121. In a Response filed on March 7, 2017, the Applicant filed a Terminal Disclaimer over Application No. 15/063,293. Exhibit 1005, Page 131. No arguments were presented in the Response regarding the Examiner’s reasoning.

On May 10, 2017, the Examiner issued a Notice of Allowance, allowing Claims 1-3. Exhibit 1005, Pages 158 and 163.

The ‘443 Patent issued on August 15, 2017.

E. Person of Ordinary Skill in the Art

A person of ordinary skill in the art in the field of the ‘443 Patent on March 26, 2011, would have had at least a bachelor’s degree in chemistry, chemical engineering, or the equivalent, and two or more years of relevant work and/or practical experience in chemical syntheses, or equivalent knowledge and work experience. Exhibit 1008, paragraph 16.

Dr. Alexander M. Klibanov meets at least these criteria and concurrently submits a Declaration (Exhibit 1008) under 37 C.F.R. § 1.68 in support of this Petition.

F. Claim construction under 37 C.F.R. § 42.104(b)(3)

How the challenged claim(s) are to be construed under 37 C.F.R. § 42.104(b)(3) is detailed herein.⁴

In this proceeding, the claims must be construed in accordance with their ordinary and customary meaning as understood by one of ordinary skill in the art and the prosecution history. 37 C.F.R. §42.100(b). Inventors can also be their own lexicographers. *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007).

Per the Memorandum setting forth an “Approach to Indefiniteness in Under 35 U.S.C. § 112 in AIA Post-Grant Proceedings” issued by the Director of the U.S.

⁴ Construction of the claims is currently the subject of briefing prior to the *Markman* hearing in the parallel litigation pending in *Enviro Tech Chemical Services, Inc. v. Clean Chemistry, Inc.*, Case No. 1:24-cv-1313 (W.D. Tx.) However, the constructions proposed herein are believed to be no broader than is reasonably possible and, in any event, the analyses of patentability set forth herein would continue to apply under any reasonable alternative constructions.

Patent and Trademark Office on January 6, 2021, available at <https://www.uspto.gov/sites/default/files/documents/IndefinitenessMemo.pdf>, the claims are to be construed as they are in district courts, using the standard set forth by the Supreme Court in its decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). Indefiniteness Memorandum, pgs. 1-2. Under the *Nautilus* standard, claims are definite when “a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus* at 910.

Indefiniteness “does not necessarily preclude the Board from addressing the patentability of the claims on section 102 and 103 grounds.” *Samsung Elecs. Am. Inc. v. Priusa Eng’g Corp.*, 948 F.3d 1342, 1355 (Fed. Cir. 2020); *see also Intel Corp. v. Qualcomm Inc.*, 21 F.4th 801, 813 (Fed. Cir. 2021) (“The indefiniteness of a limitation ... precludes a patentability determination only when the indefiniteness renders it logically impossible for the Board to reach such a decision.”). *Shenzhen Pincan Technology Co., Ltd v. Ridge Wallet, LLC*, IPR2024-00340, Paper 18, 16 (PTAB July 12, 2024).

The claim terms “hydrogen peroxide,” “water,” and “pH” as used in the ‘443 Patent are not separately defined in the ‘443 Specification and have their plain and ordinary meanings.

1. “Non-equilibrium solution of peracetic acid”

Claim 1 recites a “non-equilibrium solution of peracetic acid.” This phrase is not clearly defined in the Specification.

Because it is not clearly defined in the Specification of the ‘443 Patent, the phrase “non-equilibrium solution of peracetic acid” is taken to have its plain and ordinary meaning for purposes of this Petition only. As one of skill in the art knows, an equilibrium solution is one in which the concentrations of the components do not change over time. Exhibit 1008, paragraph 51. Those of skill in the art understand that in an equilibrium solution, the starting materials continually form product, while some of the product formed continually re-forms the starting materials at a rate that does not change the concentrations of the components of the solution. Exhibit 1008, paragraph 51. In non-equilibrium solutions, the concentrations of the components change over time and/or the product formed does not re-form the starting materials, i.e., the reaction is irreversible. Exhibit 1008, paragraph 51.

For purposes of this *inter partes* review only, the phrase “non-equilibrium solution of peracetic acid” is interpreted as a solution of peracetic acid that is not at equilibrium under a given set of conditions, because the concentrations of the components, including peracetic acid, are changing over time, and/or because the reaction is irreversible.

Petitioner submits that the interpretation that a “non-equilibrium solution of peracetic acid” as a solution that is not at equilibrium under a given set of conditions is clear enough to permit the Board to review the claims of the ‘443 Patent on the grounds set forth below. Petitioner is willing to adopt the construction of the phrase “non-equilibrium solution of peracetic acid” to mean a solution that is not at equilibrium under a given set of conditions for the purposes of *inter partes* review only.

2. “Peracetic acid”

The Specification of the ‘443 Patent specifically defines “peracetic acid” where it states that “[t]he terms ‘PAA’ and ‘peracetic acid’ mean peroxyacetic acid or peracetic acid, and/or the conjugate base of peracetic acid (the peracetate ion).” Exhibit 1001, col. 7, lines 59-61.

3. “Triacetin”

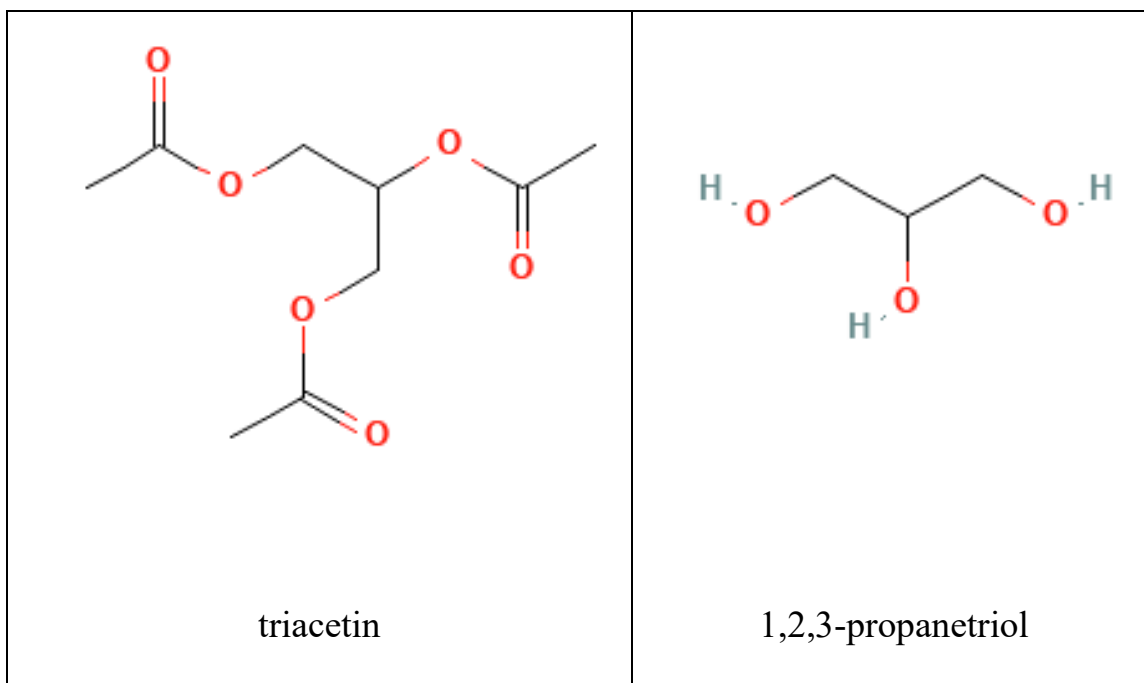
Triacetin is not defined in the Specification of the ‘443 Patent. Triacetin is a common name for a known molecule and is “synonymous with glycerin triacetate; glycerol triacetate; glyceryl triacetate; 1,2,3-triacetoxyp propane; 1,2,3-propanetriol triacetate; and all other synonyms of CAS Registry Number 102-76-1.” Exhibit 1012, Page 7, lines 26-28.

4. “1,2,3-Propanetriol”

The Specification of the ‘443 Patent makes clear that 1,2,3-propanetriol is another name for glycerin (sometimes referred to as glycerine), stating at col. 16,

lines 11-13, “When the acetyl precursors is triacetin, the product of the perhydrolysis reaction is 1,2,3-propanetriol (glycerine).” Exhibit 1001. This is consistent with synonyms for triacetin described above (e.g., glycerin triacetate). Another synonym for 1,2,3-propanetriol is glycerol, which again is consistent with synonyms for triacetin described above (e.g., glycerol triacetate).

For completeness, the structures of triacetin and 1,2,3-propanetriol are shown below.



5. “An aqueous source of an alkali metal or earth alkali metal hydroxide”

The phrase “an aqueous source of an alkali metal or earth alkali metal hydroxide,” by itself, given its plain and ordinary meaning, refers to a mixture of water and an alkali metal hydroxide or an earth alkali metal hydroxide, or a mixture

of water and a substance that releases an alkali metal hydroxide or an earth alkali metal hydroxide into the water.

In the context of the claimed peracetic acid solution, the phrase “an aqueous source of an alkali metal or earth alkali metal hydroxide” appears in the ‘443 Patent, reading:

The non-equilibrium solutions of PAA prepared by this method comprise PAA, unreacted hydrogen peroxide, unreacted acetyl precursor, the product of the perhydrolysis reaction of the acetyl precursor, the aqueous source of alkali metal or earth alkali metal hydroxide, and water.

Exhibit 1001, col. 16, lines 7-11, and col. 17, lines 61-65. No further definition or explanation of the phrase “an aqueous source of an alkali metal or earth alkali metal hydroxide” is provided in the ‘443 Patent’s Specification. From what is set forth, the phrase appears to mean an alkali metal hydroxide or an earth alkali metal hydroxide in the claimed solution.

Petitioner submits that the interpretation that of the phrase “an aqueous source of an alkali metal or earth alkali metal hydroxide” means an alkali metal hydroxide or an earth alkali metal hydroxide in the claimed solution is clear enough to permit the Board to review the claims of the ‘443 Patent on the grounds set forth below. Petitioner is willing to adopt the construction of the phrase “an aqueous source of an alkali metal or earth alkali metal hydroxide” to mean an alkali metal hydroxide or

earth alkali metal hydroxide in the claimed solution for the purposes of *inter partes* review only.

6. “1%” and “7.1%”

Claim 3 recites “The solution of claim 1, wherein said peracetic acid is about 1% to about 7.1%.” The basis for the percentage is not specified in the claim. The Specification of the ‘443 Patent states that “[t]he terms ‘percent’ and ‘%’ mean weight percent, except when referring to the percent converted.” Exhibit 1001, col. 7, lines 62-63. Claim 3 does not appear to refer to a percent converted, and so presumably refers to a weight percent of peracetic acid in the claimed solution (i.e., a weight percent that is based upon the total weight of the claimed solution). This is corroborated in the Specification of the ‘443 Patent, which refers to “solutions with a high level of PAA, from about 1% to about 7.1%.” Exhibit 1001, col. 6, lines 44-45.

V. DETAILED EXPLANATION OF THE CHALLENGE UNDER 37 C.F.R. § 42.104(B)

The construed claims are unpatentable under 37 C.F.R. § 42.104(b)(4), for at least the grounds detailed below.

A. Grounds 1a-1d: Claims 1-2 are anticipated by and/or obvious over U.S. 2009/175956 (“Buschmann 1”)

1. Ground 1a – Claim 1 of the ‘443 Patent is anticipated by Buschmann 1

U.S. 2009/175956 (“Buschmann 1”) is directed to compositions and methods for production of peroxy-carboxylic acid solutions or various disinfection and cleaning compositions that utilize non-equilibrium peroxy-carboxylic acid, specifically peracetic acid. Exhibit 1014, Abstract. Buschmann 1 discloses that “alkaline hydrogen peroxide can be produced electrochemically on-site and then mixed with triacetin or other acetyl donor to produce an alkaline mixture of **non-equilibrium PAA, hydrogen peroxide, triacetin**, and glycerol.” Exhibit 1014, paragraph 0030. As noted above, glycerol is another name for **1,2,3-propanetriol**. Buschmann 1 also discloses that “non-equilibrium peroxy-carboxylic acid solutions, particularly those of PAA” are produced “in a solvent such as, but not limited to, **water**.” Exhibit 1014, paragraph 0033. Buschmann 1 further states that “The reaction pH can be adjusted with an appropriate base (proton acceptors such as **hydroxide** or amines for example).” Exhibit 1014, paragraph 0033. Sodium hydroxide is disclosed as a base in Buschmann 1. Exhibit 1014, paragraphs 0034 and 0041.

The alkaline mixture described in U.S. 2009/175956 is a non-equilibrium solution of peracetic acid, and contains all of the components listed in Claim 1:

peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol (glycerol), an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide (i.e., sodium hydroxide), and water. Exhibit 1008, paragraph 88. Therefore, Buschmann 1 clearly anticipates Claim 1.

2. Ground 1b – Claim 1 of the ‘443 Patent is obvious over Buschmann 1

While the disclosures of Buschmann 1 described above show that Claim 1 is anticipated, Claim 1 is also obvious in view of the disclosures in Buschmann 1. Exhibit 1008, paragraph 59. It would have been obvious to one of ordinary skill in the art that water is present in the solutions of Buschmann 1 because water is expressly disclosed as a solvent in Buschmann. Exhibit 1008, paragraph 74. Further, it would have been obvious to one of ordinary skill in the art that the hydroxide can be an alkali metal hydroxide or an earth alkali metal hydroxide because Buschmann 1 discloses that the hydroxide can be sodium hydroxide. Exhibit 1014, paragraphs 0034 and 0041. Claim 1 of the ‘443 Patent is therefore obvious over Buschmann 1. Exhibit 1008, paragraph 89.

3. Ground 1c – Claim 2 of the ‘443 Patent is anticipated by Buschmann 1

Claim 2 of the ‘443 Patent recites “a pH of about 11.2 to about 13.37” for the solution of Claim 1. Buschmann 1 discloses that

non-equilibrium peracetic acid (PAA) is produced by reacting a properly chosen acetyl donor with hydrogen peroxide under alkaline conditions (pH greater than about 10) to produce non-equilibrium PAA.

Exhibit 1014, paragraph 0027. In a description of an exemplary non-equilibrium peracetic acid preparation solutions, the pH was “adjusted to pH 12.0 with sodium hydroxide.” Exhibit 1014, paragraphs 0034 and 0041.

As established above for Claim 1, Buschmann 1 discloses solutions containing non-equilibrium PAA, hydrogen peroxide, triacetin, glycerol, a hydroxide, and water. Exhibit 1008, paragraph 94. Buschmann 1 also discloses that these solutions can have a pH greater than about 10, and in exemplary solutions, a pH of 12.0. Exhibit 1014, paragraphs 0034 and 0041. Buschmann 1’s pH value of 12.0 falls within the range in Claim 2. Exhibit 1008, paragraph 93. Therefore, Buschmann 1 anticipates Claim 2 of the ‘443 Patent.

4. Ground 1d – Claim 2 of the ‘443 Patent is obvious over Buschmann 1

While Claim 2 is anticipated by the disclosures of Buschmann 1 as described above, Claim 2 is also obvious in view of the disclosures of Buschmann 1. Buschmann 1 renders obvious non-equilibrium solutions of peracetic acid containing peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water as discussed above for Claim 1. Exhibit 1008, paragraph 96.

The Specification of the '443 Patent does not disclose criticality or unexpected results for the endpoints of the pH range recited in Claim 2.

Buschmann 1 discloses alkaline pH values greater than about 10 for producing non-equilibrium PAA. Exhibit 1014, paragraph 0027. Buschmann 1 discloses a “self-reaction decomposition process at alkaline pH ($7.5 \leq \text{pH} \leq 10.5$)” for peracetic acid. Exhibit 1014, paragraphs 0038, 0039 and 0040. This self-decomposition reaction of peracetic acid is undesired, as indicated by the disclosure of methods for inhibiting the self-decomposition reaction. Exhibit 1014, paragraphs 0039 and 0040. A person of ordinary skill in the art would have understood from these disclosures that a pH of 10.5 or higher provides an alkaline pH for peracetic acid formation while minimizing or avoiding self-reaction decomposition for peracetic acid. Exhibit 1008, paragraph 97.

A person of ordinary skill in the art would have recognized that pH is a result-effective variable that can be optimized through routine experimentation, and would have been motivated to do such optimization, because Buschmann 1 discloses that pH affects the formation of peracetic acid, Exhibit 1014, paragraph 0027, and that peracetic acid's shelf stability and self-reaction decomposition reaction are pH-dependent, Exhibit 1014, paragraph 0039. Exhibit 1008, paragraph 98.

As discussed above, the solutions in Buschmann 1 are aqueous solutions. Exhibit 1014, paragraph 0024. A person of ordinary skill in the art knows that the

highest attainable alkaline pH in aqueous solution is 14. Exhibit 1008, paragraph 99. From the disclosures in Buschmann 1, one of ordinary skill in the art would have recognized that the alkaline pH values in the solutions therein have a possible range of above 10 to 14, or from 10.5 to 14. Exhibit 1008, paragraph 99. Finding an optimal pH range within these parameters would have been a motivating factor for, and routine experimentation within the capability of, a person of ordinary skill in the art, and one of ordinary skill would have been motivated to undertake such routine experimentation. Exhibit 1008, paragraph 99.

In Claim 2, the lower endpoint of the pH range, 11.2, is alkaline (greater than 10) as taught in Buschmann 1 for the formation of peracetic acid. Exhibit 1014, paragraph 0027; Exhibit 1008, paragraph 100. The lower endpoint of the claimed pH range is also above the pH range in which the self-reaction decomposition of peracetic acid occurs ($7.5 \leq \text{pH} \leq 10.5$). Exhibit 1014, paragraph 0040. Exhibit 1008, paragraph 100.

Therefore, to a person of ordinary skill in the art, the claimed pH range, about 11.2 to about 13.37, would be nothing more than routine optimization from the disclosure of Buschmann 1, which a person of ordinary skill would have been motivated to undertake at least to prevent self-decomposition of peracetic acid, and therefore Claim 2 would have been obvious to one of ordinary skill in the art. Exhibit 1008, paragraph 101.

B. Grounds 2a-2d: Claims 1-2 are anticipated by and/or obvious over U.S. 2009/314652 (“Buschmann 2”)

1. Ground 2a – Claim 1 of the ‘443 Patent is anticipated by Buschmann 2

U.S. 2009/314652 (“Buschmann 2”) is directed to methods, systems, and reactors for production of peroxy-carboxylic acid solutions or various disinfection and cleaning compositions that utilize non-equilibrium peroxy-carboxylic acid, specifically peracetic acid. Exhibit 1015, Abstract. Buschmann 2 discloses that “**non-equilibrium peracetic acid solutions** can be chemically produced by an *irreversible*, non-equilibrium reaction of **hydrogen peroxide** with an acetyl donor in a solvent such as, but not limited to, **water**.” Exhibit 1015, paragraph 0074.

Buschmann 2 also discloses that “There are a large number of known acyl or acetyl donors including, but not limited to, diacetin, **triacetin**, acetylsalicylic acid, tetraacetylenediamine.” Exhibit 1015, paragraph 0026. Hydroxides are disclosed as bases in Buschmann 2: “The reaction pH can be adjusted with an appropriate base (proton acceptors such as **hydroxide** or amines for example).” Exhibit 1015, paragraph 0074. Sodium hydroxide is disclosed as a base in Buschmann 2. Exhibit 1015, paragraphs 0077 and 0087.

Buschmann 2 further discloses that “Peracetic acid and hydrogen peroxide concentrations were determined by established titration methods. Acetic acid and

glycerol concentrations were determined by HPLC.” Exhibit 1015, paragraph 0148 and Table 5.

The reaction mixture described in U.S. 2009/314652 is a non-equilibrium solution of peracetic acid, and contains all of the components listed in Claim 1: peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol (glycerol), an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide (i.e., sodium hydroxide), and water. Exhibit 1008, paragraph 105. Therefore, Buschmann 2 clearly anticipates Claim 1.

2. Ground 2b – Claim 1 of the ‘443 Patent is obvious over Buschmann 2

While the disclosures of Buschmann 2 described above show that Claim 1 is anticipated, Claim 1 is also obvious in view of the disclosures in Buschmann 2. Exhibit 1008, paragraph 106. Further, it would have been obvious to one of ordinary skill in the art that the hydroxide can be an alkali metal hydroxide or an earth alkali metal hydroxide because Buschmann 2 discloses that the hydroxide can be sodium hydroxide. Exhibit 1015, paragraphs 0077, 0087-0088, 0132, 0139, and 0145. Claim 1 of the ‘443 Patent is therefore obvious over Buschmann 2. Exhibit 1008, paragraph 106.

3. Ground 2c – Claim 2 of the ‘443 Patent is anticipated by Buschmann 2

Claim 2 recites “a pH of about 11.2 to about 13.37” for the solution in Claim 1. Buschmann 2 discloses that “the pH is greater than about 9, greater than 10, or greater than and equal to 10 and less than and equal to 13.” Exhibit 1015, paragraph 0063. Buschmann 2 also discloses that

the hydrogen peroxide-containing catholyte solution is caustic, such as $\text{pH} \geq 9$, $\text{pH} \geq 10$, or $9.5 \leq \text{pH} \leq 13$ and is introduced to the acetyl donor containing source to generate PAA.

Exhibit 1015, paragraph 0063.

Buschmann 2 further discloses that “The reaction between the acetyl donor and hydrogen peroxide is accelerated at alkaline pH, and in some embodiments, preferably between $10 \leq \text{pH} \leq 13$.” Exhibit 1015, paragraph 0026. In a description of an exemplary non-equilibrium peracetic acid preparation solution, the pH was “adjusted to pH 12.0 with sodium hydroxide.” Exhibit 1015, paragraph 0077.

As established above for Claim 1, Buschmann 2 discloses solutions containing non-equilibrium PAA, hydrogen peroxide, triacetin, 1,2,3-propanetriol (glycerol), a hydroxide, and water. Exhibit 1008, paragraph 111. Buschmann 2 also discloses that these solutions can have a pH preferably between $10 \leq \text{pH} \leq 13$, and in exemplary solutions, a pH of 12.0. Exhibit 1015, paragraphs 0026 and 0077. Buschmann 2’s

pH range of $10 \leq \text{pH} \leq 13$ overlaps the range in Claim 2, and Buschmann 2's pH value of 12.0 falls within the range in Claim 2. Exhibit 1008, paragraph 112. Therefore, Buschmann 2 anticipates Claim 2 of the '443 Patent.

4. Ground 2d – Claim 2 of the '443 Patent is obvious over Buschmann 2

While the disclosures of Buschmann 2 described above do show that Claim 2 is anticipated, Claim 2 is also obvious in view of the disclosures of Buschmann 2. Buschmann 2 renders obvious non-equilibrium solutions of peracetic acid containing peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water as discussed above for Claim 1. Exhibit 1008, paragraph 113.

The Specification of the '443 Patent does not disclose criticality or unexpected results for the endpoints of the pH range recited in Claim 2.

Buschmann 2 discloses alkaline pH values greater than 10 for producing non-equilibrium PAA solutions. Exhibit 1015, paragraphs 0026, 0063, and 0074. Buschmann 2 discloses that peracetic acid has its lowest stability at alkaline pH ($7.5 \leq \text{pH} \leq 10.5$). Exhibit 1015, paragraphs 0078 and 0079. Peracetic acid undergoes a self-decomposition reaction in this range. Exhibit 1015, paragraph 0081. This self-decomposition reaction of peracetic acid is undesired, as indicated by the disclosure of methods for inhibiting the self-decomposition reaction. Exhibit 1015, paragraphs 0080 and 0081. A person of ordinary skill in the art would have understood from

these disclosures that a pH of 10.5 or higher provides an alkaline pH for peracetic acid formation while avoiding the pH range in which peracetic acid is not stable and minimizing the self-decomposition reaction. Exhibit 1008, paragraph 114.

A person of ordinary skill in the art would have recognized that pH is a result-effective variable that can be optimized through routine experimentation, and would have been motivated to do such optimization, because Buschmann 2 discloses that pH affects the formation of peracetic acid. Exhibit 1015, paragraph 0026; Exhibit 1008, paragraph 115. A person of ordinary skill in the art would also have recognized that peracetic acid's stability and self-decomposition reaction are pH-dependent. Exhibit 1015, paragraphs 0079 and 0081. Exhibit 1008, paragraph 115. One of ordinary skill would have been motivated to undertake such optimization. Exhibit 1008, paragraph 116.

As discussed above, the solutions in Buschmann 2 are aqueous solutions. A person of ordinary skill in the art knows that the highest attainable alkaline pH in aqueous solution is 14. Exhibit 1008, paragraph 116. From the disclosures in Buschmann 2, one of ordinary skill in the art would have recognized that the alkaline pH values in the solutions therein have a possible range of above 10 to 14, or from 10.5 to 14. Exhibit 1008, paragraph 116. Buschmann 2 also discloses that a pH between $10 \leq \text{pH} \leq 13$ is preferred. Exhibit 1015, paragraph 0026. Finding an optimal pH range within these parameters would have been routine experimentation within

the capability of a person of ordinary skill in the art, and one of ordinary skill would have been motivated to undertake such routine experimentation. Exhibit 1008, paragraph 116.

In Claim 2, the lower endpoint of the pH range, 11.2, is alkaline (greater than 10) as taught in Buschmann 2 for the formation of peracetic acid. Exhibit 1015, paragraph 0074; Exhibit 1008, paragraph 117. The lower endpoint of the claimed pH range is also above the pH range in which the self-reaction decomposition of peracetic acid occurs ($7.5 \leq \text{pH} \leq 10.5$). Exhibit 1015, paragraph 0079 and 0081; Exhibit 1008, paragraph 117.

Therefore, to a person of ordinary skill in the art, the claimed pH range, about 11.2 to about 13.37, would be nothing more than routine optimization from the disclosure of Buschmann 2, for which motivation existed for one of ordinary skill to undertake such routine optimization at the time of Buschmann 2, and thus Claim 2 would have been obvious to one of ordinary skill in the art. Exhibit 1008, paragraph 118.

C. Ground 3 – Claim 1 is obvious over U.S. 6,221,341 to Montgomery

A reference not cited in the '443 Patent, U.S. 6,221,341 (“Montgomery”), is directed to compositions that

include a low molecular weight compound having a high acetyl group functionality useful in the production of a peroxy acid which then acts as a whitening agent.

Exhibit 1016, Abstract. Montgomery discloses that “[t]he acyl group source and the peroxide precursor, upon contact with an aqueous solution, generate a peroxyacid.”

Exhibit 1016, col. 4, lines 6-8.

Montgomery states that “[a]ccording to a specific preferred embodiment of the present invention, the source of labile acetyl groups is glyceryl triacetate, glyceryl diacetate or glyceryl acetate.” Exhibit 1016, col. 6, lines 13-15. As noted above, glyceryl triacetate is a synonym for triacetin. Montgomery further states that “The use of glyceryl triacetate is advantageous due to its highly labile acetyl functionalities.” Exhibit 1016, col. 6, lines 31-32. At col. 8, lines 15-17, Montgomery explains that “The formation of peroxyacetic acid from hydrogen peroxide and glyceryl triacetate has been determined to occur most readily at pH levels in excess of about 5.2.” Exhibit 1016. For pH, Montgomery discloses that “Suitable buffers include sodium hydroxide, potassium hydroxide, [and] ammonium hydroxide.” Exhibit 1016, col. 7, lines 64-67.

In Example V of Montgomery, composition B explicitly contains most of the components listed in Claim 1: glycerin (**1,2,3-propanetriol**), **water**, ammonium hydroxide, **hydrogen peroxide**, and glycerol triacetate (**triacetin**). Exhibit 1016,

Table 5. Composition B is prepared from two separate (composite) components, one containing the hydrogen peroxide and the other containing the triacetin. Exhibit 1016, col. 15, lines 14-17. Example V states that “The resulting mixture thus contains both the hydrogen peroxide precursor and glyceryl triacetate, and alternatively, water in a sufficient amount to allow the production of **peroxyacetic acid**.” Exhibit 1016, col. 15, lines 64-67.

Although listed as an ingredient in composition B of Montgomery’s Example V, glycerin (1,2,3-propanetriol) is also produced as the perhydrolysis product of glyceryl triacetate (triacetin). Exhibit 1008, paragraphs 124 and 125.

While composition B of Example V uses ammonium hydroxide and not an alkali metal hydroxide or an earth alkali metal hydroxide, it would have been obvious to one of ordinary skill in the art to substitute an **alkali metal hydroxide** for the ammonium hydroxide, because Montgomery discloses that sodium hydroxide and potassium hydroxide, which are alkali metal hydroxides, can be used in these solutions. Exhibit 1008, paragraph 129.

The resulting mixture which is composition B in Example V explicitly contains most of the components listed in Claim 1 of the ‘443 Patent: peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, and water. Exhibit 1008, paragraph 130. The only component not present is an alkali metal hydroxide or an earth alkali metal hydroxide.

Montgomery renders obvious the presence of (an aqueous source of) an alkali metal hydroxide in a solution containing glycerin (1,2,3-propanetriol), water, hydrogen peroxide, and glycerol triacetate (triacetin), and peracetic acid. A person of ordinary skill in the art would have understood that an alkali metal hydroxide can be used instead of ammonium hydroxide in composition B in Example V, and one of ordinary skill would have been motivated to do so because Montgomery teaches that at least sodium hydroxide and potassium hydroxide are equivalent to ammonium hydroxide. Exhibit 1008, paragraph 131. Therefore, Claim 1 of the '443 Patent is obvious in view of the disclosures of Montgomery.

D. Grounds 4a-4f: Claims 1-3 are anticipated by and/or obvious over U.S. 7,919,122 (“Okano 1”)

1. Ground 4a – Claim 1 of the ‘443 Patent is anticipated by Okano 1

U.S. 7,919,122 (“Okano 1”) is directed to a composition for production of a sterilizer; the sterilizer is obtained as an aqueous solution containing an organic peracid. Exhibit 1010, Abstract. Okano 1 discloses

a composition for production of a sterilizer, having a water content of 1 to 25% by weight and containing (A) an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group which may have a hydroxyl group and (B1) hydrogen peroxide.

Exhibit 1010, col. 1, lines 58-62. Okano 1 states that “the component (A) is preferably an ester of glycerin and a C1 to C8 aliphatic monocarboxylic acid, more preferably triacetin.” Exhibit 1010, col. 4, lines 14-16.

In Example 3 of Okano 1, several ingredients are combined to form a mixture: deionized water, components (A) and (B), organic phosphonic acid (trade name: Dequest 2010) and an alkaline pH adjusting agent in the amounts shown in Table 10. Exhibit 1010, col. 29, lines 30-36. In Runs 3-3 and 3-6, component (A) was triacetin, component (B) was hydrogen peroxide, and the alkaline pH adjusting agent was sodium hydroxide. Exhibit 1010, Table 10. The amounts of the ingredients were selected such that the total weight of the mixture was 100 g; the mixture was stirred for about 10 minutes. Exhibit 1010, col. 29, lines 33-35, and col. 30, lines 28-30. Example 6 used the same ingredients and procedure, with results reported in Table 23.⁵ Exhibit 1010, col. 47, lines 43-48, and col. 48, lines 41-44).

While **1,2,3-propanetriol** is not explicitly recited, it is inherently present in the mixture, and its presence would have been recognized by a person of ordinary skill in the art at the time of the invention. Exhibit 1008, paragraph 132. One of ordinary skill in the art would have recognized that when the three acetyl groups of triacetin react with hydrogen peroxide to form peracetic acid, some amount of the

⁵ The tables are easier to read in the counterpart EP 1618786 (Exhibit 1017).

perhydrolysis product of triacetin, 1,2,3-propanetriol, is also formed. Exhibit 1008, paragraph 132. Therefore, at least some amount of 1,2,3-propanetriol is necessarily present in the solutions of Okano 1. Exhibit 1008, paragraph 132. Runs 3-3 and 3-6 in Example 3 of Okano 1 disclose mixtures comprising peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide, and water. Exhibit 1008, paragraph 132.

In Runs 3-3 and 3-6 (Table 10) and in Runs 6-3 and 6-6 (Table 23), **triacetin** was component (A), aqueous **hydrogen peroxide** was component (B), and **sodium hydroxide** was the alkaline pH adjusting agent. **Water** is present in the solution, along with **peracetic acid**, the product, and **1,2,3-propanetriol**, the perhydrolysis product of triacetin. Exhibit 1008, paragraph 133.

Moreover, because the prosecution history of the '443 Patent shows that the Applicant did not challenge the Examiner's interpretation that 1,2,3-propanetriol was inherently present in the solutions of the '293 Application, Applicant admitted that 1,2,3-propanetriol is present in such solutions. *See* Exhibit 1005, Pages 121 and 131.

Under the plain and ordinary meaning of a non-equilibrium solution as a solution that is not at equilibrium, the solutions in Okano 1 are non-equilibrium solutions of peracetic acid. Exhibit 1008, paragraph 135. Okano 1 states that "the reaction between the component (A) and the component (B1) is an irreversible

reaction ... that produces an aqueous solution.” Exhibit 1010, col. 11, lines 16-23. One of ordinary skill in the art would have recognized that a solution in which an irreversible reaction occurs is a non-equilibrium solution because no reaction to reform the starting materials can occur. Exhibit 1008, paragraph 135.

The mixtures in Runs 3-3, 3-6, 6-3, and 6-6 of Examples 3 and 6 of Okano 1 form solutions and contain all of the components listed in Claim 1: peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water, in a non-equilibrium peracetic acid solution. Exhibit 1008, paragraph 137. Therefore, Okano 1 anticipates Claim 1 of the ‘443 Patent.

2. Ground 4b – Claim 1 of the ‘443 Patent is obvious over Okano 1

While the disclosures of Okano 1 described above show that Claim 1 is anticipated, Claim 1 is also obvious in view of the disclosures in Okano 1. Okano 1 renders obvious the presence of peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol (glycerol), an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water, in a non-equilibrium peracetic acid solution. A person of ordinary skill in the art would have understood that 1,2,3-propanetriol is present in the solution of Okano 1 as a product of the reaction of hydrogen peroxide with triacetin. Exhibit 1008, paragraph 138. A person of ordinary skill in the art would have recognized that because the reaction to form peracetic acid is

irreversible, the solution is a non-equilibrium solution of peracetic acid. Exhibit 1008, paragraph 138.

3. Ground 4c – Claim 2 of the ‘443 Patent is anticipated by Okano 1

Claim 2 depends from Claim 1 and recites “a pH of about 11.2 to about 13.37.” In Examples 3 and 6 of Okano 1, when the water, components (A) and (B), organic phosphonic acid, and alkaline pH adjusting agent have been added and a mixture formed, Okano 1 states that “The pH of this mixture was 8 to 12.” Exhibit 1010, col. 29, lines 30-36; col. 47, lines 43-48. This pH range overlaps the range in Claim 2. Exhibit 1008, paragraph 139.

As discussed above, Okano 1 makes clear to a person of ordinary skill in the art that non-equilibrium solutions of peracetic acid containing peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol (glycerol), an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water, are necessarily disclosed by disclosing mixtures that are comprised of all of these components, Exhibit 1008, paragraph 141, once such mixtures are sufficiently mixed to homogeneity so as to constitute a solution. Exhibit 1010, col. 30, lines 28-30, col. 48, lines 41-44.

Therefore, Okano 1 anticipates Claim 2 of the ‘443 Patent.

4. Ground 4d – Claim 2 of the ‘443 Patent is obvious over Okano 1

While the disclosures of Okano 1 described above do show that Claim 2 is anticipated, Claim 2 is also obvious in view of the disclosures of Okano 1. The pH values of the mixtures disclosed in Okano 1 overlap with the pH range recited in Claim 2. Exhibit 1008, paragraphs 143 and 144. *UCB, Inc. v. Actavis Laboratories UT, Inc.*, 65 F.4th 679, 689 (Fed. Cir. 2023) (“A presumption of obviousness applies “[w]here a claimed range overlaps with a range disclosed in the prior art.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006).).

The Specification of the ‘443 Patent does not disclose criticality or unexpected results for the endpoints of the pH range recited in Claim 2, nor for the part of the claimed range that does not overlap with the “8 to 12” pH range disclosed in Okano 1. Exhibit 1010, col. 29, lines 30-36; col. 47, lines 43-48; Exhibit 1008, paragraph 144.

For at least the foregoing reasons, Claim 2 would have been obvious to a person of skill in the art in view of Okano 1.

5. Ground 4e – Claim 3 of the ‘443 Patent is anticipated by Okano 1

Claim 3 of the ‘443 Patent recites that “peracetic acid is about 1% to about 7.1%,” which as discussed above is understood to mean that there is about 1 wt% to about 7.1 wt% peracetic acid in the claimed solution. Exhibit 1008, paragraph 145.

In Examples 3 and 6 of Okano 1, after the deionized water, components (A) and (B), organic phosphonic acid, and alkaline pH adjusting agent have been added and then stirred for 10 minutes, Okano 1 discloses that “[a]t this point in time (just after preparation), the mixture was measured for organic peracid concentration and hydrogen peroxide concentration.” Exhibit 1010, col. 29, lines 37-39 (Example 3); col. 47, lines 53-54 (Example 6). Runs 3-3, 3-6, 6-3, and 6-6, in which triacetin was component (A), hydrogen peroxide was component (B), and sodium hydroxide was the alkaline pH adjusting agent, were each determined to have 27,000 ppm of peracetic acid present, which is equivalent to 2.7 wt% peracetic acid. Exhibit 1010, Tables 10 and 23; Exhibit 1008, paragraph 145. These concentrations fall within the peracetic acid concentration range recited in Claim 3. Exhibit 1008, paragraph 146. Therefore, Okano 1 anticipates Claim 3 of the ‘443 Patent.

6. Ground 4f – Claim 3 of the ‘443 Patent is obvious over Okano 1

While the disclosures of Okano 1 described above do show that Claim 3 is anticipated, Claim 3 is also obvious in view of the disclosures of Okano 1. Okano 1 renders obvious to a person of ordinary skill in the art non-equilibrium solutions of peracetic acid containing peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water. Exhibit 1008, paragraph 147. Further, the peracetic acid concentrations in Okano 1 overlap with the range in Claim 3. Exhibit 1008,

paragraph 148. *UCB, Inc. v. Actavis Laboratories UT, Inc.*, 65 F.4th 679, 689 (Fed. Cir. 2023) (“A presumption of obviousness applies “[w]here a claimed range overlaps with a range disclosed in the prior art.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006).).

For at least the foregoing reasons, Claim 3 would have been obvious to a person of skill in the art in view of Okano 1.

E. Grounds 5a-5f: Claims 1-3 are anticipated by and/or obvious over JP 2006-045147 A (“Okano 2”)

1. Ground 5a – Claim 1 of the ‘443 Patent is anticipated by Okano 2

A reference not cited in the ‘443 Patent, JP 2006-045147 A (“Okano 2”), is directed to, and discloses that

[T]he sterilizing detergent composition for hard surfaces of the present invention is obtained by reacting the components (A) and (B1) in water at a specific molar ratio and a pH of 8-12.

Exhibit 1018, paragraph 0015.⁶ Okano 2 states that “the component (A), an ester of glycerin and an aliphatic monocarboxylic acid having 1 to 8 carbon atoms is preferably triacetin.” Exhibit 1018, paragraph 0014 (Page 6).

⁶ A Certification of the translation is provided as Exhibit 1019. The original reference in Japanese is provided as Exhibit 1020.

In Example 1, Okano 2 discloses combining **triacetin** (component (A)), an aqueous solution of **hydrogen peroxide** (component (B1)), and **water**; to the mixture formed by combining triacetin, aqueous hydrogen peroxide, and water, alkaline **aqueous sodium hydroxide** was added, to cause formation of an organic peracid. Exhibit 1018, paragraph 0057 (Page 19). Because component (A) is triacetin, the organic peracid is necessarily **peracetic acid**. Exhibit 1008, paragraph 92. Paragraph 0057 of Okano 2 is entitled “Preparation of Sterilizing Cleaner Composition (I).” Paragraph 0059 of Okano 2 is directed to “Measurement of Organic Peroxy Acid Concentration” for sterilizing cleaner composition (I), and states that “an organic peroxy acid concentration (as peracetic acid concentration) was found using the following formula.” Exhibit 1018, Page 20. In paragraph 0023, Okano 2 states that “the sterilizing cleaner composition for hard surfaces of the present invention is an aqueous solution containing an organic peracid.” Exhibit 1018, Page 9.

The solution in Example 1 of Okano 2 explicitly contains most of the components listed in Claim 1: peracetic acid, hydrogen peroxide, triacetin, an aqueous source of an alkali metal hydroxide, and water. Exhibit 1008, paragraph 151.

The only component of Claim 1 not explicitly disclosed in Okano 2 is 1,2,3-propanetriol, but it is inherently present in the solution of Example 1 in Okano 2.

One of ordinary skill in the art would have recognized that when the three acetyl groups of triacetin react with hydrogen peroxide to form peracetic acid, some amount of the perhydrolysis product of triacetin, 1,2,3-propanetriol, is also formed. Exhibit 1008, paragraph 152. Thus, at least some amount of 1,2,3-propanetriol is necessarily present in the claimed solutions. Exhibit 1008, paragraph 152. Example 1 of Okano 2 discloses compositions comprising hydrogen peroxide, triacetin, peracetic acid, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide, and water. Exhibit 1008, paragraph 153.

Further, because the prosecution history of the '443 Patent shows that the Applicant did not challenge the Examiner's interpretation that 1,2,3-propanetriol, the perhydrolysis product of triacetin, was inherently present in the solutions of the '293 Application, Applicant admitted that 1,2,3-propanetriol is inherently present in such solutions, which contain water, peracetic acid, hydrogen peroxide, triacetin, and alkali metal or earth alkali metal hydroxide. *See* Exhibit 1005, Pages 121 and 131.

The compositions in Okano 2 are non-equilibrium solutions of peracetic acid. Exhibit 1008, paragraph 153. Using the definition of a non-equilibrium solution of peracetic acid as any solution of peracetic acid that is not at equilibrium under a given set of conditions, one of skill in the art knows that the reaction of triacetin with hydrogen peroxide to form peracetic acid is irreversible, because there is no

indication of a back-reaction of the 1,2,3-propanetriol to re-form triacetin. Thus, Okano 2 discloses non-equilibrium solutions of peracetic acid when water, hydrogen peroxide, triacetin, and aqueous sodium hydroxide are present. Exhibit 1008, paragraph 153.

Therefore, Okano 2 anticipates Claim 1.

2. Ground 5b – Claim 1 of the ‘443 Patent is obvious over Okano 2

While the disclosures of Okano 2 described above do show that Claim 1 is anticipated, Claim 1 is also obvious in view of the disclosures in Okano 2. Okano 2 renders obvious the presence of 1,2,3-propanetriol in a solution comprising peracetic acid, hydrogen peroxide, triacetin, an aqueous alkali metal hydroxide, and water. A person of ordinary skill in the art would have understood that 1,2,3-propanetriol would have been present in such a solution because Okano 2 shows that peracetic acid is formed in aqueous solutions from triacetin and hydrogen peroxide in the presence of an alkali metal hydroxide. Exhibit 1018, paragraphs 0057 and 0059 (Pages 19-20); Exhibit 1008, paragraph 155. A person of ordinary skill in the art would also have recognized that because the reaction to form peracetic acid is irreversible, the solutions are non-equilibrium solutions of peracetic acid. Exhibit 1008, paragraph 156.

3. Ground 5c – Claim 2 of the ‘443 Patent is anticipated by Okano 2

Okano 2 discloses that the sterilizer compositions therein are obtained by reacting component (A), which can be triacetin, and component (B1), which is hydrogen peroxide, in water, to form an organic peracid, which is peracetic acid when component (A) is triacetin. Exhibit 1018, paragraphs 0008, 0009, 0015, 0029, and 0030. During the reaction, 1,2,3-propanetriol is formed, as one of ordinary skill in the art would have recognized. Exhibit 1008, paragraph 159. One of ordinary skill would also have recognized that the peracetic acid solution formed was a non-equilibrium solution because no reverse reaction occurs. Exhibit 1008, paragraph 160. Okano 2 further discloses that the reacting of components (A) and (B1) in water is conducted at a pH of 8 to 12. Exhibit 1018, paragraphs 0008, 0009, 0015, 0029, and 0030. This pH range overlaps the range recited in Claim 2: “about 11.2 to about 13.37.” Exhibit 1008, paragraph 158. Therefore, Okano 2 anticipates Claim 2 of the ‘443 Patent.

4. Ground 5d – Claim 2 of the ‘443 Patent is obvious over Okano 2

While the disclosures of Okano 2 described above do show that Claim 2 is anticipated, Claim 2 is also obvious in view of the disclosures of Okano 2. Okano 2 renders obvious non-equilibrium solutions of peracetic acid containing peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali

metal hydroxide or an earth alkali metal hydroxide, and water. Exhibit 1008, paragraph 162. Further, the pH values in Okano 2 overlap with the range in Claim 2. Exhibit 1008, paragraph 163. *UCB, Inc. v. Actavis Laboratories UT, Inc.*, 65 F.4th 679, 689 (Fed. Cir. 2023) (“A presumption of obviousness applies “[w]here a claimed range overlaps with a range disclosed in the prior art.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006).).

For at least the foregoing reasons, Claim 2 is also obvious in view of Okano 2.

5. Ground 5e – Claim 3 of the ‘443 Patent is anticipated by Okano 2

Okano 2 discloses that

[T]he sterilizing cleaner composition for hard surfaces of the present invention is an aqueous solution containing an organic peracid, and the concentration of the organic peracid in the composition is preferably 10 to 20,000 ppm, more preferably 10 to 10,000 ppm.

Exhibit 1018, paragraph 0023. Okano 2 further states that

In the second composition for producing sterilizing cleaner of the present invention, an aqueous solution that is a sterilizing cleaner composition containing organic peroxy acid is prepared by adjusting the pH value through the first step and second step above during use.

The organic peroxy acid concentration in the aqueous solution is

preferably 10 to 20,000 ppm (weight ratio, same as below) and more so
10 to 10,000 ppm.

Exhibit 1018, paragraph 0044. The 10 to 20,000 ppm range is equivalent to 0.001 wt% to 2 wt% and the 10 to 10,000 ppm range is equivalent to 0.001 wt% to 1 wt%. Exhibit 1008, paragraph 166. The broader peracetic acid concentration range overlaps the peracetic acid concentration range recited in Claim 3 of the '443 Patent: "about 1% to about 7.1%." Exhibit 1008, paragraph 166. The upper value of the narrower range disclosed in Okano 2 is the same as the lower value of the range recited in Claim 3.

In Example 1, Okano 2 discloses preparation of peracetic acid from triacetin, hydrogen peroxide, water, and sodium hydroxide, in which 50 grams of triacetin and 25 grams of a 60% solution of hydrogen peroxide were used. Exhibit 1018, paragraph 0057. The 50 grams of triacetin are 0.23 moles of triacetin. The 60% solution of hydrogen peroxide contained 15 grams of hydrogen peroxide, or 0.44 mole of hydrogen peroxide. Three moles of hydrogen peroxide are needed for each mole of triacetin, so the hydrogen peroxide can only convert $0.44 \div 3 = 0.15$ moles of triacetin. Exhibit 1008, paragraph 168. Since there are more than 0.15 moles of triacetin, hydrogen peroxide is the limiting reagent. Exhibit 1008, paragraph 168. Assuming a complete reaction, 0.44 mole of peracetic acid, or 33 grams of peracetic acid, were formed. Exhibit 1008, paragraph 168. The total weight of the preparation

solution was 1000 grams,⁷ and the 33 grams of peracetic acid are 3.3 wt% peracetic acid, which falls within the range in Claim 3. Exhibit 1008, paragraphs 168 and 169.

Therefore, Okano 2 anticipates Claim 3 of the '443 Patent.

6. Ground 5f – Claim 3 of the '443 Patent is obvious over Okano 2

The disclosures of Okano 2 described above do show that Claim 3 is anticipated and Claim 3 is also obvious in view of the disclosures of Okano 2. Okano 2 renders obvious non-equilibrium solutions of peracetic acid containing peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water. Exhibit 1008, paragraphs 170 and 171. Further, the peracetic acid concentrations taught in Okano 2 overlap with the range recited in Claim 3. Exhibit 1008, paragraph 171.

For at least the foregoing reasons, Claim 3 is obvious in view of Okano 2.

F. Grounds 6a–6c: Claims 1-3 are obvious over the combination of Okano 1 and Okano 2

As discussed above, U.S. 7,919,122 (Okano 1) discloses production of a sterilizer from (A) an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group which may have a hydroxyl group and (B1) hydrogen peroxide.

⁷ Total weight: 50 g triacetin + 25 g 60% H₂O₂ + 850 g water + 75 g aq. NaOH = 1000 grams.

Exhibit 1010, col. 1, lines 58-62. In Okano 1, component (A) is more preferably triacetin. Exhibit 1010, col. 4, lines 14-16.

Similarly, Okano 2 discloses forming a sterilizer composition from components (A) and (B1) in water at a specific molar ratio and a pH of 8-12. Exhibit 1018, paragraph 0015. In Okano 2, component (A) is preferably triacetin, and component (B1) is hydrogen peroxide. Exhibit 1018, paragraph 0014.

Okano 2 states that sterilizing cleaners for hard surfaces are known, such as those containing a chlorine-based disinfectant. Exhibit 1018, paragraph 0004. Okano 2 acknowledges that oxygen-based sterilizing cleansers are known but have defects; in particular, peracetic acid has an odor. Exhibit 1018, paragraph 0004. Okano 1 also notes the drawbacks to chlorinated sterilizers, adding that they are corrosive to metals, and further states that hydrogen peroxide has problems, such as a need for high concentration and long contact times. Exhibit 1010, col. 1, lines 16-27.

A person of ordinary skill in the art would have been motivated to find a sterilizer or sterilizing cleanser that is not chlorine-based, due to the known problems with such sterilizers. Exhibit 1008, paragraph 174. One of ordinary skill in the art would have been motivated to combine Okano 1 and Okano 2 because both references address this problem, and the solution to the problem in both references involves preparation of a sterilizer or sterilizer composition from an ester, which is preferably triacetin, and hydrogen peroxide. Exhibit 1008, paragraph 174. Both

Okano 1 and Okano 2 use the same components, so there would have been a reasonable expectation of success for their combination. Exhibit 1008, paragraph 174.

1. Ground 6a – Claim 1 of the ‘443 Patent is obvious over the combination of Okano 1 and Okano 2

In Runs 3-3 and 3-6 of Okano 1, component (A) was **triacetin**, component (B) was **hydrogen peroxide**, and the alkaline pH adjusting agent was **sodium hydroxide**. Exhibit 1010, Table 10. Runs 6-3 and 6-6 of Example 6 used the same ingredients and procedure, with results reported in Table 23. Exhibit 1010, col. 47, lines 43-48, and col. 48, lines 41-44. **Water** was present in these solutions, along with **peracetic acid**, the product. Exhibit 1010, col. 29, lines 33-35, and col. 30, lines 28-30; Exhibit 1008, paragraph 177.

Okano 2’s Example 1 solution explicitly contains most of the components listed in Claim 1: peracetic acid, hydrogen peroxide, triacetin, an aqueous source of an alkali metal hydroxide, and water. Exhibit 1008, paragraph 178. Example 1 of Okano 2 discloses combining **triacetin** (component (A)), an aqueous solution of **hydrogen peroxide** (component (B1)), and **water** to form a mixture, and adding **aqueous sodium hydroxide** to the mixture, to cause formation of an organic peracid. Exhibit 1018, paragraph 0057 (Page 19). Because component (A) is triacetin, the organic peracid is necessarily **peracetic acid**. Exhibit 1008, paragraph 179.

The only component of Claim 1 not explicitly disclosed in either Okano 1 or Okano 2 is 1,2,3-propanetriol. One of ordinary skill in the art would have recognized that when the three acetyl groups of triacetin react with hydrogen peroxide to form peracetic acid, some amount of the perhydrolysis product of triacetin, 1,2,3-propanetriol, is also formed. Exhibit 1008, paragraph 180. Therefore, at least some amount of 1,2,3-propanetriol is necessarily present in the solutions of Okano 1 and Okano 2. Exhibit 1008, paragraph 180.

In addition, because the prosecution history of the '443 Patent shows that the Applicant did not challenge the Examiner's interpretation that 1,2,3-propanetriol, the perhydrolysis product of triacetin, was inherently present in the solutions of the '293 Application, Applicant admitted that 1,2,3-propanetriol is inherently present in such solutions. See Exhibit 1005, Pages 121 and 131.

The mixtures in Run 3-3, 3-6, 6-3, and 6-6 of Examples 3 and 6 of Okano 1 contain all of the components listed in Claim 1: peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water, in a non-equilibrium peracetic acid solution. Exhibit 1008, paragraph 177.

Similarly, Example 1 of Okano 2 contains all the components listed in Claim 1: peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source

of an alkali metal hydroxide or an earth alkali metal hydroxide, and water, in a non-equilibrium peracetic acid solution. Exhibit 1008, paragraph 178.

The solutions in Okano 1 and Okano 2 are non-equilibrium solutions of peracetic acid. Exhibit 1008, paragraphs 180-182. Okano 1 states that “the reaction between the component (A) and the component (B1) is an irreversible reaction.” Exhibit 1010, col. 11, lines 16-23. One of ordinary skill in the art would have recognized that a solution in which an irreversible reaction occurs is a non-equilibrium solution because no reaction to re-form the starting materials can occur, and that the solutions in Okano 1 and Okano 2 are non-equilibrium solutions. Exhibit 1008, paragraphs 181 and 182.

Therefore, for at least the foregoing reasons, Claim 1 of the ‘443 Patent would have been obvious to a person of ordinary skill in the art over the combination of Okano 1 and Okano 2.

2. Ground 6b – Claim 2 of the ‘443 Patent is obvious over the combination of Okano 1 and Okano 2

As discussed above, Okano 1 and Okano 2 disclose and render obvious non-equilibrium solutions of peracetic acid containing peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water. Exhibit 1008, paragraph 185.

Claim 2 of the ‘443 Patent depends from Claim 1 and recites “a pH of about 11.2 to about 13.37.”

In Examples 3 and 6 of Okano 1, when the water, components (A) and (B), organic phosphonic acid, and alkaline pH adjusting agent have been added and a mixture formed, Okano 1 states that “The pH of this mixture was 8 to 12.” Exhibit 1010, col. 29, lines 30-36; col. 47, lines 43-48. This pH range overlaps the range in Claim 2. Exhibit 1008, paragraph 187.

Okano 2 discloses that the preparation is conducted at a pH of 8 to 12. Exhibit 1018, paragraphs 0008, 0009, 0015, and 0029. This pH range overlaps the range recited in Claim 2: “about 11.2 to about 13.37.” Exhibit 1008, paragraph 188.

The pH values in both Okano 1 and Okano 2 overlap with the range in Claim 2. Exhibit 1008, paragraph 189. *UCB, Inc. v. Actavis Laboratories UT, Inc.*, 65 F.4th 679, 689 (Fed. Cir. 2023) (“A presumption of obviousness applies “[w]here a claimed range overlaps with a range disclosed in the prior art.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006).).

For at least the foregoing reasons, Claim 2 would have been obvious to a person of ordinary skill in the art over the combination of Okano 1 and Okano 2.

3. Ground 6c – Claim 3 of the ‘443 Patent is obvious over the combination of Okano 1 and Okano 2

As discussed above, Okano 1 and Okano 2 disclose and render obvious non-equilibrium solutions of peracetic acid containing peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol, an aqueous source of an alkali metal hydroxide or an earth alkali metal hydroxide, and water. Exhibit 1008, paragraph 190.

Claim 3 of the '443 Patent recites that “peracetic acid is about 1% to about 7.1%,” which as discussed above is understood to mean that there is about 1 wt% to about 7.1 wt% peracetic acid in the claimed solution. Exhibit 1008, paragraph 118.

In Runs 3-3 and 3-6 of Example 3 and Runs 6-3 and 6-6 of Example 6 of Okano 1, after the water, triacetin and hydrogen peroxide, and sodium hydroxide (alkaline pH adjusting agent) have been added and then stirred for 10 minutes, Okano 1 discloses that “[a]t this point in time (just after preparation), the mixture was measured for organic peracid concentration and hydrogen peroxide concentration.” Exhibit 1010, col. 29, lines 37-39 (Example 3), also col. 47, lines 53-54 (Example 6). For Runs 3-3 and 3-6 of Example 3 and Runs 6-3 and 6-6 of Example 6, the peracetic acid concentrations were determined to be 27,000 ppm, which is equivalent to 2.7 wt% peracetic acid in solution. Exhibit 1010, Tables 10 and 23; Exhibit 1008, paragraph 191. These concentrations fall within the peracetic acid concentration range recited in Claim 3. Exhibit 1008, paragraph 192.

As noted above, Okano 2, in paragraph 0023, discloses that “the concentration of the organic peracid in the composition is preferably 10 to 20,000 ppm, more preferably 10 to 10,000 ppm,” and in paragraph 0044, Okano 2 states that “In the second composition ... The organic peroxy acid concentration ... is preferably 10 to 20,000 ppm (weight ratio, same as below) and more so 10 to 10,000 ppm.” Exhibit 1018, paragraph 0023. Okano 2's 10 to 20,000 ppm range is equivalent to 0.001 wt%

to 2 wt%, which overlaps the peracetic acid concentration range recited in Claim 3 of the '443 Patent. Exhibit 1008, paragraph 193. Okano 2's 10 to 10,000 ppm range is equivalent to 0.001 wt% to 1 wt%, the upper value of which range is the same as the lower value of the range recited in Claim 3 of the '443 Patent.

In Example 1, Okano 2 discloses preparation of peracetic acid from triacetin, hydrogen peroxide, water, and sodium hydroxide, in which 50 g of triacetin and 25 g of a 60% solution of hydrogen peroxide were used. Exhibit 1018, paragraph 0057. As described in detail above for this Example of Okano 2, assuming a complete reaction, 0.44 mole of peracetic acid, or 33 g of peracetic acid, were formed. Exhibit 1008, paragraph 195. The total weight of the preparation solution was 1000 g, and the 33 g of peracetic acid is 3.3 wt% of peracetic acid. Exhibit 1008, paragraph 195. This peracetic acid concentration taught in Okano 2 falls within the range recited in Claim 3 of the '443 Patent. Exhibit 1008, paragraph 196.

From the combined disclosures of Okano 1 and Okano 2, the peracetic acid concentrations in Claim 3 of the '443 Patent would have been obvious to one of ordinary skill in the art. Exhibit 1008, paragraph 197. The peracetic acid concentrations in Okano 1 and Okano 2 overlap with the range in Claim 3. Exhibit 1008, paragraph 197. *UCB, Inc. v. Actavis Laboratories UT, Inc.*, 65 F.4th 679, 689 (Fed. Cir. 2023) ("A presumption of obviousness applies "[w]here a claimed range

overlaps with a range disclosed in the prior art.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006).).

For at least the foregoing reasons, Claim 3 would have been obvious to a person of skill in the art in view of the combination of Okano 1 and Okano 2.

VI. CONCLUSION

Claims 1-3 of the ‘443 Patent are anticipated or rendered obvious for at least the reasons set forth above. There is a reasonable likelihood that Petitioner will prevail as to each of these claims. *Inter partes* review of Claims 1-3 of the ‘443 patent is accordingly requested.

This Petition meets the minimum threshold of a reasonable likelihood that at least one claim of the ‘443 Patent is unpatentable. Petitioner, therefore, requests that an *inter partes* review trial be ordered and that Claims 1-3 of the ‘443 Patent be canceled.

[signature page follows]

Dated: August 27, 2025

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. § 42.24(D)

To comply with the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that this Petition for *Inter Partes* Review of U.S. Patent 9,730,443 has 11,012 words (excluding the sections exempted under 37 C.F.R. § 42.24(a)(1)) as counted by a word processing system, which is less than the maximum of 14,000 words permitted by 37 C.F.R. § 42.24.

Dated: August 27, 2025

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CERTIFICATE OF SERVICE ON THE PATENT OWNER

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner (by Priority Mail Express) of a copy of this Petition for *Inter Partes* Review and supporting materials at the correspondence address of record for the 9,730,443 Patent:

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