

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.

Case IPR2025-01459
Patent 9,730,443

PATENT OWNER'S PRELIMINARY RESPONSE

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2003	<i>Enviro Tech v. Clean Chemistry</i> Scheduling Order (Docket No. 22)	11/5/2025
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2019	U.S. Patent No. 8,546,449 Notice of Allowance (July 15, 2013)	Presently Submitted
2020	<i>Enviro Tech v. Clean Chemistry</i> Declaration of Gregory T. Whiteker, Ph.D. (Exhibit E to Docket No. 35)	Presently Submitted
2021	<i>Enviro Tech v. Clean Chemistry</i> Claim Construction Order (Docket No. 47)	Presently Submitted
2022	<i>Enviro Tech v. Clean Chemistry</i> Clean Chemistry's Opening Claim Construction Brief (Docket No. 34)	Presently Submitted

I. INTRODUCTION

This Petition should be denied, both on the basis of the compelling grounds for discretionary denial briefed in Paper 9, as well as for the reasons delineated herein.

As an initial matter, this Petition is emblematic of the overarching problems with *inter partes* review (“IPR”) proceedings. Congress’s goal in creating the IPR process was to “improve patent quality by providing a more efficient means to adjudicate patent validity issues” using a process that was faster and cheaper. *The Patent Trial and Appeal Board and Inter Partes Review*, Congress.Gov, R48016, (May 28, 2024).¹ In theory, the USPTO would consider whether the patent would still have issued if the art presented to it in the IPR had been presented during prosecution. And yet, the IPR process has become essentially a mini court case, relying heavily on bloated expert declarations and mini treatises interpreting the art, none of which would have been present during the original examination.

Moreover, all the expert testimony in the world cannot overcome the fact that none of the cited art teaches all of the elements of any of the claims of U.S. Patent No. 9,730,443 (the “443 Patent”). Rather, in order to cobble together its

¹ <https://www.congress.gov/crs-product/R48016#:~:text=Congress's%20stated%20aim%20when%20creating,the%20patent%20in%20that%20forum.>

arguments that the cited art invalidates the '443 Patent, Petitioner repeatedly presents the composition of a reaction solution (*i.e.*, the composition of a solution that is a precursor to the non-equilibrium solution of peracetic acid) as if it were the composition of the claimed non-equilibrium solution of peracetic acid. It is not. Similarly, Petitioner attempts to show that claim elements that are present based on a series of unsupported assumptions that are internally inconsistent. As a result, Petitioner fails to show that any of the prior art teaches all of the claimed elements of the non-equilibrium solution of peracetic acid taught by the '443 Patent.

Because the Petition, therefore, does not have a "reasonable likelihood of success" of establishing that the claims of the '443 Patent are unpatentable, institution should be denied.

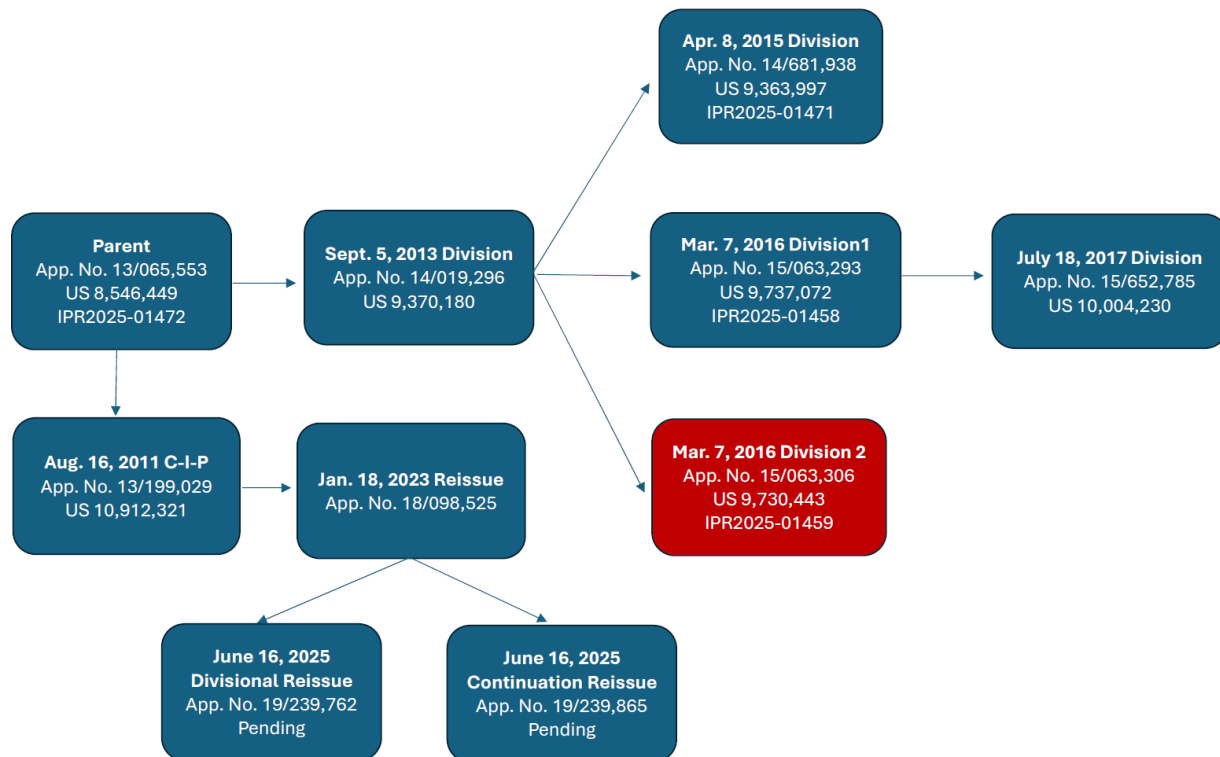
II. BACKGROUND

A. Technology Overview of the 8,546,449 Patent Family

1. The 8,546,449 Patent Family

The '443 Patent is a part of a larger patent family, the 8,546,449 Patent Family, which is directed to methods and compositions for the generation of peracetic acid on site at the point-of-use. U.S. Patent No. 8,546,449 (the "'449 Patent"), the parent patent, was subject to a restriction requirement during prosecution and, as a result, multiple divisional applications and a continuation-in-

part application followed. The '449 Patent is itself the subject of IPR2025-01472, and two other divisional patents, U.S. Patent No. 9,737,072 (the “072 Patent”) and U.S. Patent No. 9,363,997 (the “997 Patent”) are also presently facing their own IPRs, IPR2025-01458 and -01471, respectively. A representation of the U.S. 8,546,449 Patent Family is as follows, where the subject patent is shown in red:



2. *The Prior Art: Equilibrium Solutions of Peracetic Acid*

The '449 Patent and its divisionals share a common specification and are directed to a novel method of generating peracetic acid (“PAA”) on-site, in the

location where it will ultimately be used as a sanitizer. (Exhibit 1001, '443 Patent.)

Prior art PAA formulations were directed to methods of making equilibrium peracetic acid solutions off-site and then transporting the PAA to the location where it would be used. (*Id.* at 1:36-53.) The prior use methodology was fraught with complications for several reasons.

First, due to the typically low concentration of the equilibrium solutions of PAA (1-15%), in order to have sufficient active ingredients, it is necessary to keep, store, and transport large volumes of solution, consisting mostly of inert ingredients, which increases the cost of storage and transportation of the equilibrium PAA, as well as the cost of the inert ingredients needed to stabilize the PAA. (*Id.* at 1:54-60.)

Second, the vast amount of inert ingredients needed to stabilize the PAA also increases the cost of the solution. (*Id.* at 1:60-66.)

Third, certain of the stabilizers needed for the equilibrium PAA solutions are subject to FDA regulations limiting the amount of those stabilizers (such as hydroxyethylidene diphosphonic acid (“HEDP”) or dipicolinic acid) that can be applied to food products. (*Id.* at 1:66-2:3.) As a result, the amount of equilibrium PAA that can be used is similarly limited because the stabilizers are part and parcel of the PAA solution.

Fourth, the reaction that creates the PAA continues over time, such that PAA does not reach its maximum concentration until several days after the initial reaction. (*Id.* at 1:41-43; 2:3-6.) As a result, the equilibrium PAA solutions must be stored for several days before they can be tested for quality control purposes and before the solution can be shipped to customers, again increasing storage costs. (*Id.* at 2:3-9.)

Fifth, although commercial products can yield up to 30% PAA concentration, solutions with that high a concentration of PAA cannot be safely transported, due to the “extremely hazardous and explosive properties” of such a solution. (*Id.* at 1:48-53.) In fact, any solution that is more than 6% PAA is considered a dangerous product and must be labeled with the DOT marking “Organic Peroxide,” Hazard Class 5.2, 8 (oxidizer, corrosive). (*Id.* at 2:9-13). Producers are limited to an annual amount of 6,666 pounds of 15% PAA before they are required to file Risk Management Plans with the EPA and local authorities, and anyone shipping PAA over 6% must be permitted by their local fire department and pay an extra hazardous material shipping fee. (*Id.* at 2:13-20.)

3. *The Prior Art: Prior Attempts to Create Non-Equilibrium Peracetic Acid Solutions*

Due to the challenges involved with equilibrium solutions of PAA, those in the industry attempted to make non-equilibrium solutions of PAA, which could be made on-site at the point of use. (Exhibit 1001 at 2:25-27.) These attempts, however, failed to achieve a commercially feasible product due to various issues with their manufacture. Vineyard (U.S. Patent No. 7,012,154) proposed a system for making non-equilibrium PAA, but it was expensive, suffered from “significant safety hazards associated with the production of pure PAA due to its explosive properties,” and was complex and required highly trained personnel to execute. (*Id.* at 2:25-43.) Methods and devices belonging to Steris Corp. (U.S. Patent No. 6,171,551) and Applied Biosystems LLC (U.S. Patent No. 6,387,236) were expensive, energy-intensive, resulted in an extremely low yield of PAA, and were ideally performed on a continuous basis. (*Id.* at 2:44-57.) Other methods, including those taught by Permelec (WO 2004/0245116), Danisco (WO 2008/140988), and Buschmann (U.S. Pub. No. 2009/0314652) required expensive equipment and a large footprint for the equipment, presented challenges in maintaining the conditions needed for the reactions, and experienced challenges in operating with air as a source of the oxygen, which can limit or eliminate PAA production. (*Id.* at

2:58-3:27.) Other methods were not suitable for large-scale production, required expensive and quickly degraded equipment, created explosion hazards and contaminants, used chemicals that are hazardous, and were challenging to perform. (*Id.* at 3:28-4:52.)

4. The Inventions of the U.S. 8,546,449 Patent Family Solved the Prior Art Problems

The shared specification for the members of the 8,546,449 Patent Family teaches a method of preparing a non-equilibrium solution of PAA that does not suffer from the limitations of prior art solutions. The invention is directed to the creation of hydrogen peroxide-acetyl precursor solutions (“Precursor Solutions”) that can be used to create a non-equilibrium solution of PAA. (Exhibit 1001 at 5:26-37.) The Precursor Solutions are efficient and “remarkably stable,” therefore “overcom[ing] one or more problems of the known prior art,” including being “free of the regulatory reporting, permitting, and shipping restrictions that govern equilibrium PAA products.” (*Id.* at 5:38-47.) Similarly:

This method addresses one or more problems of the known prior art. The method is easy to perform, inexpensive to operate, and requires only basic and common equipment. The method is safe, in that it does not isolate pure PAA, and there is no possibility of a catastrophic event due to an equipment failure, such as over-pressurization or explosions.

When triacetin is used as the acetyl precursor, it is inexpensive, non-toxic, safe, non-corrosive, non-irritating, non-flammable, sanctioned as Generally Recognized as Safe (GRAS) by the FDA, and converted quickly and with a high conversion rate into PAA. The method does not require the use of perhydrolase enzymes, acetic acid, or acetic anhydride, all of which suffer from the aforementioned limitations and problems. The method generates a PAA product that does not contain ammonium hydroxide. The method can be performed to generate a PAA product in a continuous or intermittent fashion. Further, the method allows the end-user the choice of utilizing the on site generated PAA immediately or later over the course of a working day.

(*Id.* at 6:57-7:8.) The non-equilibrium PAA ultimately generated by the methods of the U.S. 8,546,449 Patent Family in turn have unique properties that are generally advantageous. They yield high levels of PAA (1-7.1%), are alkaline (thus avoiding the risks associated with the acidic formulations of the prior art), and may be used flexibly, as the reaction can be stopped at will by neutralizing the solution, and then the reaction can be re-started and used as needed. (*Id.* at 18:23-37.)

B. Prosecution History of the '449 Patent

Because the '443 Patent descends from the '449 Patent and U.S. Patent No. 9,370,180 (the "'180 Patent") and expressly "incorporates both applications by reference in their entirety," the prosecution history of both parent patents is

relevant to the '443 Patent. The prosecution history of the '180 Patent, however, is largely unremarkable; it noted that the single piece of art cited by the examiner was not prior art and issued following a restriction requirement.

The '449 Patent prosecution history, however, provides greater insight as to the key aspects of the inventions of the 8,546,449 Patent Family. As an initial matter, it is important to note that the '449 Patent and, by extension, its progeny,² peremptorily discusses thirteen prior art references in the “Background of the Invention,” and the '449 Patent cites a total of 25 patents and 5 non-patent references on its face, all of which were considered by the Examiner during examination. (**Exhibit 2002**, *Enviro Tech v. Clean Chemistry* Complaint at Exhibit E, '449 Patent.) In the sole Office Action (other than a restriction requirement), the Examiner noted that “[t]he level of skill in the art is high,” and that there is a “high

² M.P.E.P. § 609.02 (Ninth ed., Rev. 01.2024) states that “[t]he examiner will consider information which has been considered by the Office in a parent application [] when examining: ... (B) a divisional application filed under 37 CFR 1.53(b)... . . . A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent.”

degree of unpredictability of the chemical art” disclosed in the specification.

(**Exhibit 2018**, '449 Patent Office Action at 7, 8.) In the Notice of Allowance, the Examiner stated that the claims were “neither anticipated nor rendered obvious over the art of record, and therefore are allowable. A suggestion for modification of a reference to obtain the instant processes has not been found.” (**Exhibit 2019**, '449 Patent Notice of Allowance at 9.)

C. Prosecution History of the '443 Patent

Following the restriction requirement limiting the scope of the claims of the '449 Patent, Enviro Tech filed a divisional application that led to U.S. Patent No. 9,370,180, which then led to three additional divisional applications, including the application that matured to become the '443 Patent. The '443 Patent prosecution history is unremarkable. The sole office action raised a double patenting rejection (Exhibit 1005 at 118-123), Enviro Tech filed a terminal disclaimer as to the '072 Patent (the basis for the double patenting rejection) (*id.* at 130-133), and the application was allowed (*id.* at 158-164), noting that “[c]laims 1-3 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. A suggestion for modification of a reference to obtain the instant composition has not been found.”

D. Person of Ordinary Skill in the Art

Petitioner proposes that a person of ordinary skill in the art (“POSITA”) would be of a relatively low skill level, having only a bachelor’s degree in chemistry or chemical engineering and two or more years of experience. (Petition, Paper 2 at 11.) This is inconsistent with the level of skill in the art defined by the USPTO during prosecution of the parent patent, the ’449 Patent, which defined the level of skill in the art as “high.” (**Exhibit 2018**, ’449 Patent Office Action at 7.) Consistent with this assessment by the USPTO, Enviro Tech proposes that a POSITA be determined based upon a combination of education and work experience, where a higher degree in chemistry, chemical engineering, or a related discipline requires less work experience in chemical syntheses:

- Bachelor’s Degree – A person with a bachelor’s degree in chemistry, chemical engineering, or a related discipline would need 5 years of working experience in chemical syntheses.
- Master’s Degree - A person with a master’s degree in chemistry, chemical engineering, or a related discipline would need 3 years of working experience in chemical syntheses.
- Doctorate Degree – A person with a Ph.D. in chemistry, chemical engineering, or a related discipline would not need additional working experience by virtue of the additional training and lab work associated with their educational training.

(Exhibit 2020, Declaration of Dr. Whiteker at ¶15.)

III. CLAIM CONSTRUCTION

Petitioner has provided constructions for certain claims that Petitioner has deemed to be important to its invalidity positions. Curiously, many of these terms that now must be construed in the present proceeding were *not* before the District Court in the parallel proceeding. It is unclear why there are additional claim terms listed in the Petition for construction outside of those listed in *Enviro Tech Chemical Services, Inc. v. Clean Chemistry, Inc.*, No. 1:24-cv-01313-ADA (W.D. Tex.) (the “District Court Case”), which asserts the same claims as those at issue here; no explanation is given for why the meaning of those terms did not require construction in one venue but do in another.³ Nevertheless, each of the proposed constructions is addressed below.

A. Non-Equilibrium Solution of Peracetic Acid

Petitioner argues, both here and in the District Court Case, that this term should be construed as having its plain and ordinary meaning, but that it includes

³ Although the District Court has a presumptive limit to the number of terms for construction, parties may overcome the limit; Petitioners did not seek to do so.

irreversibility.⁴ As Enviro Tech noted during the District Court Case, this argument is a false flag. If at least one reaction in a solution is still occurring at a greater rate than the reverse reaction, then the solution is a non-equilibrium solution, so irreversibility is not an essential element of a non-equilibrium solution. (*See Exhibit 2020*, Declaration of Dr. Whiteker at ¶ 52.) In the District Court Case, the Court agreed with Enviro Tech, and construed this term as having its “[p]lain and ordinary meaning.” (*Exhibit 2021*, Claim Construction Order at Term #3.)

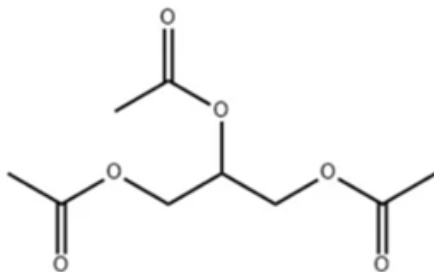
B. Peracetic Acid

This is the same construction agreed-upon by the parties in the District Court Case, and Enviro Tech agrees that it is the correct construction to use herein. (*Exhibit 2022*, Clean Chemistry's Opening Claim Construction Brief at 12.)

C. Triacetin

During the claim construction proceedings in the District Court Case, the parties agreed upon the following definition of triacetin, which should similarly apply herein:

⁴ In the District Court Case, Petitioner also argued that this claim term was indefinite. The District Court rejected this argument.

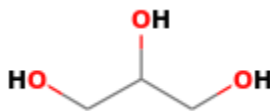


The chemical compound having the structural formula depicted above

(Exhibit 2022, Clean Chemistry's Opening Claim Construction Brief at 12.)

D. 1,2,3-Propanetriol⁵

As defined in the '443 Patent, 1,2,3-propanetriol is also referred to as glycerine. For avoidance of uncertainty, the simplest definition is the chemical compound having the following structural formula:



E. An Aqueous Source of an Alkali Metal or Earth Alkali Metal Hydroxide

Petitioner contends that this term is not defined in the '443 Patent; this is not true because the specification provides multiple examples:

⁵ Petitioner did not seek to construe this term or the following terms in the *Markman* proceedings in the District Court Case.

- “An aqueous source of an alkali metal or earth alkali metal hydroxide, such as sodium hydroxide, is provided on the site having the point-of-use.”
(Exhibit 1001 at 6:10-12).
- “An aqueous source of an alkali metal or earth alkali metal hydroxide is provided on the site having the point-of-use. A preferable aqueous source of an alkali metal hydroxide is sodium hydroxide, and 50% sodium hydroxide is most preferable. Other suitable alkali metal hydroxides include 45% potassium hydroxide.” (*Id.* at 15:31-36.)

Petitioner's proposed definition reads out the requirement that the alkali metal be aqueous. Alkali metals (contained in group one of the periodic table) comprise lithium, sodium, potassium, rubidium, cesium, and francium. The alkali metals form alkaline solutions when they react with water. Alkaline earth metals (contained in group two of the periodic table) comprise beryllium, magnesium, calcium, strontium, barium, and radium, and also form alkaline solutions when reacted with water. Based on the examples given in the '443 Patent (both of group one alkali metal hydroxide solutions that are diluted in water), it is plain that the proper definition is: An alkali metal hydroxide or an alkali earth metal hydroxide which is provided in an aqueous solution.

F. 1% and 7.1%

Petitioner agrees that, as used in Claim 3, these percentages are properly interpreted as referring to the weight percent of peracetic acid in the solution.

IV. ALLEGED PRIOR ART ASSERTED BY PETITIONER

A. Buschmann 1

U.S. 2009/175956 (“Buschmann 1”), which was identified as prior art during the prosecution of the ’449 Patent and its progeny and therefore previously considered by the USPTO, is entitled “Method of Preparation and Composition of Antimicrobial Ice.” (Exhibit 1014). The focus of the invention is not generally disinfecting food and industrial applications but rather specifically providing “frozen compositions useful as antimicrobial ice.” (*Id.* at [0024]). As a result, a POSITA would be unlikely to turn to Buschmann for a more general industrial purpose, as Buschmann 1 is narrowly tailored to a very specific, narrow use not relevant to general disinfecting purposes.

B. Buschmann 2

U.S. 2009/314652 (“Buschmann 2”) (Exhibit 1015) was both identified as prior art during the prosecution of the ’449 Patent and its progeny, but was also expressly discussed – and distinguished – as prior art in the “Background of the Invention” of the ’443 Patent:

Other methods of generating non-equilibrium solutions of PAA on site, using electrolysis, are described in WIPO International Publication Nos. WO 2004/0245116 and WO 2008/140988, and *U.S. Patent Application Publication No. 2009/0314652*. These references disclose cation membrane-divided electrolysis cells and the use of gas diffusion electrodes to effect the cathodic reduction of oxygen gas to hydrogen peroxide under alkaline conditions. The hydrogen peroxide was then allowed to react with acetic acid or an acetyl precursor to form PAA in the bulk solution, whereupon the catholyte was directed to the acidic anode compartment of the cell to stabilize the PAA. This system suffers from several disadvantages. Due to the low solubility of oxygen in water (about 8 ppm maximum), the concentration of electroactive species is very low, which forces the cell to operate at low current density (amperage per surface area of electrode). In order to produce a meaningful amount of hydrogen peroxide, the cells must have a very large surface area. This requires high capital equipment costs and a very large footprint for the electrolysis equipment. Another disadvantage of this system is that it is very difficult to maintain steady-state conditions and simultaneously balance the feed of acetic acid or acetyl precursor to the cathode compartment with the concurrent withdrawal of acidified PAA solution from the anode compartment. This is because cations carrying the cell current through the cation exchange membrane are always hydrated so as the cations move through the membrane, they are accompanied by water molecules. As a result, the volume of the anolyte decreases and the volume of the catholyte increases, making the steady-

state condition difficult to maintain. It is difficult to perform this process intermittently. Finally, this system can only be of economic value if the source of oxygen is air, which comprises 23% oxygen. However, the carbon dioxide contained in air causes carbonates to precipitate, which impedes the flow of electrical current, limiting or eliminating the production of hydrogen peroxide, and hence, PAA.

(Exhibit 1001 at 2:58-3:27 (emphasis added).)

C. Montgomery

U.S. Patent No. 6,221,341 (“Montgomery”) is entitled “Tooth Whitening Composition.” (Exhibit 1016.) Montgomery discloses “[n]ovel compositions and methods...for cosmetically treating teeth in a manner to increase brightness or shade of the teeth.” (*Id.* at Abstract.) Montgomery discloses various methods and compositions for whitening teeth and is not directed to peroxyacetic acid sanitizer used at a point of use.

D. Okano 1

U.S. Patent No. 7,919,122 (“Okano 1”) is directed to a “Composition for Production of a Sterilizer and a Process for Producing Organic Peracid.” (Exhibit 1010.) Okano 1 teaches a formulation for a reaction mixture and provides limited information about the composition of the final product that contains peracetic acid.

E. Okano 2 (Translated)

JP 2006-045147 (“Okano 2”) is directed to “[a] sterilizing cleaner composition for hard surfaces, containing water and an organic peracid obtained by reacting (A) an ester of polyhydric alcohol and an organic acid with (B1) hydrogen peroxide in a specific molar ration in water at a pH of 8 to 12, and having a pH of 1 or more and less than 7 at 25°C.” (Exhibit 1018 at 1.) Like Okano 1, it teaches a formulation for a reaction mixture and provides limited information about the composition of the final product that contains peracetic acid.

V. NO CLAIMS OF THE '443 PATENT ARE ANTICIPATED OR OBVIOUS

A. Grounds 1a and 1b: Claim 1 is neither anticipated nor rendered obvious by Buschmann 1

Petitioner argues that Buschmann 1 anticipates or renders obvious Claim 1 of the '443 Patent. Buschmann 1 does not include all of the elements of Claim 1 and therefore cannot anticipate Claim 1. “[A] prior art reference must provide every element of the claimed invention arranged as in the claim in order to anticipate.” *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1069 (Fed. Cir. 2017).

Claim 1 is directed to a non-equilibrium solution of peracetic acid, comprising: (a) peracetic acid; (b) hydrogen peroxide; (c) triacetin; (d) 1,2,3-propanetriol; (e) an aqueous source of an alkali metal or earth alkali metal hydroxide; and (f) water. (Exhibit 1001 at 35:13-21.) None of the portions of

Buschmann 1 cited by Petitioner teaches a non-equilibrium solution of peracetic acid comprising those six components:

<p>“... an alkaline mixture of non-equilibrium PAA, hydrogen peroxide, triacetin, and glycerol.” (Exhibit 1014 at [0030].)</p>	<p>Does not disclose (e) an aqueous source of an alkali metal or earth alkali metal hydroxide and (f) water.</p>
<p>“In the present invention non-equilibrium peroxy-carboxylic acid solutions, particularly those of PAA, are chemically produced by an irreversible, non-equilibrium reaction of hydrogen peroxide with an acyl donor, particularly an acetyl donor, in a solvent such as, but not limited to, water.” (<i>Id.</i> at [0033]).</p>	<p>This teaches the use of water in the <u>reaction solution</u>, not in the <u>product solution</u>.</p>
<p>“The reaction pH can be adjusted with an appropriate base (proton acceptors such as hydroxide or amines for example).” (<i>Id.</i> at [0033].)</p>	<p>This teaches the use of a hydroxide base to adjust the pH of the <u>reaction solution</u>, not in the <u>product solution</u>.</p>

<p>“Sodium hydroxide is disclosed as a base in Buschmann 1.” (Petition, Paper 2, at 19, citing to Exhibit 1014 at [0034] and [0041].)</p>	<p>[0034] and [0041] disclose the use of sodium hydroxide as part of a <u>reaction solution</u>, not the <u>product solution</u>. The disclosed <u>product solutions</u> of [0034] and [0041] do not disclose the presence of sodium hydroxide (or of other critical components of Claim 1).</p>
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Because Buschmann 1 does not teach all of the elements of Claim 1, it therefore does not anticipate Claim 1 of the '443 Patent.

Nor does Buschmann 1 render Claim 1 obvious; Petitioner fails to explain how the existence of water and/or sodium hydroxide in a reaction solution teaches the presence of those components in the resulting non-equilibrium solution of peracetic acid. Moreover, Petitioner fails to explain why an inventor searching for methods of creating a stable peracetic acid solution would turn to a patent directed to a “Method of Preparation and Composition of Antimicrobial Ice” to solve that problem. Because there would be no motivation to review Buschmann 1, it would

not have informed a POSITA in its development of the invention of the '443 Patent. It is a fundamental principle that, in addition to identifying a motion to combine references or to otherwise rely upon the art in question to solve a problem, in order to render a claim obvious, every claim element must be taught in the prior art. *See* M.P.E.P. § 2143.03 (Ninth ed., Rev. 01.2024) (“Examiners must consider all claim limitations when determining patentability of an invention over the prior art.”); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.”); *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1366-67 (Fed. Cir. 2012).

In reviewing the Petition, the Director and the Board are limited to the arguments raised by Petitioner in the Petition, and, as stated by the Board in the underlying *inter partes* review, “failure to direct the [Board] to evidence sufficient to establish” obviousness of a claim will mean that such an argument is not properly before the Director and the Board. *AMP Plus, Inc. v. DMF, Inc.*, 131 F.4th 1320, 1323-24 (Fed. Cir. 2025). “[T]he law of obviousness does not require the court, or the Board, to develop arguments for a limitation that the petition simply did not make.” *Id.* at 1325.

B. Grounds 1c and 1d: Claim 2 is neither anticipated nor rendered obvious by Buschmann 1

As an initial matter, Buschmann 1 cannot anticipate or render obvious Claim 2 of the '443 Patent because Claim 2 of the '443 Patent depends from Claim 1, and Buschmann 1 fails to teach all of the elements of Claim 1. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (“Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.”).

Even if that were not the case, Buschmann 1 does not disclose a pH of 11.2 to 13.37 in a non-equilibrium solution of peracetic acid. Buschmann 1 discloses a pH of 12.0 in a reaction solution but does not explicitly disclose the pH of the product solution. The disclosure of Buschmann 1 does, however, imply that the product solution has a pH in a range of 7.5 to 10.5, which is below the disclosed range: “As disclosed herein, ***the above self-reaction decomposition process at alkaline pH ($7.5 \leq \text{pH} \leq 10.5$)*** may also be inhibited by addition of an appropriate peroxide stabilizer.” (Exhibit 1014 at [0040].) Moreover, although Buschmann 1 teaches the use of a pH of more than 10 to accelerate the reaction (Exhibit 1014 at [0033]), it teaches away from a non-equilibrium solution of peracetic acid with an alkaline pH stating that such a solution is unstable, subject to decomposition, and suggests that the pH should be adjusted to become acidic. (*Id.* at [0036]-[0039],

[0042].) Because Buschmann 1 fails to teach a non-equilibrium solution of peracetic acid with a pH of about 11.2 to about 13.37, it cannot anticipate Claim 2 of the '443 Patent.

Moreover, because Buschmann 1 does not disclose this range, and instead teaches away from a non-equilibrium solution of peracetic acid with an alkaline pH, it cannot render the alkaline pH taught by Claim 2 obvious. “[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *KSR Int'l Co.*, 550 U.S. at 416; *see also Arctic Cat Inc. v. Bombardier Rec. Prods.*, 876 F.3d 1350, 1363 (Fed. Cir. 2017).

In addition, as discussed *supra*, Petitioner fails to explain why an inventor searching for methods of creating a stable peracetic acid solution would turn to a patent directed to a “Method of Preparation and Composition of Antimicrobial Ice” to solve that problem; for this additional reason, Buschmann 1 does not render obvious the claims of the '443 Patent.

C. Grounds 2a and 2b: Claim 1 is neither anticipated nor rendered obvious by Buschmann 2

Petitioner argues that Buschmann 2 anticipates Claim 1 of the '443 Patent based on a series of separate citations contained within Buschmann 2 that reference

the various claimed components of Claim 1. But that is not sufficient for anticipation; an anticipatory prior art reference must “provide every element of the claimed invention arranged as in the claim in order.” *Biscotti*, 878 F.3d at 1069. Buschmann 2 does not do so. Claim 1 of the '443 Patent is directed to a non-equilibrium solution of peracetic acid and its components. In order to assert inclusion of each of the listed components, Petitioner relies upon listings of the components that are placed into solution to generate the reaction that creates the non-equilibrium solution of peracetic acid, but it does not appear that those same components are present in the resulting non-equilibrium solution of peracetic acid. Rather, the PAA composition taught by Buschmann 2 and as listed in Table 5, as cited to by Petitioner, omits key components:

TABLE 5

Peracetic acid product composition from continuous 2-chamber reactor using triacetin as feedstock

Constituent	Trial 1 Concentration	Trial 2 Concentration
peracetic acid	950 mg/L	950 mg/L
hydrogen peroxide	212 mg/L	170 mg/L
acetic acid	1560 mg/L	1500 mg/L
glycerol	1120 mg/L	1110 mg/L
sodium	348 mg/L	NA
pH	3.40	NA

(Exhibit 1015, Table 5, p. 16.) The PAA produced by the methods of Buschmann 2 neither yields water, an aqueous source of an alkali metal or earth alkali metal

hydroxide,⁶ nor does it include triacetin.⁷ Nor, as discussed *supra*, are the methods of Buschmann 2 comparable to those used in the '443 Patent, and would not teach that a non-equilibrium PAA solution such as that taught by the '443 Patent could be made without the use of cation membrane-divided electrolysis cells and/or gas diffusion electrodes. As a result, it cannot anticipate Claim 1 of the '443 Patent.

Petitioner's argument that Buschmann 2 renders Claim 1 obvious is simply flawed, relying solely on Buschmann 2's purported teaching that hydroxide can be sodium hydroxide. This is irrelevant; in Buschmann 2, there is no hydroxide listed at all in the PAA Composition of Table 5. Petitioner does not address the missing elements of Buschmann 2, and therefore Buschmann 2 cannot render Claim 1 obvious. Moreover, as discussed above, a POSITA would not have relied upon Buschmann 2 to teach the elements of Claim 1, because Buschmann 2 relies upon the use of cation membrane-divided electrolysis cells and/or gas diffusion electrodes, a problematic method that the '443 Patent expressly identifies as a

⁶ Sodium is an alkali metal, but it does not appear to be a hydroxide, as required by Claim 1. The method taught by Buschmann 2 includes the addition of sodium sulfate, which may also contribute to the presence of sodium in the PAA solution.

⁷ Acetic acid is a precursor to triacetin but is not triacetin.

method that is impractical and inefficient. Petitioner has failed to show that Buschmann 2 renders Claim 1 obvious, nor can it, because Buschmann 2 is art that the '443 Patent expressly avoids.

D. Grounds 2c and 2d: Claim 2 is neither anticipated nor rendered obvious by Buschmann 2

As an initial matter, Buschmann 2 cannot anticipate or render obvious Claim 2 of the '443 Patent because Claim 2 of the '443 Patent depends from Claim 1, and Buschmann 2 fails to teach all of the elements of Claim 1. *In re Fine*, 837 F.2d at 1076.

Moreover, Buschmann 2 can neither anticipate nor render obvious the pH range taught by Claim 2 of the '443 Patent because that pH range is not disclosed by Buschmann 2 in the context of a non-equilibrium solution of peracetic acid and, in fact, the pH associated with the Buschmann 2 non-equilibrium solution of peracetic acid is outside this range. Specifically, the portions of Buschmann 2 cited by Petitioner are all directed to precursors to the non-equilibrium solution of peracetic acid (“the product solution”):

[0026]	This is the pH of the reaction solution, not the product solution.
[0063]	This is the pH of the catholyte solution, not the product solution.
[0077]	This is the pH of the reaction solution, not the product solution.

In contrast, the pH of the disclosed product solution is far outside of the claimed range:

TABLE 5

Peracetic acid product composition from continuous 2-chamber reactor using triacetin as feedstock

Constituent	Trial 1 Concentration	Trial 2 Concentration
peracetic acid	950 mg/L	950 mg/L
hydrogen peroxide	212 mg/L	170 mg/L
acetic acid	1560 mg/L	1500 mg/L
glycerol	1120 mg/L	1110 mg/L
sodium	348 mg/L	NA
pH	3.40	NA

(Exhibit 1015, Table 5, p. 16.) The pH of the product taught by Buschmann 2 is acidic, not basic, as is taught by the '443 Patent, and therefore Buschmann 2 can neither anticipate nor render obvious Claim 2 of the '443 Patent, which is directed to the product and not its precursors.

E. Ground 3: Claim 1 is not rendered obvious by Montgomery

Petitioner asserts that Montgomery, which is directed to a tooth whitening composition, renders Claim 1 of the '443 Patent obvious, despite providing no explanation as to why a POSITA looking to an improved industrial cleaner would turn to the dental arts to solve that problem. Moreover, Montgomery does not teach the formulation of Claim 1. Specifically, the example upon which Petitioner relies to show the presence of the elements of Claim 1, the formulation of Table 5, does

not teach the composition of a “non-equilibrium solution of peracetic acid,” but rather provides the ingredients for two precursor solutions which, when combined, purport to result in peroxyacetic acid, as the components of the precursor solutions may be completely used up during the reaction, or may form different or new components as a result of the reaction. The composition of a precursor solution is not representative of the composition of the solution that results after the precursor solutions are combined and create peracetic acid. Thus, the formulations of Montgomery do not teach the composition of Claim 1.

In fact, the composition of the resulting mixture in Montgomery is disclosed as comprising “both the hydrogen peroxide precursor and glyceryl triacetate, *and alternatively*, water in a sufficient amount of peroxyacetic acid for whitening the teeth.” (Exhibit 1016 at 15:64-67 (emphasis added).) This composition does not, therefore, include two of the key components of Claim 1: the 1,2,3-propanetriol and the aqueous source of an alkali metal or earth alkali metal hydroxide. And, moreover, the other elements of Claim 1 (hydrogen peroxide precursor and glyceryl triacetate, on the one hand, and water, on the other hand) cannot be simultaneously present in the composition of the resulting mixture. Nor does Petitioner provide any evidence that the solution of Montgomery is a non-equilibrium solution. Because Petitioner does not contend that Montgomery

teaches a non-equilibrium solution of peracetic acid, because Montgomery does not teach any mixtures that do or could contain all of the ingredients of Claim 1, and because Montgomery’s tooth whitening teachings do not teach a method of creating an industrial cleaner, Montgomery does not render Claim 1 of the ’443 Patent obvious.

F. Ground 4a and 4b: Claim 1 is neither anticipated nor rendered obvious by Okano 1

Petitioner contends that Okano 1 teaches all of the elements of Claim 1 of the ’443 Patent. But Petitioner has again mistaken a precursor solution and/or a reaction composition for a product composition. In attempting to show that Okano 1 includes all of the elements of Claim 1, Petitioner repeatedly cites to the precursor solution (the “first composition for production of a sterilizer”) or the reaction composition (the “compounding components”), and not the product composition:

Ex. 1010 at 1:58-62	Petition at 32-33.	This is a precursor solution.
Ex. 1010 at 29:30-36	<i>Id.</i> at 33	This is a precursor solution.
Ex. 1010 at Table 10	<i>Id.</i>	The “Compounding components” are the reaction

		composition. Note also that the reaction composition does not include an <u>aqueous</u> source of an alkali metal or earth alkali metal hydroxide
Ex. 1010 at 29:33-35 and 30:28-30	<i>Id.</i>	This is a reaction composition.
Ex. 1010 at 47:43-48 and 48:41-44	<i>Id.</i>	This is a reaction composition.

The only product composition data provided in the cited portions of Okano 1 is the organic peracid concentration (at various points in time), the hydrogen peroxide composition, and the pH of the solution. Okano 1 is silent as to whether the product composition includes triacetin, 1,2,3-propanetriol, an aqueous source of alkali metal or alkali earth metal hydroxide, or water. Even assuming that Petitioner is correct that the existence of 1,2,3-propanetriol is inherently present in the product composition, Okano 1 still fails to disclose the presence of multiple other elements of Claim 1.

Moreover, that Petitioner is correct that 1,2,3-propanetriol is inherently present is indeed, an assumption, and not one that Enviro Tech is willing to concede. Petitioner relies largely on the declaration of its expert for this conclusion, and Petitioner's expert report fails to address how the inclusion of other compounding ingredients might affect this conclusion. For example, all examples cited include phosphonic acid, which reacts with 1,2,3-propanetriol to form glycerophosphoric acid; it is therefore reasonable to conclude that the product composition might include glycerophosphoric acid, and not 1,2,3-propanetriol. Similarly, Petitioner misunderstands the discussion of inherency in the prosecution history of the '443 Patent, which is discussing the inherency of an element between two patents with a shared specification, and not the inherency of a component as a result of a chemical reaction. (Exhibit 1005 at 121.) Because Okano 1 does not teach every element of Claim 1, it cannot anticipate Claim 1. *Biscotti*, 878 F.3d at 1069.

Petitioner further argues that Okano 1 also renders Claim 1 obvious but fails to provide any explanation as to how Okano 1 teaches any of the missing elements discussed above. *See AMP Plus, Inc.*, 131 F.4th at 1325 (“[T]he law of obviousness does not require the court, or the Board, to develop arguments for a

limitation that the petition simply did not make.”). As a result, Okano 1 cannot render Claim 1 obvious because it does not disclose all elements of Claim 1.

G. Grounds 4c and 4d: Claim 2 is neither anticipated nor rendered obvious by Okano 1

Petitioner also argues that Claim 2 is anticipated and rendered obvious by Okano 1. As an initial matter, Okano 1 cannot anticipate or render obvious Claim 2 of the '443 Patent because Claim 2 of the '443 Patent depends from Claim 1, and Okano 1 fails to teach all of the elements of Claim 1. *In re Fine*, 837 F.2d at 1076.

Claim 2 is also neither anticipated nor obvious because Okano 1 does not disclose a non-equilibrium solution of peracetic acid with a pH of about 11.2 to about 13.37, as is required by Claim 1. To the contrary, the portions of Okano 1 that are cited by Petitioner reference a pH for the reaction composition,⁸ and not

⁸ Note that the initial reaction mixture pH varies from 8 to 12, and that the initial reaction mixture does not include peracetic acid, as is required by Claim 1. The pH of the mixture decreases over time as the reaction occurs and a greater volume of acid is created. As a result, the pH of 12 is the pH prior to the start of the reaction, and the lower pH is observed once peracetic acid is generated. Petitioner contends that a non-equilibrium solution of peracetic acid does not occur until “such mixtures are sufficiently mixed to homogeneity so as to constitute a solution,”

the pH of the non-equilibrium solution of peracetic acid. The pH of the peracetic acid solutions disclosed in Examples 3 and 6 ranges from 1.2 to 3.7 and are clearly outside the claimed range. (Exhibit 1010 at Table 10 (30:42-31:23) and Table 23 (48:56-49:43.) There is therefore no anticipation and no presumption of obviousness.

H. Grounds 4e and 4f: Claim 3 is neither anticipated nor rendered obvious by Okano 1

Petitioner further argues that Claim 3 is anticipated and rendered obvious by Okano 1. But Okano 1 cannot anticipate or render obvious Claim 3 of the '443 Patent because Claim 3 of the '443 Patent depends from Claim 1, and Okano 1 fails to teach all of the elements of Claim 1. *In re Fine*, 837 F.2d at 1076.

I. Grounds 5a and 5b: Claim 1 is neither anticipated nor rendered obvious by Okano 2

(Petition, Paper 2 at 36) and cites to the portions of Okano referring to a period of time “about thirty minutes after the stirring.” (Exhibit 1010 at 30:28-30 and 48:41-44.) As a result, it is unlikely that the pH of the reaction solution, when measured thirty minutes after stirring, overlaps with that of Claim 2.

1. Okano 2 does not disclose the required product solution components.

Petitioner's invalidity arguments arising from Okano 2 suffer from the same problems as its prior invalidity arguments – Petitioner conflates the composition of a precursor or reaction solution with that of the resulting non-equilibrium solution of peracetic acid. For example, Petitioner argues that Okano 2 includes triacetin, hydrogen peroxide, water, and aqueous sodium hydroxide. (Petition, Paper 2 at 40, citing Exhibit 1018 at [0057].) But these components are present as precursors, and Petitioner fails to show that those components are present in the resulting solution of peracetic acid. Petitioner cannot do so because Okano 2 is largely silent as to the content of the solution of peracetic acid. (*See, e.g.*, Exhibit 1018 at [0057] (disclosing only that the sterilizing cleaner composition containing the organic peroxy acid has a pH of about 2 and hydrogen peroxide content of about 1500 ppm).) Okano 2 does not identify whether the solution of peracetic acid is a non-equilibrium solution,⁹ or provide evidence that triacetin, 1,2,3-propanetriol, or an

⁹ Petitioner argues that the reaction must be irreversible and, as reactants are still present, it is not yet at equilibrium. Therefore, they allege, it is a non-equilibrium solution. But both of these conclusions are questionable: the Okano 2 reference itself does not refer to the solution as a non-equilibrium solution, nor does it state

aqueous source of an alkali metal or earth alkali metal hydroxide are present in the sterilizing cleaner composition. And the presence of water is merely inferred because the cleaner is referred to as being an aqueous solution.

Petitioner proffers an elaborate, multi-part argument insisting that 1,2,3-propanetriol is inherently present in the sterilizing cleaner composition (Petition, Paper 2 at 40-42) but the argument fails to account for the actual content of the solution at issue, nor does it properly interpret the file history of the '443 Patent upon which it relies.

First, Petitioner's expert report fails to address how the inclusion of other compounding ingredients might affect his conclusion that 1,2,3-propanetriol is inherently present in the cleaning solution. For example, the formula recited in Okano 2 at [0057] includes phosphonic acid, which reacts with 1,2,3-propanetriol to form glycerophosphoric acid. Petitioner's expert ignores the presence of the phosphonic acid entirely (Exhibit 1008 at ¶ 152) and does not address the fact that

that the reaction is irreversible. The expert declaration Petitioner relies upon to support this proposition is conclusory and fails to demonstrate how either of these elements are taught in Okano 2.

any generated 1,2,3-propanetriol was likely converted into glycerophosphoric acid and is therefore not present in the Okana 2 sterilizing cleaner.

Similarly, in asserting that Enviro Tech somehow “admitted” that 1,2,3-propanetriol was inherently present in the sterilizing cleaner of Okano 2, Petitioner misunderstands the discussion of inherency in the prosecution history of the '443 Patent. During the prosecution of the '443 Patent, the Examiner asserted that the patent was subject to an obvious-type double patenting rejection and specifically noted that “[t]he difference between instant claims and [the claims of the application that matured to the '072 Patent] is that [the claims of the application that matured to the '072 Patent] is silent on the instant element 1,2,3-propanetriol. [The application that matured to the '072 Patent] inherently overlap with the instant invention.” (Exhibit 1005 at 121.) Contrary to Petitioner's arguments, the Examiner is clearly not asserting that 1,2,3-propanetriol is inherently present in a reaction. Rather, the Examiner is discussing the inherency of an element between two patents with a shared specification, and not the inherency of a component as a result of a chemical reaction. (*Id.*) In other words, the Examiner is stating that when two patents share a specification, even if Component X is not mentioned in both claims, it is inherently present because its presence is taught in the shared specification. Nothing more. Thus, Petitioner has

failed to show that 1,2,3-propanetriol is inherently present in the Okana 2 sterilizing cleaner.

Because multiple elements of Claim 1 are not disclosed in the sterilizing cleaner of Okana 2, and because Petitioner has failed to show that those elements are inherent, Okana 2 cannot anticipate Claim 1. *Biscotti*, 878 F.3d at 1069. Nor does Petitioner make any arguments that overcome these shortfalls in its argument that Okana 2 renders Claim 1 obvious, and therefore Okana 2 neither anticipates nor renders obvious Claim 1 of the '443 Patent. *See AMP Plus, Inc.*, 131 F.4th at 1325 (“[T]he law of obviousness does not require the court, or the Board, to develop arguments for a limitation that the petition simply did not make.”)

2. Okano 2 teaches away from the invention of the '443 patent.

One of the novel features of the invention of the '443 patent is that it achieves a non-equilibrium solution of peracetic acid using a stable, basic solution. A POSITA reading Okano 2, however, would note both the use of a stabilizer (phosphonic acid) and the immediate addition of an acidic solution to the Okano 2 solution taught at [0057], and would understand the invention of Okano 2 to be highly unstable. (Ex. 1018 ¶ 57.) As a result, a POSITA would (1) believe that the combination of triacetin and hydrogen peroxide to yield peracetic acid is an unstable reaction, and would not teach a stable solution that could easily be

transported and used at the point of use; (2) believe that any solution combining triacetin and hydrogen peroxide to make peracetic acid would require the use of a stabilizer; and (3) believe that it is necessary to stop the triacetin-hydrogen peroxide reaction quickly and stabilize the solution with acid, because it could not run over a period of time.

As a result, a POSITA would not expect that the combination of triacetin and hydrogen peroxide taught by Okano 2 would yield a stable, readily transportable solution for on-site use absent the use of stabilizers and acids to limit the reaction, and would not turn to Okano to solve the problem that the '443 patent seeks to address. For this additional reason, there is no motivation to use the Okano reference, and Okano cannot render obvious Claim 1 or any other claim of the '443 Patent. *KSR Int'l Co.*, 550 U.S. at 418 (there must be “a reason” for a skilled artisan to “combine the elements in the way the new invention does” in order for a reference to render the patent obvious).

J. Grounds 5c and 5d: Claim 2 is neither anticipated nor rendered obvious by Okano 2

Petitioner further argues that Claim 2 is anticipated and rendered obvious by Okano 2. But Okano 2 cannot anticipate or render obvious Claim 2 of the '443

Patent because Claim 2 of the '443 Patent depends from Claim 1, and Okano 2 fails to teach all of the elements of Claim 1. *In re Fine*, 837 F.2d at 1076.

Claim 2 is also neither anticipated nor obvious because Okano 2 does not disclose a non-equilibrium solution of peracetic acid with a pH of about 11.2 to about 13.37, as is required by Claim 1. To the contrary, the portions of Okano 2 that are cited by Petitioner reference a pH for the reaction composition,¹⁰ and not the pH of the sterilizing cleaner. The pH of the peracetic acid solutions disclosed in [0008], [0009], [0015], [0029], and [0030] range from 1 to 7 and are clearly outside the claimed range. (Exhibit 1018.) There is therefore no anticipation and no presumption of obviousness.

K. Grounds 5e and 5f: Claim 3 is neither anticipated nor rendered obvious by Okano 2

¹⁰ As with Okano 1, the initial reaction mixture pH varies from 8 to 12, and the initial reaction mixture does not include peracetic acid, as is required by Claim 1. The pH of the mixture decreases over time as the reaction occurs and a greater volume of acid is created. As a result, the pH of 12 is the pH prior to the start of the reaction, and the lower pH is observed once peracetic acid is generated. As a result, it is unlikely that the pH of the reaction solution overlaps with that of Claim 2.

Petitioner further argues that Claim 3 is anticipated and rendered obvious by Okano 2. But Okano 2 cannot anticipate or render obvious Claim 3 of the '443 Patent because Claim 3 of the '443 Patent depends from Claim 1, and Okano 2 fails to teach all of the elements of Claim 1. *In re Fine*, 837 F.2d at 1076.

In addition, Petitioner argues that the concentration of peracid in the composition is “preferably 10 to 20,000 ppm, more preferably 10 to 10,000 ppm.” (Exhibit 1018 at [0023].) This is a range of .001 to 2.000%, which overlaps the claimed range of “about 1% to about 7%.” But the range claimed by Okano 2 is quite large (a two-thousand-fold difference), and such a range must be enabled in order to render Claim 3 anticipated or obvious. *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005) (“Although published subject matter is ‘prior art’ for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art must enable a person of ordinary skill to make and use the invention.”).

Moreover:

Although a patent's specification need not ‘describe how to make and use every possible variant of the claimed invention,’ ‘when a range is claimed, there must be reasonable enablement of the scope of the range.’ *AK Steel*, 344 F.3d at 1244. To qualify as ‘reasonable,’ ‘the specification . . . must teach those skilled in the art how to make and use the full scope of the claimed invention without “undue

experimentation.” *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (citing *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)).

McRO, Inc. v. Bandai Namco Games Am., Inc., 959 F.3d 1091, 1100 (Fed. Cir. 2020).

Thus, the Okano 2 range must be supported by specific examples or other explicit teachings that enable the claimed range. Such specific examples do not, however, exist. Petitioner attempts to *create* such an example by walking through the alleged reaction of Example 1 ([0057]), but the level of creativity involved in the calculations presented by Petitioner render Petitioner's example worthless. For example, Petitioner bases its calculation on the assumption that hydrogen peroxide is the limiting reagent (meaning that the reaction will cease once all hydrogen peroxide is utilized, even though other components of the reaction may remain). (Petition, Paper 2 at 45.) Petitioner also assumes that there is a “complete reaction,” again, meaning that all of the hydrogen peroxide is used. (*Id.*) But these assumptions are problematic for two reasons.

First, hydrogen peroxide must be present in the peracetic acid solution in order to read on Claim 1; if there is a complete reaction, all of the hydrogen

peroxide will be used, and there will be no hydrogen peroxide present, and therefore none of claims 1-3 can be infringed.

Second, [0057], which is the basis for Petitioner's calculation, explicitly discloses that the peracetic acid solution has a hydrogen peroxide content of "about 1500 ppm." As a result, there is no "complete reaction" because not all hydrogen peroxide was used, and Petitioner's conclusion that 3.3 wt% peracetic acid is created grossly overstates the efficiency of the actual reaction, rendering the entire calculation unreliable.

Because Petitioner has failed to show a single reliable example of the total amount of peracetic acid produced by the methods of Okano 2, much less that any of the methods of Okano 2 result in the amounts of peracetic acid within the range claimed by Okano 2 or Claim 2 of the '443 Patent, the range of Okano 2 is not enabled and cannot render obvious the range taught by Claim 3 of the '443 Patent. *See AMP Plus, Inc.*, 131 F.4th at 1325 ("[T]he law of obviousness does not require the court, or the Board, to develop arguments for a limitation that the petition simply did not make.")

L. Grounds 6a, 6b, and 6c: Claims 1-3 are not rendered obvious by the combination of Okano 1 and Okano 2

Petitioner's reliance on a combination of Okano 1 and Okano 2 to render Claims 1-3 of the '443 Patent is misplaced. As discussed above, neither Okano 1 nor Okano 2 disclose all of the elements of any of the claims of the '443 Patent:

Claim Elements	Okano 1	Okano 2
1. A non-equilibrium solution of peracetic acid, comprising:	X	-
a. Peracetic acid	X	X
b. Hydrogen peroxide	X	X
c. Triacetin	-	-
d. 1,2,3-propanetriol	-	-
e. An aqueous source of an alkali metal or earth alkali metal hydroxide; and	-	-
f. Water.	-	X
2. The solution of claim 1, wherein said solution has a pH of about 11.2 to about 13.37.	1.2-3.7	"about 2"
3. The solution of claim 1, wherein said peracetic acid is about 1% to about 7.1%.	2.7 wt%	-

Petitioner fails to show how the combination of Okano 1 and Okano 2 fill these gaps, nor does it attempt to do so, as it concedes that “Okano 1 and Okano 2 use the same components.” (Petition, Paper 2 at 48.) *See AMP Plus, Inc.*, 131 F.4th at 1325 (“The law of obviousness does not require the court, or the Board, to develop arguments for a limitation that the petition simply did not make.”). As a result, the combination of these references fails to render any claims of the '443 Patent obvious.

VI. CONCLUSION

None of the *five* references identified by Petitioner contains all of the elements of Claim 1 of the '443 Patent, and therefore these references fail to anticipate or render obvious the claims of the '443 Patent. Because Petitioner has failed to meet the “reasonable likelihood of success” standard that any of the claims of the '443 Patent are unpatentable, Enviro Tech respectfully requests that the Director deny institution of *Inter Partes* Review of Claims 1-3 of the '443 Patent.

Dated: December 5, 2025

Respectfully Submitted,

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CERTIFICATION OF WORD COUNT

This Petition complies with the type-volume limitations as mandated in 37 C.F.R. § 42.24, totaling 9,122 words. Counsel has relied upon the word count feature provided by Microsoft Word.

Dated: December 5, 2025

By: /Anna C. Halsey/
Anna C. Halsey

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing *Patent Owner's Preliminary Response* was served via electronic mail, per agreement of the parties, in its entirety, on Petitioner's attorneys of record in IPR2025-01459 on the date indicated below.

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