

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 IPR2025-01458
Patent 9,737,072

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

Page

Table of Contents

I.	INTRODUCTION	1
II.	BACKGROUND	2
A.	Technology Overview of the 8,546,449 Patent Family	2
1.	The 8,546,449 Patent Family	2
2.	The Prior Art: Equilibrium Solutions of Peracetic Acid	3
3.	The Prior Art: Prior Attempts to Create Non-Equilibrium Peracetic Acid Solutions	5
4.	The Inventions of the U.S. 8,546,449 Patent Family Solved the Prior Art Problems	7
B.	Prosecution History of the '449 Patent	8
C.	Prosecution History of the '072 Patent	10
D.	Person of Ordinary Skill in the Art	10
III.	CLAIM CONSTRUCTION	11
A.	Hydrogen peroxide-acetyl precursor solution.....	12
B.	Aqueous hydrogen peroxide.....	12
C.	Triacetin.....	14
D.	Peracetic Acid.....	14
E.	Trace Amount.....	15
IV.	ALLEGED PRIOR ART ASSERTED BY PETITIONER.....	15
A.	Stauffer	16
B.	Okano (Translated).....	18

V.	NO CLAIMS OF THE '072 PATENT ARE ANTICIPATED OR OBVIOUS.....	20
A.	Grounds 1a and 1b: Stauffer Neither Anticipates Nor Renders Obvious Claim 1.....	20
B.	Grounds 2a and 2b: Okano Neither Anticipates Nor Renders Obvious Claim 1.....	25
1.	Okano does not disclose the required Precursor Solution components.	25
2.	Okano teaches away from the required Precursor Solution components.....	27
C.	Grounds 2c and 2d: Okano Neither Anticipates Nor Renders Obvious Claims 2 and 3	28
VI.	CONCLUSION.....	35

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>AMP Plus, Inc. v. DMF, Inc.</i> , 131 F.4th 1320 (Fed. Cir. 2025)	24, 27
<i>Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP</i> , 616 F.3d 1249 (Fed. Cir. 2010)	13
<i>Bicon, Inc. v. Straumann Co.</i> , 441 F.3d 945 (Fed. Cir. 2006)	13
<i>Cat Tech LLC v. TubeMaster, Inc.</i> , 528 F.3d 871 (Fed. Cir. 2008)	13
<i>Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.</i> , 214 F.3d 1302 (Fed. Cir. 2000)	13
<i>Ex parte A</i> , 17 USPQ.2d 1716 (Bd. Pat. App. & Inter. 1990)	32
<i>In re Fine</i> , 837 F.2d 1071 (Fed. Cir. 1988)	29
<i>In re Petering</i> , 301 F.2d 676, 133 USPQ 275 (CCPA 1962)	33
<i>Kinetic Concepts, Inc. v. Smith & Nephew, Inc.</i> , 688 F.3d 1342 (Fed. Cir. 2012)	24, 27
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	24, 27, 28
<i>Microsoft Corp. v. Biscotti, Inc.</i> , 878 F.3d 1052 (Fed. Cir. 2017)	21, 26
<i>Osram Sylvania Inc. v. Am. Induction Tech. Inc.</i> , 701 F.3d 698, 105 USPQ.2d 1368 (Fed. Cir. 2012).	32
<i>Sanofi-Synthelabo v. Apotex, Inc.</i> , 550 F.3d 1075, 89 USPQ.2d 1370 (Fed. Cir. 2008)	32

Other

M.P.E.P. § 609.02 (Ninth ed., Rev. 01.2024)	9
M.P.E.P. § 2131.02 (Ninth ed., Rev. 01.2024)	32-33
M.P.E.P. § 2143.03 (Ninth ed., Rev. 01.2024)	13, 24, 27

UPDATED EXHIBIT LIST		
2001	<i>Pro Hac Vice</i> Declaration of Ann G. Fort	10/27/2025
2002	<i>Enviro Tech v. Clean Chemistry</i> Complaint (Docket No. 1)	11/4/2025
2003	<i>Enviro Tech v. Clean Chemistry</i> Scheduling Order (Docket No. 22)	11/4/2025
2004	March 24, 2025 PTAB Memo On IPR Proceedings	11/4/2025
2005	March 26, 2025 PTAB Memo on Interim Processes	11/4/2025
2006	Docket Navigator: Motion Success for Stay Pending IPR	11/4/2025
2007	Docket Navigator: Time to Trial	11/4/2025
2008	<i>Enviro Tech v. Clean Chemistry</i> Preliminary Invalidity Contentions	11/4/2025
2009	Bankosky LinkedIn Profile	11/4/2025
2010	Declaration of Joseph Donabed	11/4/2025
2011	Wiseman LinkedIn Profile	11/4/2025
2012	WO2024108086A1	11/4/2025
2013	WO2024238884A1	11/4/2025
2014	Clean Chemistry Google Patent Search, Page 1	11/4/2025
2015	Interim Director Discretionary Process (Oct. 3, 2025)	11/4/2025
2016	FAQs for Interim Processes	11/4/2025
2017	<i>Pro Hac Vice</i> Declaration of Jennifer R. Sandlin	11/12/2025
2018	U.S. Patent No. 8,546,449 Office Action (April 1, 2013)	Presently Submitted

UPDATED EXHIBIT LIST		
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> Clean Chemistry's Opening Claim Construction Brief (Docket No. 34)	Presently Submitted
2022	<i>Enviro Tech v. Clean Chemistry</i> Claim Construction Order (Docket No. 47)	Presently Submitted
2023	U.S. 7,919,122	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.

Here, Petitioner’s arguments are readily dispelled. The art cited by Petitioner fails to teach all of the elements of independent Claim 1, and therefore Petitioner’s

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

references can neither anticipate nor render obvious any claims of U.S. Patent No. 9,737,072 (the “’072 Patent”).

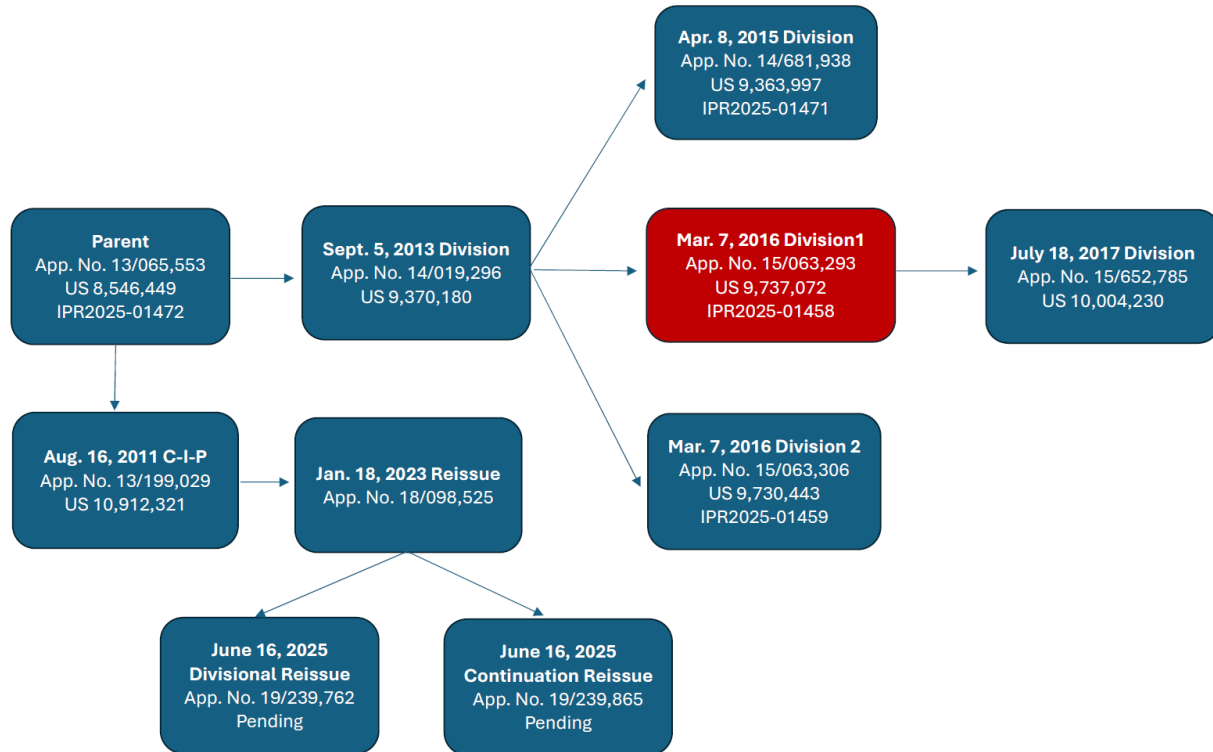
Because the Petition does not, therefore, have a “reasonable likelihood of success” in rendering the claims of ’072 Patent unpatentable, institution should be denied.

II. BACKGROUND

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

1. The 8,546,449 Patent Family

The ’072 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. 9,730,443 (the “’443 Patent”) and U.S. Patent No. 9,363,997 (the “’997 Patent”) are also presently facing their own IPRs, IPR2025-01459 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, '072 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, these solutions cannot be safely transported due to the “extremely hazardous and explosive properties” at such a high concentration. (*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 2:27-43.) 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 5:24-35.) 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 5:36-45.) 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 6:55-7:6.) 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 18:12-26.)

B. Prosecution History of the '449 Patent

Because the '072 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 '072 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 progeny² 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 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

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.”

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 '072 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 '072 Patent. The '072 Patent prosecution history is unremarkable. Following a restriction requirement that limited the scope of the asserted claims to a product composition, the sole office action raised a nonstatutory double patenting rejection (Exhibit 1005 at 134-139), Enviro Tech filed a terminal disclaimer as to the '443 Patent (the basis for the double patenting rejection) (*id.* at 146-149), and the application was allowed (*id.* at 174-181), noting that “[c]laims 1-3 are neither anticipated nor rendered obvious over the art of record and therefore are allowable. A suggestion or modification of a reference to obtain the instant compositions 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 relatively low skill level, having only a bachelor’s degree in chemistry or chemical engineering and “a couple of 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 must now 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. Hydrogen peroxide-acetyl precursor solution

Petitioner proposes the construction “hydrogen-peroxide-triacetin solution.” (Petition, Paper 2, at 13-14.) Enviro Tech does not dispute this construction.

B. Aqueous hydrogen peroxide

Petitioner proposes that this term be construed to mean “hydrogen peroxide.” (Petition, Paper 2 at 14-15.) Because Petitioner’s construction reads out the word “aqueous” from the claim, Patent Owner disputes this construction and

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

proposes an accurate construction below, because all claim limitations must be considered in analyzing claim language:

Claims must be “interpreted with an eye toward giving effect to all terms in the claim.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). . . . *See Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 885 (Fed. Cir. 2008) (refusing to adopt a claim construction which would render a claim limitation meaningless); *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1305-07 (Fed. Cir. 2000) (refusing to adopt a claim construction which would render claim language superfluous).

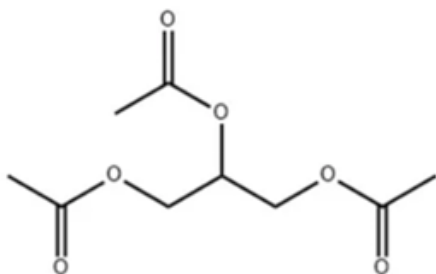
Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP, 616 F.3d 1249, 1257 (Fed. Cir. 2010); *see also* M.P.E.P. § 2143.03 (Ninth ed., Rev. 01.2024). Petitioner's construction could, in theory, read upon a solution where non-aqueous hydrogen peroxide were to be added to triacetin, and then water were to be added later, which would completely eliminate any aqueous component from the hydrogen peroxide when used in the initial solution. Enviro Tech therefore proposes that the proper construction of this term is as follows:

Aqueous hydrogen peroxide refers to hydrogen peroxide combined with water, whether combined prior to its addition to the precursor solution, or whether combined with water contemporaneously with its addition to the precursor solution. The addition of hydrogen peroxide

to one or more other ingredients of a precursor solution that does not, at the time of the addition of the hydrogen peroxide, include water would not comprise the use of aqueous hydrogen peroxide.

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:



The chemical compound having the structural formula depicted above

(Exhibit 2021, Clean Chemistry's Opening Claim Construction Brief at 12.)

D. 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 2021 at 12.)

E. Trace Amount

Petitioner (who, in the District Court Case claimed this term was indefinite), now claims that this term should be defined as “less than about 1%.” (**Exhibit 2022**, Claim Construction Order at Term # 14; Petition, Paper 2 at 15-17.)

Petitioner has conceded, however, that “the claims are to be construed as they are in district courts...” (Petition, Paper 2 at 12.) Here, there is no need to rely upon Petitioner's arguments about the proper construction of this claim term, as it has already been construed by the district court in the parallel proceeding. (**Exhibit 2022**, at Term #14.) Consistent with the District Court Case construction, “trace amount” should be construed to have its plain and ordinary meaning of “a non-zero amount that is detectible.” (*Id.*)

IV. ALLEGED PRIOR ART ASSERTED BY PETITIONER

Petitioner has identified two purported prior art references that it contends render the '072 Patent invalid as anticipated or obvious: WO 2011/017095 (“Stauffer”) as to Claim 1, and JP 2006-045147 (“Okano”) as to Claims 1 and 3. As is discussed further below, neither reference suffices to invalidate the '072 Patent.

A. Stauffer

Stauffer is directed to “a method for controlling microorganisms comprising coating a surface with a removable, antimicrobial film-forming composition that contains *in situ* enzymatically generated peroxyacids and methods of applying said compositions.” (Exhibit 1012 at 1:9-12.) As is evident from its description, Stauffer creates PAA using an enzyme reaction, a methodology specifically identified in the specification of the '072 Patent as problematic. The '072 Patent specification specifically identifies multiple prior art references that use perhydrolase enzymes to create a non-equilibrium PAA solution, just as Stauffer does, and explains that:

However, peracid or PAA solutions that are produced with enzymes have limited appeal because they are very expensive to produce, and for regulatory reasons, the enzyme must be removed from the solution before the solution can be applied to food or hard surfaces for disinfection purposes. Removing the enzyme from the solution is not an easy task; thus, it is typically not done. Therefore, PAA solutions prepared by enzymatic methods are not suitable for the more broad commercial uses in the food, dairy, beverage, meat, and poultry industries, which are regulated by the FDA and the Environmental Protection Agency (EPA).

(Exhibit 1001 at 3:44-54.) The need to remove the enzyme from solution prior to use as a sanitizer is of particular note as the presence of the enzyme in a hypothetical solution would prevent such solution from being used as a “Precursor Solution,” as that term is used in the '072 Patent: a “liquid composition[] for generating non-equilibrium solutions of PAA on a site having a point-of-use of peracetic acid.” (*Id.* at 9:3-5.)

Moreover, the '072 Patent specification expressly distinguishes the invention of the '072 Patent because it “does not require the use of perhydrolase enzymes, acetic acid, or acetic anhydride, all of which suffer from the aforementioned limitations and problems.” (*Id.* at 6:65-7:1.)

To the extent that Petitioner is relying on the enzyme-free control samples used in Stauffer to argue that Stauffer renders the '072 Patent anticipated and/or obvious, there is an additional reason that Stauffer cannot serve as prior art. The Stauffer method is not creating a Precursor Solution that will generate PAA when activated; instead, it is creating actual PAA using an enzyme, as well as polyvinyl alcohol and/or a film-forming composition to do so. (Exhibit 1012 at 63:1-65:19.) Thus, the goal of Stauffer is neither the creation of a Precursor Solution nor a method of creating such a solution. The enzyme-free control sample includes additional components that would not be present in a Precursor Solution, such as

sodium bicarbonate buffer and Turpinal®. (*Id.* at 63:20-26; 65:2-8.) The purpose of the control sample is not to create a Precursor Solution, but to control for the inclusion of an enzyme in the reaction. (*Id.*) As a result, the control sample simply does not teach the creation of a Precursor Solution, nor does it teach that a Precursor Solution could use only the four components taught by the '072 Patent.

For the foregoing reasons, it is clear that (a) references similar to Stauffer were disclosed during the prosecution of the '072 Patent, rendering Stauffer cumulative to the prior art; (b) due to the use of enzymes, the methods taught by Stauffer were not practical for commercial uses, and therefore one of skill in the art would understand that a solution that includes enzymes is not comparable to the Precursor Solution taught by the '072 Patent; (c) due to the use of enzymes, the compositions taught by Stauffer were not functional as “Precursor Solutions”; and (d) the Stauffer control solution is intended to mirror the method of manufacturing PAA with the exclusion of the enzyme rather than teaching the creation of a Precursor Solution.

B. Okano (Translated)

Okano 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 ratio 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 1013 at 1.) It further discloses a “Composition for Producing Sterilizing Cleaner” (“CPSC”) that includes components (A) and (B1), with a moisture content of 1-25 wt%. (*Id.* at [0034].) The disclosed method includes extremely large ranges of components (A) and (B1) that may be used, and a similarly broad range of potential molar ratios between the two components. (*Id.* at [0035].) The “Composition for Producing Sterilizing Cleaner” does not, however, appear to include any amount of peracetic acid, as Okano teaches that producing peracetic acid using the CPSC requires an adjustment to the pH of the original solution in order to render the solution alkaline, which in turn triggers the production of peracetic acid. (*See, e.g., id.* at [0039] and [0048] (“The component (A) and the component (B1) react under alkaline conditions [] in water to generate an organic peroxy acid...”).) The CPSC taught by Okano is not, on its own, alkaline; it contains only component A (which includes triacetin, which has a neutral pH) and hydrogen peroxide (slightly acidic). (*Id.* at [0035].) In support for its claim that Example 1 of Okano includes peracetic acid, Petitioner cites to Paragraphs [0057] and [0059]. (Petition, Paper 2 at 20.) But these paragraphs are *not* about the creation of CPSC, as taught by Example 1, but rather the creation of the actual Sterilizing Cleaner Composition I, which is not a precursor solution and

which instead combines triacetin, hydrogen peroxide, and water with an alkaline aqueous solution which, as discussed above, is needed, according to Okano, to generate peracetic acid. Okano does not, therefore, teach the creation of a precursor solution that includes peracetic acid; it teaches a precursor solution that does not include peracetic acid, and it teaches a final solution that does include peracetic acid but does not teach the claimed combination.

V. NO CLAIMS OF THE '072 PATENT ARE ANTICIPATED OR OBVIOUS

A. Grounds 1a and 1b: Stauffer Neither Anticipates Nor Renders Obvious Claim 1

Petitioner contends that Stauffer and explicitly, Examples 4 and 5 of Stauffer, anticipate and/or render obvious Claim 1 of the '072 Patent. Petitioner's interpretation of Stauffer is incorrect, and it neither anticipates nor renders obvious Claim 1 of the '072 Patent.

Claim 1 is directed to the composition of "a hydrogen peroxide-acetyl precursor solution, comprising" (a) aqueous hydrogen peroxide; (b) triacetin; (c) a trace amount of peracetic acid; and (d) water. Notably, during claim construction in the District Court Case, Petitioner argued that the preamble of this claim is limiting, and the Court agreed. (**Exhibit 2022** at Term #13.) Examples 4 and 5 of Stauffer teach the *in situ* generation of peracetic acid using polyvinyl alcohol and a

perhydrolase enzyme (Example 4) or using a film-forming composition with a perhydrolase enzyme (Example 5). (Exhibit 1012 at 63:1-65:19.) Both methods are directed to the generation of PAA, not the generation of a Precursor Solution. (*Id.*) As a result, Stauffer does not teach the generation of a Precursor Solution. Nor do the control samples identified in these examples do so; the control samples do not comprise a “hydrogen peroxide-acetyl precursor solution,” but rather – as is typical of a control sample – serve simply as a point of comparison against the enzymatically active samples, to show the increased production of PAA in those enzymatically active samples. (*Id.* at 63:20-26; 65:2-8; Table 1 and Table 2.) Because Stauffer does not teach the preamble of Claim 1, it cannot anticipate Claim 1. *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1069 (Fed. Cir. 2017) (“[A] prior art reference must provide every element of the claimed invention arranged as in the claim in order to anticipate.”).

There is no indication in Stauffer or in the Petition that the control samples could function in such a manner and the information provided – showing that the minute amount of PAA produced in the controls (114 ppm) did not increase at all over time (Exhibit 1012 at Table 1, Table 2) – counsels against such an assumption, as the low levels of PAA present in the Precursor Solutions of the '072 Patent increase over time as the hydrogen peroxide in the solution is consumed

(Exhibit 1001 at Tables I-VI). For this additional reason, Stauffer does not, and cannot, anticipate Claim 1 of the '072 Patent.

As described in the '072 Patent, the “Precursor Solutions” referred to in the preamble of Claim 1 of the '072 Patent relate to “liquid compositions for generating non-equilibrium solutions of PAA on a site having a point-of-use of peracetic acid.” (Exhibit 1001 at 9:3-5.) This Precursor Solution is then added directly to water at the point-of-use:

The hydrogen peroxide-acetyl precursor solution may be prepared off site and then transported to the site having the point-of-use, or the acetyl precursor and the aqueous hydrogen peroxide may be transported to the site having the point-of-use and then used to prepare the hydrogen peroxide-acetyl precursor solution on the site. The hydrogen peroxide-acetyl precursor solution is then introduced to the water.

(*Id.* at 5:63-6:3.) Since the biosynthetic methods of producing peracids using perhydrolase enzymes must also include removal of the enzyme before using the solution at the point-of-use (*see, e.g., id.* at 3:44-54), the Precursor Solution *cannot include enzymes* for it to be applicable “at the point-of-use” as described in the '072 Patent.

As noted above, during claim construction in the District Court Case, Petitioner argued that the preamble of Claim 1 of the '072 Patent is limiting, and the Court agreed. (**Exhibit 2022** at Term #13.) Therefore, since Claim 1 of the '072 Patent refers to a "Precursor Solution," which Petitioner agrees is limiting, and the Precursor Solution cannot include enzymes because those enzymes preclude application at the point of use, the enzyme-containing compositions and methods for making the same taught in Stauffer are insufficient to invalidate the '072 Patent.

The Petition does not explain how Stauffer renders Claim 1 of the '072 Patent obvious, other than reiterating the alleged presence of the listed elements (a) through (d) of Claim 1, and arguing that the control samples teach that peracetic acid is formed in hydrogen peroxide-triacetin aqueous compositions. No explanation is provided as to how that information would lead one to believe that a Precursor Solution could be created. Furthermore, the enzymes present in the compositions taught by Stauffer prevent the compositions of Stauffer from being introduceable at the point-of-use and therefore prevent the compositions of Stauffer from being "Precursor Solutions." Therefore, Petitioner fails to show that the limiting preamble of Claim 1 is taught by Stauffer.

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, every claim element must be taught in the prior art in order to render a claim obvious. *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). Moreover, 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.

For the foregoing reasons, Stauffer neither anticipates nor renders obvious Claim 1 of the '072 Patent.

B. Grounds 2a and 2b: Okano Neither Anticipates Nor Renders Obvious Claim 1

1. Okano does not disclose the required Precursor Solution components.

Petitioner contends that Example 1 of Okano anticipates or renders obvious Claim 1 of the '072 Patent.⁴ As noted in the earlier discussion of Okano, however, Okano does not teach the existence of a precursor solution that includes trace amounts of peracetic acid and therefore cannot read on Claim 1 of the '072 Patent.

Claim 1 of the '072 Patent claims “[a] hydrogen peroxide-acetyl precursor solution, comprising: (a) aqueous hydrogen peroxide; (b) triacetin; (c) a trace amount of peracetic acid; and (d) water.” (Exhibit 1001 at 34:57-62.) Example 1 of Okano teaches a “Composition for Producing Sterilizing Cleaner” (“CPSC”) that contains an extremely variable amount of an ester of polyhydric alcohol and an

⁴ Okano, like Stauffer, is also cumulative of art that was before the USPTO during prosecution of the '072 Patent. Specifically, U.S. Patent No. 7,919,122, also to Okano, contains similar teachings to the Okano patent application cited herein. (Exhibit 2023.)

organic acid, hydrogen peroxide, and “moisture.” (Exhibit 1013 at [0034].) But Example 1 of Okano does not indicate that *any* peracetic acid is created by the CPSC. To the contrary, Okano teaches that peracetic acid is not created until the CPSC solution is treated to become alkaline, which will cause the generation of peracetic acid. (*See, e.g., id.* at [0039] and [0048] (“The component (A) and the component (B1) react under alkaline conditions [] in water to generate an organic peroxy acid...”).) Okano does not disclose the creation of peracetic acid until its later discussion of Sterilizing Cleaner Composition I, which is not a precursor solution, but rather an active solution, and which combines triacetin, hydrogen peroxide, and water with an alkaline aqueous solution to cause the solution to create peracetic acid. (*Id.* at [0057] and [0059].) Okano does not, therefore, teach the creation of a precursor solution that includes peracetic acid; it teaches a precursor solution that does not include peracetic acid, and it teaches a final solution that does include peracetic acid but does not teach the claimed combination, and therefore it is not an anticipatory reference. *Biscotti*, 878 F.3d at 1069 (“[A] prior art reference must provide every element of the claimed invention arranged as in the claim in order to anticipate.”). Because Okano does not teach that all the elements of Claim 1 are present in a precursor solution, it does not anticipate Claim 1 of the '072 Patent.

Furthermore, no argument for obviousness can overcome this fact. Whether “peracetic acid is necessarily formed” in the solution Okano discloses (Petition, Paper 2 at 21), Okano does nothing to teach that it is present in the precursor solution of the '072 Patent. *See also* 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.*, 550 U.S. at 418 (“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.*, 688 F.3d at 1366-67; *AMP Plus, Inc.*, 131 F.4th at 1323-24.

2. Okano teaches away from the required Precursor Solution components.

One of the novel features of the invention of the '072 patent is that it achieves a non-equilibrium solution of peracetic acid using a stable, basic solution. A POSITA reading Okano, however, would note both the use of a stabilizer (phosphonic acid) and the immediate addition of an acidic solution to the Okano solution taught at [0057], and would understand the invention of Okano to be highly unstable. (Ex. 1013 ¶ 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 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 '072 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 '072 Patent. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (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).

C. Grounds 2c and 2d: Okano Neither Anticipates Nor Renders Obvious Claims 2 and 3

Petitioner claims that Okano anticipates and/or renders obvious claims 2 and 3 of the '072 Patent, which are directed to specific amounts of triacetin and hydrogen peroxide. Petitioner is incorrect for several reasons.

First, Claims 2 and 3 cannot be anticipated or rendered obvious by Okano because Claim 2 depends from Claim 1, and Claim 3 depends from Claim 2, which means that all three claims include all of the elements of Claim 1. As discussed *supra*, Okano does not teach all of the elements of Claim 1, and therefore none of the claims that depend from Claim 1 can be anticipated or rendered obvious by Okano. *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.”).

Second, even if that were not the case, Okano can neither anticipate nor render obvious Claim 3 of the '072 Patent because it does not include all of the elements listed therein either. Specifically, in addition to including the elements of Claims 1 and 2, Claim 3 discloses a specific amount of aqueous hydrogen peroxide, a specific amount of triacetin, and a specific molar ratio of hydrogen peroxide to triacetin. (Exhibit 1001 at 35:1-4.) Petitioner concedes that, based on the claimed amounts of hydrogen peroxide and triacetin, the “water content” of Claim 3 is 27%. (Petition, Paper 2 at 24.) But the claimed water content range of

Okano is 1-25% - in other words, the water content taught by Claim 3 is not taught by Okano. Because Okano does not teach the water content inherent to Claim 3 of the '072 Patent, it can neither anticipate nor render obvious Claim 3 of the '072 Patent for this additional reason.

Finally, Petitioner claims that the molar ratio and concentrations of hydrogen peroxide and triacetin taught by Okano anticipate the amounts claimed by the '072 Patent. Claims 2 and 3 are directed to a narrowly-defined hydrogen peroxide-acetyl precursor solution that was found to be surprisingly suitable to the methods claimed in the '449 and '072 Patents.⁵ Claim 3, in particular, is directed to a precursor solution with very specific concentrations and ratios of several reagents: a 3.8:1 ratio of peroxide to triacetin; a 27% hydrogen peroxide concentration; and a 46% triacetin concentration.

In contrast, Okano only discloses broad ranges for these components. Okano recites a peroxide:triacetin ratio spanning three orders of magnitude (0.05:1 to

⁵ In particular, the '072 Patent noted the “unexpectedly high” solubility of triacetin in hydrogen peroxide (Exhibit 1001 at 5:29-31), which is exemplified by the parameters of Claims 2 and 3.

10:1).⁶ Okano also recites similarly broad peroxide, triacetin, and water concentrations spanning two orders of magnitude: 1 to 30% peroxide; 20 to 90% triacetin; and 1 to 25% water. Okano provides no guidance regarding the preparation of specific peroxide-acetyl precursor solutions with the narrower ranges of concentrations recited in Claim 2, much less the very specific concentrations required by Claim 3. Multivariate optimization of the concentrations of two or three different components in a reaction mixture is a complex procedure at best and is almost completely intractable at worst. A disclosure that triacetin could be used at 20-90%, as in Okano, certainly does not provide sufficient guidance to arrive at the optimized 46% concentration and 3.8:1 peroxide-to-triacetin ratio required by claim 3. (*See, e.g., Exhibit 2018*, '449 Patent Office Action at 7, 8 (where the Examiner noted that “the level of skill in the art is high,” and that there is a “high degree of unpredictability of the chemical art” disclosed in the specification).)

Furthermore, the generic disclosure of Okano would not have anticipated Claim 3 of the '072 Patent because a POSITA would not have “at once envisaged”

⁶ Incidentally, the full range of claimed ratios in Okano is not enabled; using the volumes provided, the range cannot fall below 0.0713:1 or above 9.62:1.

the claimed concentrations from the disclosure of Okano, as explained at section 2131.02(III) of the M.P.E.P.:

“[W]hether a generic disclosure necessarily anticipates everything within the genus ... depends on the factual aspects of the specific disclosure and the particular products at issue.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083, 89 USPQ.2d 1370, 1375 (Fed. Cir. 2008). See also *Osram Sylvania Inc. v. American Induction Tech. Inc.*, 701 F.3d 698, 706, 105 USPQ.2d 1368, 1374 (Fed. Cir. 2012)...

...

When a claimed compound is not specifically named in a reference, but instead it is necessary to select portions of teachings within the reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, **anticipation can only be found if the classes of substituents are sufficiently limited or well delineated.** *Ex parte A*, 17 USPQ.2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be

able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.” **One may look to the preferred embodiments to determine which compounds can be anticipated.** *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

(emphasis added). In view of this guidance, a POSITA would not have “at once envisaged” the composition of the '072 Patent in view of Okano for several reasons. First, the “preferred embodiments” of Okano refer to, at best, the range of “preferably 40 to 80% by weight” for “component (A).” This is insufficient to enable a POSITA to “at once envisage” both that component (A) is triacetin and that the triacetin is specifically present in the amount of “about 46%.”

Second, the “preferred” ratio for (B1):(A) in Okano is, at best, 1:10 to 5:1⁷. This is insufficient to enable a POSITA to “at once envisage” that component (A)

⁷ Okano describes these ratios in terms of “(A)/(B1)” but this ratio has been inverted and depicted using the “colon (:)” nomenclature herein to make direct comparison with Claim 3 of the '072 Patent easier.

is triacetin, component (B1) is hydrogen peroxide, and that the specific mole ratio of hydrogen peroxide to triacetin is “about 3.8:1.” Indeed, the claimed “about 3.8:1” is just one of **five hundred** ratios having one decimal point contained within the “preferred” range of “1:10 to 5:1” taught by Okano. To expect a POSITA to select one ratio from a disclosure of five hundred available ratios (notwithstanding that Okano actually discloses “(A)/(B1) = 1/10 to 20/1,” a range that includes two thousand ratios to one decimal point), is far beyond the scope of what the M.P.E.P. contemplates by the phrase “at once envisage.”

Third, Okano only teaches two examples of its sterilizing cleaner composition, both of which use the same amount of hydrogen peroxide and triacetin. These examples, which are taught at Paragraphs 57 and 58, use 50 g of 100% triacetin and 25 g of 60% hydrogen peroxide, and therefore have a hydrogen peroxide:triacetin molar ratio of 1.93:1, which is below the claimed range of Claim 2 and is not the same as the specific ratio of Claim 3. Therefore, not only does Okano fail to enable the range that it discloses, it does not enable any ranges that would read on the claims of the '072 Patent.

As such, a skilled artisan would not be able to take the disclosures of Okano and modify them to arrive at the subject matter of Claims 2 and 3 without undue

experimentation. Thus, for this additional reason, Claims 2 and 3 cannot be anticipated or rendered obvious by Okano.

VI. CONCLUSION

Neither of the references identified by Petitioner contain all of the elements of Claim 1 of the '072 Patent, and therefore these references fail to anticipate or render obvious the claims of the '072 Patent. Because Petitioner has failed to meet the "reasonable likelihood of success" standard that any of the claims of the '072 Patent are unpatentable, Enviro Tech respectfully requests that the Director deny institution of *Inter Partes* Review of Claims 1-3 of the '072 Patent.

Dated: December 5, 2025

Respectfully Submitted,

Eversheds Sutherland (US) LLP

By: /Anna C. Halsey/

Anna C. Halsey (Reg. No. 73,960)

Ann G. Fort (admitted *pro hac vice*)

Peter G. Pappas (Reg. No. 33,205)

Chancellor S. Shafor (Reg. No. 76,993)

EVERSHEDS SUTHERLAND (US) LLP

999 Peachtree St. NE, Suite 2300

Atlanta, GA 30309

Tel.: (404) 853-8173 (Ms. Halsey)

Tel: (404) 853-8493 (Ms. Fort)

Tel: (404) 853-8064 (Mr. Pappas)

Tel. (404) 853-8329 (Mr. Shafor)

Fax: (404) 853-8806

Email: AnnaHalsey@eversheds-sutherland.us

Email: AnnFort@eversheds-sutherland.us
Email: PetePappas@eversheds-sutherland.us
Email: ChancellorShafor@eversheds-sutherland.us

Cameron C. Murphy (Reg. No. 74,736)
EVERSHEDS SUTHERLAND (US) LLP
12255 El Camino Real, Suite 100
San Diego, CA 92130
Tel: (858) 252-6502
Fax: (858) 252-6503
Email: CameronMurphy@eversheds-sutherland.us

Michael J. Behlen (Reg. No. 81,473)
EVERSHEDS SUTHERLAND (US) LLP
101 California Street, Suite 4750
San Francisco, CA 94111
Tel: (415) 580-6131
Fax: (415) 506-4859
Email: MichaelBehlen@eversheds-sutherland.us

Attorneys for Patent Owner

CERTIFICATION OF WORD COUNT

This Petition complies with the type-volume limitations as mandated in 37 C.F.R. § 42.24, totaling 7,095 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 IPR2025-01458 on the date indicated below.

Lead Counsel: R. Andrew Patty II (Reg. No. 38,992)
Phelps Dunbar LLP
400 Convention Street, Suite 1100
Baton Rouge, LA 70802
drew.patty@phelps.com
ipdocket@phelps.com
n.gardiner@cleanchemi.com

Backup Counsel: Mary H. Drabnis (Reg. No. 45,909)
Phelps Dunbar LLP
400 Convention Street, Suite 1100
Baton Rouge, LA 70802
mary.drabnis@phelps.com

Dated: December 5, 2025

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