EXHIBIT 2020

Enviro Tech v. Clean Chemistry

Declaration of Gregory T. Whiteker, Ph.D.

(Exhibit E to Docket No. 35)

Exhibit E

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

ENVIROTECH CHEMICAL SERVICES, INC.	§	
	§	
	§	Case No. 1:24-CV-01313-ADA
v.	§	
	§	
CLEAN CHEMISTRY, INC.		

DECLARATION OF GREGORY T. WHITEKER, PH.D. IN SUPPORT OF PLAINTIFF ENVIROTECH CHEMICAL SERVICES, INC.'S RESPONSE TO DEFENDANT CLEAN CHEMISTRY, INC.'S OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

I, Gregory T. Whiteker, hereby declare the following pursuant to 28 U.S.C. § 1746:

1. I have been retained by Envirotech Chemical Services, Inc. to provide expert services in the above captioned matter.

2. I am a resident of Pennsylvania.

3. I obtained a Bachelor of Science in Chemistry degree, with honors, from Earlham College in 1985.

4. I obtained my Ph.D. in Inorganic Chemistry with a minor in Organic Chemistry from the University of Wisconsin-Madison in 1989.

5. I was a National Institute of Health & American Cancer Society Postdoctoral Fellow at the Massachusetts Institute of Technology from November 1989 through June 1991.

6. I am a named inventor on seventy-nine U.S. patents.

7. My CV is attached as **Appendix 1**, which further details my education, work experience, granted patents, research publications, and presentations.

8. I have reviewed U.S. Patent Nos. 8,546,449; 9,363,997; 9,730,443; and 9,737,072 (the "Asserted Patents"). *See* **Ex. A** ('449 Patent); **Ex. B** ('997 Patent); **Ex. C** ('443 Patent); **Ex. D** ('072 Patent).

9. I have also reviewed Dr. Klibanov's Declaration filed in support of the Defendant's Opening Claim Construction Brief. **Ex. F** (Klibanov Decl.).

10. I understand the chemistry of the generation and the composition of peroxyacetic acid (PAA), commonly known as peracetic acid, and consider myself a person of ordinary skill in the art ("POSA") as it relates to the Asserted Patents.

II. LEGAL PRINCIPLES

11. Envirotech's attorneys have informed me of certain legal principles relevant to patent law and claim construction. I also have a general understanding of patents and interpretation of patent claims via the patent prosecution process for the seventy-nine (79) granted patents on which I am a named inventor and my 15 years of experience on the corporate Intellectual Property Steering Team while I was employed with Dow AgroSciences and Corteva Agriscience where I helped develop patent strategies and filing decisions for all chemical processes in the R&D pipeline.

A. Priority Date

12. I understand that the Asserted Patents' constructive priority date is March 24, 2011. I further understand that Envirotech's Preliminary Infringement Contentions informed Clean Chemistry that the earliest date of invention for the Asserted Patents is not earlier than June 18, 2008.

B. Person of Ordinary Skill in the Art

13. I understand that patents are evaluated from the perspective of a person of ordinary skill in the art ("POSA").

14. A POSA is a competent person of ordinary skills and creativity. He or she is presumed to be familiar with all publicly available relevant prior art at the time of the invention of the Asserted Patents.

15. In my opinion, a POSA would have more experience than that suggested by Dr. Klibanov. A person with a bachelor's degree in chemistry, chemical engineering, or a related discipline would need 5 years of working experience in chemical synthesis. A person with a master's degree in chemistry, chemical engineering, or a related discipline would need 3 years of working experience in chemical synthesis. And if the person had a Ph.D. in chemistry, chemical

engineering, or a related discipline, he or she would not need additional working experience by virtue of the additional training and lab work associated with his or her educational training.

16. I have considered the issues and arrived at my conclusions from the perspective of a POSA.

C. Claim Construction

17. I understand that claim construction is the process by which a court determines, as a matter of law, the scope and meaning of terms used in the claims of a patent. I further understand that the goal of this process is to give claim terms the ordinary and customary meaning they would have had to a POSA at the time of the invention, after reading the entire patent and prosecution history.

18. Here, the time of the actual invention is as early as June 18, 2008, and the time for constructive invention is March 24, 2011, because each of the Asserted Patents is a divisional, directly or through another divisional, of the original parent application giving rise to the ’449 Patent, the first patent in the series.

19. I further understand that it is possible that the patent specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise have to a POSA. In such cases, I understand that the patentee's definition usually controls.

20. I understand that the prosecution history of a patent can inform the meaning of some claim language and must be taken into account in construing the claims.

21. I understand that, in some cases, the court may consider extrinsic evidence, such as technical dictionaries, treatises, and expert opinions, to understand the underlying technology and the way in which claim terms would be understood by a POSA at the relevant time. However, such

extrinsic evidence should not be used to vary, contradict, expand, or limit the claim language from how it is defined in the specification or prosecution history.

22. A claim preamble (the initial words prior to the transitional term, such as, e.g., "comprising," or "consisting of," or "consisting essentially of") may also be a limitation of the scope of a patent claim being construed when it provides essential structure, steps, or meaning to the claimed invention, or when it is necessary to give life, meaning, and vitality to the claim. This can be particularly true when a key aspect or attribute of the claimed subject matter is not described in the body of the claim but is mentioned in the preamble.

D. Indefiniteness

23. I understand that a patent will be held invalid for indefiniteness if its claims fail to inform a POSA with reasonable certainty about the scope of the invention. A patent claim is required to particularly point out and distinctly claim the subject matter which the inventor(s) regard(s) as the invention. In addition, a claim must be sufficiently definite and clear so that a POSA can understand the boundaries of the invention.

24. I further understand that definiteness is to be evaluated from the perspective of someone with skill in the relevant art at the time that the patent was filed.

25. As with claim construction, the analysis of indefiniteness primarily involves intrinsic evidence, including the patent's claims, specification, and prosecution history. Extrinsic evidence such as technical treatises and dictionaries or expert testimony can be used to support a proper claim construction, as long as it supplements the intrinsic record and does not contradict or override the clear meaning derived from intrinsic evidence. All of this information is examined to determine whether the patent claim defines the scope of the invention with reasonable certainty.

26. Indefiniteness may arise from, for example, ambiguous claim language, inconsistent terminology, or lack of clarity in defining the patent's invention notwithstanding the available evidence. A claim may be found indefinite if it contains terms that are subjective, lack antecedent (i.e., predecessor) basis, or are otherwise unclear to a POSA.

III. TECHNOLOGY BACKGROUND

27. The Asserted Patents' claims relate either to specific solutions containing peracetic acid (PAA) or to specific methods for the production of such solutions, all employing triacetin either as a claimed solution component or as an acetyl group donor present in a reaction that occurs during the practice of a claimed method. In general, PAA-containing solutions were known at the time of the invention as microbial control solutions and disinfectants that could have utility, for example, in energy industry, food processing, and healthcare.

IV. CLAIM CONSTRUCTION

28. Preliminarily, a person of ordinary skill in the art would understand that the plain and ordinary meanings of the following terms, in the context of the disclosures of the Asserted Patents, would be as set forth below:

A. Arrangement; order of steps (Patent Nos. 8,546,449 and 9,363,997; All Claims)

Envirotech Proposed Construction	Clean Chemistry Proposed Construction
Plain and ordinary meaning: the steps can be performed in any order.	Plain and ordinary meaning: "steps a to e must be performed sequentially in the same order in which they are recited in the claim"

29. Claim 1 of the '449 Patent is reproduced below:

> 1. A method of generating non-equilibrium solution of peracetic acid, comprising:
>
> a. providing water;
> b. introducing a hydrogen peroxide-triacetin solution to the water;
> c. mixing the hydrogen peroxide-triacetin solution and the water to form a mixture;

d. adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture; and e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.

30. Claim 1 of the '997 Patent is reproduced below:

1. A method of generating a non-equilibrium solution of peracetic acid, comprising: a. providing water; b. introducing triacetin and aqueous hydrogen peroxide to the water; c. mixing the triacetin and the aqueous hydrogen peroxide with the water to form a mixture; d. adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture; and e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.

Differences in the Language of Claim 1 in the '449 and '997 Patents

31. Dr. Klibanov's Declaration provides no analysis of the differences in Claim 1 language for the '449 and '997 Patents and conflates Claim 1 of the '449 Patent with that of the '997 Patent, as paragraph 29 of the Declaration states that "Claim 1 of the '997 Patent . . . is reproduced below," but the Claim 1 he reproduced is that of the '449 Patent, not the '997 Patent.

32. The difference between Claim 1 of the '449 and '997 Patents is reference to a "hydrogen peroxide-triacetin solution" versus separate reference to "triacetin and aqueous hydrogen peroxide." In other words, the '449 Patent claims the addition of reactants in the context of a hydrogen peroxide-triacetin solution versus the '997 Patent claiming the addition of triacetin and aqueous hydrogen peroxide.

Antecedent Basis

33. Dr. Klibanov's argument for a required order of addition for reactants is based on the use of antecedent basis. *See* **Ex. F** (Klibanov Decl.), ¶ 29.

34. I understand that antecedent basis is required by law to promote clarity in reference to specific terms in claim language. I am not aware that use of antecedent basis is intended to, or understood as, a practice where patent law presumes that the use of antecedent basis introduces temporal claim limitations. And, when the claims are viewed in light of the intrinsic evidence by a POSA, the plain and ordinary reading does not import a sequencing limitation, as discussed in the next subsection.

Intrinsic Evidence Teaches Multiple Orders of Addition for the Reactants and the Technical Feasibility Thereof

35. A POSA would understand that the addition of reactants for the claims are not restricted to being "performed sequentially in the same order in which they are recited in the claim," as Dr. Klibanov and Clean Chemistry contend, because the specification of the Asserted Patents teaches multiple embodiments where the order of addition of the reaction components can vary, and that the reactants can also be added simultaneously. This intrinsic evidence, supported by experimental data, teaches a POSA that there is no technological barrier to performing the steps in a different order or performing steps simultaneously.

36. Below are quotes from the specification that teach the existence of multiple embodiments that vary the order of addition of reactants and also show simultaneous addition. The Asserted Patents also note how "the invention has been described with reference to the preferred embodiments" and that "[t]hose skilled in the art may envision other embodiments and variations of the invention that fall within the scope of the claims," which further informs a POSA that the disclosures are not limiting. **Ex. A** ('449 Patent), 34:42-45; **Ex. B** ('997 Patent), 34:43-45.

- "The hydrogen peroxide-triacetin solution and the sodium hydroxide solution may be added in a sequential manner as described, where the hydrogen peroxide-triacetin solution was added first, or they may be added to the water simultaneously through a "T" fitting placed before static mixer." **Ex. A** ('449 Patent), 25:1-5; **Ex. B** ('997 Patent), 25:1-5.

- "In other embodiments, the hydrogen peroxide and triacetin may be added separately, or sequentially, with either one first, or simultaneously, with the sodium hydroxide added either simultaneously with, or after, the hydrogen peroxide and triacetin." **Ex. A** ('449 Patent), 25:10-13; **Ex. B** ('997 Patent), 25:9-13.
- "The reactants were introduced to the solution in one of three ways: simultaneously (referred to in Table VIII as "double'), sequentially (triacetin followed shortly by hydrogen peroxide), or by mixing the hydrogen peroxide and triacetin together and adding them in a single charge (referred to in Table VIII as "mixed")." **Ex. A** ('449 Patent), 19:42-48; **Ex. B** ('997 Patent), l8:43-48.
- "As an alternative to step (b), the liquid acetyl precursor and the solution of aqueous hydrogen peroxide may be introduced to the water separately, either simultaneously or sequentially. If they are introduced sequentially, either one may be added first. If the liquid acetyl precursor and the aqueous hydrogen peroxide are introduced separately, rather than as an hydrogen peroxide-acetyl precursor solution, then in step (c) the liquid acetyl precursor and the aqueous hydrogen peroxide are mixed with the water to form a mixture." **Ex. A** ('449 Patent), 14:24-32; **Ex. B** ('997 Patent), 14:24-32.
- "Step (d) may be performed after step (c), or it may be performed simultaneously with step (b)." **Ex. A** ('449 Patent), 15:20-21; **Ex. B** ('997 Patent), 15:20-21.
- "In the first test, a mixture of triacetin and hydrogen peroxide was prepared by blending 50% hydrogen peroxide (54.24%) and triacetin (45.76%). . . . The mixture (51.22 g) was dissolved in soft water (911.9 g) in a one-liter beaker to yield a solution with a pH of 6.47. Then, 50% NaOH (36.47 g) was introduced with stirring. . . . The pH of the resulting solution initially measured 12.1. Using the ceric sulfate-iodometric titration method, the PAA generated and the hydrogen peroxide remaining were measured over the next 10 minutes." **Ex. A** ('449 Patent), 23:26-38; **Ex. B** ('997 Patent), 23:27-38.

37. This intrinsic evidence shows that there is no technological requirement that the reactants must be added in the order proposed by Clean Chemistry and Dr. Klibanov.

38. And, the specification *directly contradicts* Dr. Klibanov's statements that "[c]hanging the order of steps, e.g. such that step c. is performed earlier is not possible" and that "the order of steps to have step d. performed earlier is also not possible." *Compare* **Ex. F** (Klibanov Decl.) ¶ 29 *with* **Ex. A** ('449 Patent), 15:20-21 ("Step (d) may be performed after step (c), or it may be performed simultaneously with step (b).") *and id.* 25:10-13 ("In other embodiments, the hydrogen peroxide and triacetin may be added separately, or sequentially, with either one first, or

simultaneously, with the sodium hydroxide added either simultaneously with, or after, the hydrogen peroxide and triacetin.") *and* **Ex. B** ('997 Patent), 15:20-21 *and id*. 25: 9-13.

39. It follows that it would be obvious to a POSA that the reactants can be added in multiple different orders, and the claims *do not require* Clean Chemistry's interpretation of "performing the steps sequentially in the same order in which they are recited in the claim."

40. As a side note, Dr. Klibanov attempts to attack my use of *likely* in my prior statement that the claims do not require a specific order of addition of reactants because "[a] skilled artisan would recognize that the reaction is likely initiated by the high pH created by the sodium hydroxide." **Ex. F** (Klibanov Decl.), ¶ 31. According to Dr. Klibanov, my use of likely supposedly "undermines any probative value" of my statement. *Id*.

41. My statement was not, and is not, lacking in probative value because it is based on the data disclosed in Asserted Patents. *See* **Ex. A** ('449 Patent), 18:57-9:41 (showing via Table VIII, which discloses reaction data based on differing orders and simultaneous addition of reactants, that "[o]nly when the pH was above 12 was a meaningful percent of the triacetin converted into PAA."); *see also* **Ex. B** ('997 Patent), 19:1-47. Accordingly, *it is likely* that the reaction is initiated by the high pH created by the sodium hydroxide, and not the order of addition for the reactants.

Dr. Klibanov Offers No Technical Justification for Requiring Clean Chemistry's Proposed Order of Addition for the Reactants

42. Dr. Klibannov provides no technical explanation as to whether the reactants are *required* to be added in Clean Chemistry's proposed sequencing to produce the non-equilibrium peracetic acid.

43. Dr. Klibanov generally posits that "[a] POSA would understand that the order of addition of reaction components in process chemistry can be critical in achieving desired results."

Ex. F (Klibanov Decl.) ¶ 30. And while that can be true in many instances, here it is not. The intrinsic evidence in the preceding subsection shows that there is no technological requirement or need to restrict the order of addition of the reactants as Clean Chemistry proposes.

44. Moreover, Dr. Klibanov incorrectly concludes that the specification of the Asserted Patents requires a strict ordering of steps based on a selective citation to testing data in Tables XV and XVI—to the exclusion of the extensive intrinsic references teaching multiple orders of addition. **Ex. F** (Klibanov Decl.) ¶ 32.

45. Dr. Klibanov's cherry-picked data simply indicate that adding sodium hydroxide last is an embodiment that yields the highest amount of peracetic acid. However, the data do not limit the claims—especially given excerpts above, showing that peracetic acid can be produced with any of several reactions differing only in the order of the steps.

46. The Asserted Patents' disclosure of a possible "best mode" in the specification for the generation of peracetic acid also does not limit the order of steps in the claim—especially so in the face of the multiple disclosures and data multiple embodiments where the reaction is accomplished through different sequencing variations.

B. "[A] non-equilibrium solution [of peracetic acid]" (Patent Nos. 8,546,449, 9,363,997, and 9,730,443; All Claims)

Envirotech Proposed Construction	Clean Chemistry Proposed Construction
Plain and ordinary meaning.	Indefinite; otherwise plain and ordinary meaning, but includes irreversibility

47. The Klibanov Declaration advanced two purported issues with a POSA's ability to understand the meaning of a "non-equilibrium solution of peracetic acid," each of which are misguided and attempt to manufacture nonexistent issues.

48. First, Dr. Klibanov contends that a POSA would not be able to understand what "non-equilibrium" means in relation to the Asserted Patents because some aspects of the peracetic acid reaction are "essentially irreversible." **Ex. F** (Klibanov Decl.), ¶ 35.

49. Second, Dr. Klibanov contends that a POSA would be unable to understand the scope and meaning of "solution" without additional information about potential homogeneity or heterogeneity. *Id.* ¶ 37.

50. Each of these points are easily dispatched, and FDA and patent filings associated with Clean Chemistry are further evidence that a non-equilibrium solution of peracetic acid is not an indefinite term. The disclosures from the Asserted Patents are consistent with Clean Chemistry's own uses and references to non-equilibrium solutions of peracetic acid, which demonstrates Clean Chemistry understands the plain and ordinary meaning of the term "non-equilibrium solution [of peracetic acid]" and that it is not indefinite.

Non-Equilibrium of Peracetic Acid and its Decomposition into Peroxide and Acetic Acid

51. As to the first issue—the plain and ordinary meaning of "non-equilibrium" for a non-equilibrium peracetic acid solution in the context of the Asserted Patents—Dr. Klibanov focused on whether an equilibrium can exist solely with respect to triacetin and hydrogen peroxide since those reactants cannot be reformed. *Id.* ¶¶ 35-36.

52. Dr. Klibanov's focus on a sub-part of the overall reaction ignores that the continuation of any sub-reaction within the non-equilibrium solution of peracetic acid would render the solution "non-equilibrium." It also ignores how my prior statement on non-equilibrium accounted for multiple reactions when I stated that "*at least* one reaction is still occurring at a greater rate than the reverse reaction in a non-equilibrium solution," and I identified the conversion of reactants into peracetic acid and the decomposition of peracetic acid into hydrogen peroxide

and acetic acid as examples. Dr. Klibanov's silence on the relationship of the decomposition of peracetic acid in connection with a non-equilibrium solution of peracetic acid is telling.

53. A POSA would further understand that the primary equilibrium in question from the Asserted Patents for the "non-equilibrium solution of peracetic acid" is the decomposition of peracetic acid into peroxide and acetic acid, which is clearly pointed out in the Asserted Patents' specifications.

54. The Asserted Patents also describes what an *equilibrium* solution of peracetic acid is, which provides additional context for a non-equilibrium solution of peracetic acid. *See* **Ex. B** ('997 Patent), 1:25-35.

55. The '449 Patent first describes what the "non-equilibrium solution [of peracetic acid]" comprises, which sets the stage for a POSA to identify potential equilibriums of concern: "The non-equilibrium solutions of PAA that are formed comprise PAA, unreacted hydrogen peroxide, unreacted acetyl precursor, the product of the perhydrolysis reaction of the acetyl precursor, the aqueous source of alkali metal or earth alkali metal hydroxide, and water." **Ex. A** ('449 Patent), 6:17-21; **Ex. B** ('997 Patent), 6:25-29; **Ex. C** ('443 Patent), 6:36-40.

56. The specification then describes how the "[non-equilibrium solution of peracetic acid can be] introduced to receiving water ... immediately, or stabilized with the addition of a source of acid and used throughout a working day." **Ex. A** ('449 Patent), 6:28-30; **Ex. B** ('997 Patent), 6:35-38; **Ex. C** ('443 Patent), 6:46-49. A POSA would understand that the purpose for stabilizing the nonequilibrium solution of peracetic acid would be to help prevent the decomposition of peracetic acid into peroxide and acetic acid. It follows that a POSA would understand that the equilibrium in question for the "non-equilibrium solution [of peracetic acid]" is the decomposition of peracetic acid into peroxide and acetic acid.

57. Example 7 from the Asserted Patents further reinforces how the equilibrium in question for the non-equilibrium solution of peracetic acid is the decomposition of peracetic acid into peroxide and acetic acid because the "[non-equilibrium solutions of peracetic acid] *may be stabilized by halting the decomposition of the PAA* by adding a source of acid to lower the elevated pH of the reaction medium caused by the addition of an alkali metal or earth alkali metal hydroxide, and to provide neutral to mildly acid[ic] pH conditions to stabilize the PAA to elevated pH degradation." **Ex. A** ('449 Patent), 18:3-8 (emphasis added); **Ex. B** ('997 Patent), 18:3-8 (emphasis added); **Ex. C** ('443 Patent), 18:30-35 (emphasis added).

58. Clearly, a POSA would understand from reading the Asserted Patents that the equilibrium in question for the subject "non-equilibrium solution [of peracetic acid]" is the decomposition of peracetic acid into peroxide and acetic acid.

59. For additional comparison, the Asserted Patents describe what an *equilibrium* solution of peracetic acid entails:

> Peroxyacetic acid products are supplied as stable equilibrium ternary aqueous solutions of peroxyacetic acid, acetic acid, and hydrogen peroxide. They are prepared in advance of delivery, typically by reacting hydrogen peroxide with acetic acid in the presence of a mineral acid catalyst. Although some PAA is formed immediately, the PAA does not reach its maximum concentration until after several days. A metal chelating agent, such as hydroxyethylidene diphosphonic acid (HEDP) or dipicolinic acid, is also introduced to suppress the transition metal cation catalyzed decomposition of peroxygen compounds.

Ex. A ('449 Patent), 1:25-35; **Ex. B** ('997 Patent), 1:34-44; **Ex. C** ('443 Patent), 1:36-46.

Degree of Homogeneity of the Solution

60. Dr. Klibanov contends that a POSA cannot determine if a non-equilibrium solution of peracetic acid is actually a "solution" unless the specifications provided explicit guidance on "when a mixture becomes sufficiently homogeneous to constitute" the non-equilibrium peracetic acid solution. **Ex. F** (Klibanov Decl.) ¶ 37.

61. Here the specification identifies that the reaction occurs almost instantaneously upon the combination of reactants, and generally informs a POSA about mixing throughout the addition of reactants and suitable mixing devices for combining reactants:

- "The solution is mixed until a homogenous solution has been formed. The solution is allowed to mix by diffusion or by using a mixing device that is suitable for mixing liquids together. For example, 50% hydrogen peroxide can be introduced to a batch tank equipped with an overhead agitator blade. Triacetin can then be introduced to the 50% hydrogen peroxide when the agitator is in motion so that the components are thoroughly mixed." **Ex. A** ('449 Patent), 9:9-16; **Ex. B** ('997 Patent), 9:17-24; **Ex. C** ('443 Patent), 9:37-44.
- "Any mixing device suitable for mixing liquids may be used. An example is a static mixer located just after the point that the hydrogen peroxide-acetyl precursor solution is introduced to the flowing water. One type of static mixer utilizes a non-moving element such as a series of baffles. As the mixture flows through the static mixer under the motive force of the flowing water, the non-moving element divides the flow several times to provide radial mixing. Another type of static mixer utilizes a series of obstructions, such as column packing or glass beads, provided there is a low differential pressure drop across the mixer. The obstructions provide for turbulent mixing of the hydrogen peroxide-acetyl precursor solution and the flowing water. The mixing should yield a homogeneous solution with no concentration gradients before the next step is performed. The velocity of the water will determine the time it takes to complete the mixing and the efficiency of the mixing. **For example, with ¾″ pipe, a static mixer of ¾″ diameter and 6″ long, and a velocity of about 1 gal/min., mixing should be accomplished in less than about one second**." **Ex. A** ('449 Patent), 14:35-54 (emphasis added); **Ex. B** ('997 Patent), 14:35-54 (emphasis added); **Ex. C** ('443 Patent), 15:9-28.
- "The reaction medium that is formed in this step almost instantaneously forms a non-equilibrium solution of PAA. The hydrogen peroxide reacts with the acetyl precursor to form peracetic acid. Depending upon the temperature of the water, the efficiency of mixing, and the mole ratio of NaOH:hydrogen peroxide:acetyl precursor employed, the amount of hydrogen peroxide and acetyl precursor that are converted into PAA is maximized within about 30 seconds to about five minutes." **Ex. A** ('449 Patent), 15:24-32; **Ex. B** ('997 Patent), 15:24-32; **Ex. C** ('443 Patent), 15:65-16:6.

62. A POSA would understand that a "solution" is a portion of solvent with at least some minimal amount of dissolved solute. If the solvent has dissolved solute, then it is, by definition, a solution.

63. In contrast, the degree of homo- or heterogeneity of that solution has no impact on whether or not a given composition is a solution. Solutions are often homogeneous, but they may also be heterogeneous.

64. For example, it is common in the art for POSAs to use a saturated sodium chloride solution, i.e. brine, to remove water from organic solvents. Brine solutions generally have solid sodium chloride particles at the bottom of their storage containers; this is the commonly-accepted method that a POSA would use to determine that a brine solution is indeed saturated. However, these sodium chloride particles also render the solution heterogeneous. Crucially, the fact that the brine solution is heterogeneous *does not mean* that it is not also a solution.

65. Solutions can be either homogeneous or heterogeneous; this has no bearing on whether they are solutions. Since none of the claims require a homogeneous solution, Dr. Klibanov's discussion of heterogeneity is totally irrelevant to the determination of whether or not a given composition constitutes a peracetic acid solution.

66. Dr. Klibanov's statement that "there is no guidance in the intrinsic record about" when a mixture is a solution is severely misplaced. A POSA would easily understand from the teaching of the specification and general knowledge in the art that ordinary mixing methods would quickly result in the formation of a non-equilibrium peracetic acid solution.

Clean Chemistry FDA and Patent Filings

67. It is also apparent from Clean Chemistry's own disclosures, including FDA filings and patent submissions by Clean Chemistry's CTO, that it understands what a "non-equilibrium solution of [peracetic acid]" entails. The disclosures present no confusion as to what "non-equilibrium" or "solution" mean in the context of a non-equilibrium solution of peracetic acid.

Clean Chemistry's FDA Submissions Use of Non-Equilibrium Solutions of Peracetic Acid

68. Clean Chemistry's Environmental Assessment for Food Contact Notification FCN 2352, submitted to the Food and Drug Administration for Accused Product PeroxyMax ("FCN"), discusses non-equilibrium solutions of peracetic acid in a manner that mirrors the Asserted Patents' discussions, such that the term is *not* indefinite and has a plain and ordinary meaning to a POSA.

69. Clean Chemistry's FCN filing explains that it generates an on-demand non-equilibrium solution of peracetic acid from triacetin, hydrogen peroxide, sodium hydroxide, and water—the same reactants as the Asserted Patents. Clean Chemistry disclosed that its generation of the non-equilibrium solution of peracetic acid does not require stabilizers, confirming that the equilibrium of concern is the degradation of peracetic acid into peroxide and acetic acid. The FCN further identifies that there is no ambiguity around whether the non-equilibrium solution of peracetic acid must be heterogeneous or homogeneous because the blending of triacetin with water, sodium hydroxide, and hydrogen peroxide under agitation results in a rapid reaction at ambient temperature and pressure, such that the non-equilibrium solution of peracetic acid is produced almost instantaneously. Below are excerpts from the FCN and the Asserted Patents on the same subjects, illustrating there is not a lack of understanding by Clean Chemistry as to their meaning in relation to a non-equilibrium solution of peracetic acid.

Discussion Topic	**Disclosure from FCN**	**Disclosure from Asserted Patents**
Reaction Components for the non-equilibrium solution of peracetic acid	"In the current reaction scheme associated with this FCS, a mixture of hydrogen peroxide is blended with sodium hydroxide and dilution water. Triacetin is then added to this diluted mixture. The resulting reaction converts the three available acetyl groups on triacetin into PAA with a resulting aqueous solution	"The non-equilibrium solutions of PAA prepared by this method comprise PAA, unreacted hydrogen peroxide, unreacted acetyl precursor, the product of the perhydrolysis reaction of the acetyl precursor, the aqueous source of alkali metal or earth alkali metal hydroxide, and water. When the acetyl precursors is triacetin, the product of the

Discussion Topic	Disclosure from FCN	Disclosure from Asserted Patents
	having a PAA purity of greater than 94 percent." **Ex. G** (FCN), 12.	perhydrolysis reaction is 1,2,3-propanetriol (glycerine)." **Ex. AB**('449 Patent), 15:33-39; **Ex. B** ('997 Patent), 15:33-39; **Ex. C** ('443 Patent), 16:7-13.
Non-equilibrium solution of peracetic acid and the decomposition of peracetic acid into peroxide and acetic acid	"On-demand generation of the FCS eliminates the need to incorporate a stabilizer such as 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP) in the formulation. *As described below, the FCS is prepared in a non-equilibrium process that produces PAA that is immediately applied in the desired concentration*. No stabilizers are contained in this FCS since it is produced and used on demand." **Ex. G** (FCN), 9. "3. In the next step, under continuous agitation, triacetin is added to the process. Triacetin rapidly reacts with the alkaline peroxide to form an aqueous mixture of PAA. Alkaline pH (pH>10) is used to accelerate the reaction since the hydrogen peroxide anion is a much better nucleophile than hydrogen peroxide. *Both the hydrogen peroxide anion, O_2^{2-} and HO^- compete in the reaction with triacetin's acetyl groups, the former producing a PAA and the latter producing acetate.* The reaction takes place at ambient temperature and pressure." **Ex. G** (FCN), 10 "PAA, acetic acid, and hydrogen peroxide are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. *The half-life of PAA in buffered solutions was 63 hours at pH 7 for a 748 ppm solution, and 48*	"Peroxyacetic acid products are supplied as stable equilibrium ternary aqueous solutions of peroxyacetic acid, acetic acid, and hydrogen peroxide. They are prepared in advance of delivery, typically by reacting hydrogen peroxide with acetic acid in the presence of a mineral acid catalyst. . . . A metal chelating agent, such as hydroxyethylidene diphosphonic acid (HEDP) or dipicolinic acid, is also introduced to suppress the transition metal cation catalyzed decomposition of peroxygen compounds." **Ex. A** ('449 Patent), 1:25-35; **Ex. B** ('997 Patent), 1:34-44; **Ex. C** ('443 Patent), 1:36-46.

Discussion Topic	**Disclosure from FCN**	**Disclosure from Asserted Patents**
	hours at pH 7 for a 95 ppm solution." **Ex. G** (FCN), 12.	
Near instantaneous creation of a non-equilibrium peracetic acid solution	1. Water is fed into the generator/mixer followed by concentrated sodium hydroxide providing the alkaline environment needed for the next steps. 2. Next, hydrogen peroxide is blended into the mixer's alkaline solution and forms an alkaline peroxide solution. 3. In the next step, under continuous agitation, triacetin is added to the process. . . The reaction takes place at ambient temperature and pressure. **The reaction medium that is formed in this step almost instantaneously forms a non-equilibrium solution of PAA**. The hydrogen peroxide reacts with triacetin, the acetyl precursor, to form peracetic acid." **Ex. G** (FCN), 10.	"The non-equilibrium solutions of PAA that are formed comprise PAA, unreacted hydrogen peroxide, unreacted acetyl precursor, the product of the perhydrolysis reaction of the acetyl precursor, the aqueous source of alkali metal or earth alkali metal hydroxide, and water. The peracetic acid solutions are alkaline, having a pH of about 11.2 to about 13.37. **The reaction is remarkably fast, proceeds with a high conversion of the acetyl precursor into PAA.**" **Ex. A** ('449 Patent), 6:17-24 (emphasis added); **Ex. B** ('997 Patent), 6:25-32 (emphasis added); **Ex. C** ('443 Patent), 6:36-43 (emphasis added). "**The reaction medium that is formed in this step almost instantaneously forms a non-equilibrium solution of PAA**. The hydrogen peroxide reacts with the acetyl precursor to form peracetic acid." **Ex. A** ('449 Patent), 15:24-27 (emphasis added); **Ex. B** ('997 Patent), 15:24-27 (emphasis added); **Ex. C** ('443 Patent), 15:65-16:1 (emphasis added).

70. What is more, Clean Chemistry's FCN copied, verbatim, language from the Asserted Patents (highlighted above) on how the reaction medium instantaneously forms a non-equilibrium solution of peracetic acid. And, as discussed above, Dr. Klibanov's concerns on whether the non-equilibrium solution is homogeneous are irrelevant to the determination of whether the composition is a solution. *See supra*, ¶¶ 62-66.

71. A POSA would recognize that empirical methods for determining the homogeneity of a non-equilibrium solution of peracetic acid are not required for a POSA to practice the claimed invention.

Clean Chemistry's CTO's Use of Non-Equilibrium Solutions of Peracetic Acid in Patents

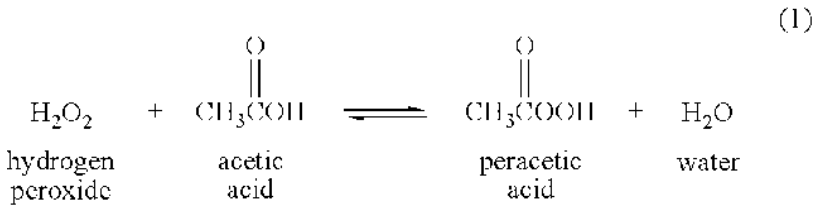
72. The '449 Patent cites to U.S. Patent Application No. 2009/0314652, which eventually issued as U.S. Patent No. 8,318,972 with Wayne E. Buschman as the first named inventor ("'972 Patent") and has a priority date of March 19, 2008. **Ex. H** ('972 Patent). *See* **Ex. A** ('449 Patent), at References Cited. Clean Chemistry's website, https://cleanchemi.com/about, identifies Wayne Buschmann as its current Chief Technology Officer. **Ex. I** (Clean Chemistry Website).

73. The '972 Patent not only undermines each of Dr. Klibanov's arguments on the indefiniteness of "non-equilibrium solution [of peracetic acid]," but also supports Envirotech's statement that the non-equilibrium solution of peracetic acid would be reasonably understood by a POSA to have a plain and ordinary meaning.

74. The '972 Patent is directed to "improved methods of production of peroxycarboxylic acids and peroxycarboxylic acid containing solutions for various applications that utilize *non-equilibrium peroxycarbooxylic acids*." **Ex. H** ('972 Patent), 1:24-27 (emphasis added). "More specifically, *peracetic acid solutions of this invention have non-equilibrium compositions* such as characterized by high peracetic acid (PAA) and water (H_2O) to acetic acid (AA) and hydrogen peroxide (H_2O_2) ratios." *Id*. at 1:41-44 (emphasis added).

75. The '972 Patent also discusses that the equilibrium of concern for solutions of peracetic acid is the balance between peracetic acid and its decomposition into hydrogen peroxide

and acetic acid and how the reaction goes both forward and backward—contrary to Dr. Klibanov's statement in paragraph 35 of his declaration that the reaction is "essentially irreversible":

> *In aqueous solution peracetic acid is in a chemical equilibrium with acetic acid, hydrogen peroxide and water*. This equilibrium is represented in the following
> Equation (1):
>
> 
>
>
> For example, a higher concentration of reactants is required to produce a higher concentration of peracetic acid. *Conversely, a higher concentration of water will drive the reaction backwards*, which means dilute solutions have very low peracetic acid equilibrium concentrations and mostly contain water and unused starting materials.
>
> *Id*. at 11:3-22 (emphasis added).

76. The '972 Patent does not provide any discussion of whether the non-equilibrium solution of peracetic acid is restricted in any way by homogeneity or heterogeneity, and there is no reason for a POSA to independently do so on their own accord.

77. Contrary to Dr. Klibanov's contention that homogeneity and heterogeneity of the peracetic acid solution are critically important, the '972 Patent states that "[a]n advantage of the acetyl or acyl donor dosing and mixing approach is the ability to use materials in the form of a solid, liquid, dispersion, suspension or combination of such forms. The acetyl or acyl donor may also have limited or minimal solubility in alkaline hydrogen peroxide solution and be mixed as a two-phase system until reaction has occurred." **Ex. H** ('972 Patent), 20:25-30; *see also id.* at 6:7-10 ("The acetyl donor or mixture of donors may be in liquid or solid form or dissolved in a solvent

when reacted with a solution of hydrogen peroxide, preferably at an alkaline pH, to form peracetic acid.”).

78. Accordingly, a POSA would recognize that simple addition of the reactants to a mixture, and the mixing thereof, would result in a non-equilibrium solution of peracetic acid.

C. “About” (all the Asserted Patents; various dependent Claims)

Envirotech Proposed Construction	Clean Chemistry Proposed Construction
Plain and ordinary meaning.	Indefinite.

79. The recited claim term “about” is used within various dependent claims in the Asserted Patents as a permissible term of degree with various numerical values associated with mole ratios, concentrations (in %), pH, and time, as follows (emphases added):

Claim limitations reciting “about [a numerical value]	Patent(s) and claim(s)
a mole ratio of hydrogen peroxide to triacetin of **about 2.98:1 to about 12.84:1**;	8,546,449, Claims 3, 20
said mole ratio of said hydrogen peroxide to said triacetin is **about 3.8:1**	9,737,072, Claims 2-3
the sodium hydroxide is **about 1.82% to about 7.28%**	8,546,449, Claims 7, 22; 9,363,997, Claim 7
the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is **about 4.2:3.8:1;**	8,546,449, Claim 13; 9,363,997, Claim 12
the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is **about 4.2:18:1**	8,546,449, Claim 23
a pH of **about 11.2 to about 13.37**	9,730,443, Claim 2
said peracetic acid is **about 1% to about 7.1%**	9,730,443, Claim 3
said aqueous hydrogen peroxide is **about 23% to about 40%**; said aqueous hydrogen peroxide is **about 27%**	9,737,072, Claims 2-3
said triacetin is **about 20% to about 53%**; said triacetin is **about 46%**	9,737,072, Claims 2-3
time to maximize the conversion of the hydrogen peroxide triacetin into peracetic acid is **about 30 seconds to about five minutes**	8,546,449, Claims 10-11; 9,363,997, Claims 10-11
wherein the percent of triacetin that is converted into peracetic acid is **about 40.9% to about 85.7%**	8,546,449, Claim 12; 9,363,997, Claim 11

80. "About" is commonly understood to mean approximately, and there is no intrinsic evidence that would lead a POSA to interpret "about" otherwise.

81. Dr. Klibanov states "a POSA would not be able to determine the scope of the "about" claims of the Asserted Patents to determine how far from their claimed numerical values he/she must go to escape their scope based on the intrinsic evidence." **Ex. F** (Klibanov Decl.), ¶ 44. This assertion is inconsistent with Dr. Klibanov's definition of a POSA as, in part, having a minimum educational level of a "bachelor's degree in chemistry, chemical engineering or a related field" because a person having a bachelor's degree in chemistry, chemical engineering or a related field would have been educated on the concept of significant figures. *Id.* ¶ 15.

82. As a POSA interprets these patent claims, that process is guided both by the specification and by the POSA's knowledge of the standards of measurement. Even if Dr. Klibanov were correct that in each instance the specification is devoid of guidance, at the very least a POSA would understand based on the number of significant figures for a numerical value how "to determine how far from their claimed numerical values he/she must go to escape their scope based on the intrinsic evidence." *Id.* ¶ 44.

83. The relationship between the number of significant figures reported and "implied precision" is commonly taught as a fundamental concept to undergraduate science and engineering students and corresponds to an implied precision of 1/2 of the last significant digit.

84. Below are numerous references that confirm how a POSA would understand the concept of significant figures, including a handout from an undergraduate engineering class and excerpts from two textbooks on error analysis.

85. Attached as **Ex. L** is a handout titled "Accuracy, Precision, Errors, and Significant Figures" from Stanford University's "Engineering 1N: The Nature of Engineering" course

("Stanford Handout"). This handout states how "[s]ignificant digits carry with them an implied precision of ±1/2 unit in the rightmost significant digit." **Ex. L** (Stanford Handout), 4.

86. The fundamental concept of significant figures, and the implied precision to half of the last digit of precision, is also reflected in textbooks on error analysis.

87. Attached as **Ex. M** is an excerpt from R. Khoury & Douglas Wilhelm Harder, *Numerical Methods and Modelling for Engineering* (2016) ("Khoury & Harder"), that confirms the implied precision to half of the last digit of precision: "given no other information except a value, it is implied that the accuracy is half the last digit of precision. For example, a car measured as going to 102.3 km/h is implied to have been accurately measured to 0.05 km/h to get that precision. This accuracy is called the implied precision of the measure." **Ex. M** (Khoury & Harder), 6.

88. This concept is confirmed in another error analysis textbook John R. Taylor, *An Introduction to Error Analysis. The Study of Uncertainties in Physical Measurements*, (2d ed. 1997) ("Taylor"), attached as **Ex. N.** The applicable excerpt is provided below:

> the convention that the statement "l = 36 mm" without any qualification is presumed to mean that l is closer to 36 than to 35 or 37; that is,
>
> $$l = 36 \text{ mm}$$
>
> means
>
> $$35.5 \text{ mm} \leq l \leq 36.5 \text{ mm}$$
>
> In the same way, an answer such as $x = 1.27$ without any stated uncertainty would be presumed to mean that x lies between 1.265 and 1.275.

Ex. N (Taylor), 9.

89. Since significant figures are a core part of any undergraduate science and engineering curriculum, it is clear that a POSA would understand that use of "about" in relation to a numerical value of a range to fundamentally encompass to 1/2 of the last significant digit of precision to the lower or higher end of the range, depending on whether the value corresponded to

the upper or lower end of the range. For example, a "range of about 1 to 5" would correspond to 1±.5 and 5±.5, resulting in a POSA understanding that the plain and ordinary meaning of a "range of about 1 to 5" means a range of .5 to 5.5.

90. With this discussion in mind, below are the plain and ordinary meanings that a POSA would give to the numerical ranges of the Asserted Patents that include "about" based on a POSA's undergraduate science or engineering education, which would have covered the topic of significant figures:

Claim limitations reciting "about [a numerical value]	**Patent(s) and claim(s)**
"a mole ratio of hydrogen peroxide to triacetin of **about** 2.98:1 to **about** 12.84:1" means 2.98 ± 0.005 to 12.94 ± 0.005, which corresponds to a mole ratio of hydrogen peroxide to triacetin **between 2.975:1 and 12.845:1**;	8,546,449, Claims 3, 20
"said mole ratio of said hydrogen peroxide to said triacetin is **about 3.8:1**" means 3.8 ± 0.05:1, which corresponds to said mole ratio of said hydrogen peroxide to said triacetin is **between 3.75:1 and 3.85:1.**	9,737,072, Claims 2-3
"the sodium hydroxide is **about 1.82% to about 7.28%**" means 1.82 ± 0.005% to about 7.28± 0.005%, which corresponds to the sodium hydroxide is **between 1.815% and 7.285%.**	8,546,449, Claims 7, 22; 9,363,997, Claim 7
"the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is **about 4.2:3.8:1**" means the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is **4.2 ± 0.05 : 3.8 ± 0.05 : 1**.	8,546,449, Claim 13; 9,363,997, Claim 12
"the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is **about 4.2:18:1**" means the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is **4.2 ± 0.05 : 18 ± 0.5 : 1.**	8,546,449, Claim 23
"a pH of **about 11.2 to about 13.37**" means 11.2 ± 0.05 to 13.37 ± 0.005, which corresponds to a pH of **between 11.15 and 13.375.**	9,730,443, Claim 2
"said peracetic acid is **about 1% to about 7.1%**" means 1 ± 0.5% to 7.1 ± 0.05%, which corresponds to a pH of **between 0.5% and 7.15%.**	9,730,443, Claim 3
"said aqueous hydrogen peroxide is **about 23% to about 40%**" means 23 ± 0.5% to 40 ± 0.5% which corresponds to said aqueous hydrogen peroxide is **between 22.5% to 40.5%**.	9,737,072, Claim 2
"said aqueous hydrogen peroxide is **about 27%**" means 27 ± 0.5%, which corresponds to said aqueous hydrogen peroxide is **between 26.5% to 27.5%**.	9,737,072, Claim 3
"said triacetin is **about 20% to about 53%"** means 20 ± 0.5% to 53 ± 0.5%, which corresponds to said triacetin is **between 19.5% to 53.5%.**	9,737,072, Claim 2

Claim limitations reciting "about [a numerical value]	Patent(s) and claim(s)
"said triacetin is **about 46%"** means 46 ± 0.5%, which corresponds to said triacetin is **between 45.5% to 46.5%.**	9,737,072, Claim 3
"time to maximize the conversion of the hydrogen peroxide triacetin into peracetic acid is **about 30 seconds to about five minutes"** means 30 ± 0.5 seconds to 5 ± 0.5 minutes, which corresponds to the time to maximize the conversion of the hydrogen peroxide triacetin into peracetic acid is **between 29.5 seconds to 5.5 minutes**	8,546,449, Claims 10-11; 9,363,997, Claims 10-11
"wherein the percent of triacetin that is converted into peracetic acid is **about 40.9% to about 85.7%"** means 40.9 ± 0.05% to 85.7 ± 0.05%, which corresponds to wherein the precent of triacetin that is converted into peracetic acid is **between 40.85% to 85.75%.**[1]	8,546,449, Claim 12; 9,363,997, Claim 11

91. Of note, when Dr. Klibanov does discuss the actual application of significant figures to individual numerical values, the "±" examples he provides agree with those I have provided above. *See* **Ex. F** (Klibanov Decl.) ¶ 47 ("a POSA would recognize the 'about 2.98' claimed value to cover the range between 2.975 and 2.285 [sic 2.985] (i.e., ± 0.005 or ± 0.17%), the 'about 12.84' claimed value to cover the range between 12.835 and 12.845 (i.e., ± 0.005 or ± 0.04%), and the 'about 3.8' claimed value to cover the range between 3.75 and 3.85 (i.e., ± 0.05 or ± 1.38%)" (emphasis added)).

92. In sum, a POSA would readily understand the concept of significant figures and would at least apply that concept when "about" is used in connection with a numerical value, resulting in a plain and ordinary meaning in each instance.

[1] Claim 12 in the '449 patent and claim 11 in the '997 patent relate to methods where "the percent of triacetin that is converted into peracetic acid" is between two values. As such, the formula for conversion of triacetin must account for both (i) the initial amount of triacetin, and (ii) the amount of peracetic acid that is formed. This is because it is possible that some amount of triacetin will be consumed but will not be converted into PAA, instead being diverted to various side reactions, such as the formation of acetic acid. The appropriate formula, shown here, compares the amount of peracetic acid that is formed with the initial amount of triacetin provided:

$$Triacetin\ conversion = \frac{initial\ moles\ of\ triacetin - {}^{1}/_{3}\ moles\ of\ peracetic\ acid\ formed}{initial\ moles\ of\ triacetin}$$

D. "Allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide[-]triacetin [solution] into peracetic acid." (Patent No. 8,546,449, Claims 9-12); "allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid." Patent No. 9,363,997, Claims 9-11)

Envirotech Proposed Construction	Clean Chemistry Proposed Construction
Plain and ordinary meaning.	"allowing the reaction medium sufficient time to achieve the highest possible conversion of the hydrogen peroxide and the triacetin into peracetic acid;" otherwise indefinite

93. Claims 9-12 of the '449 Patent recite "allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide triacetin into peracetic acid." Claims 9-11 of the '997 Patent recite "allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid."

The Prosecution History Supports Reading "hydrogen peroxide triacetin" as "hydrogen peroxide[-]triacetin [solution]" for the '449 Patent

94. Claims 9, 10, and 11 of the '449 Patent recite the phrase "hydrogen peroxide triacetin." For example, Claim 9 recites "allowing the reaction medium sufficient time to maximize the conversion of hydrogen peroxide triacetin into peracetic acid."

95. Clean Chemistry contends that the proper reading of this phrase is "hydrogen peroxide and triacetin." This reading is consistent with its contention that claim 9 requires conversion of all of both the hydrogen peroxide and the triacetin, rather than only the limiting reagent, as a skilled artisan would conclude, which is further discussed in Section E below. *See* **Ex. F** (Klibanov Decl.), ¶¶ 66-67.

96. However, this reading is inconsistent with the '449 Patent's prosecution history and the principles of claim construction.

97. Claim 1 of the '449 Patent does not recite hydrogen peroxide and triacetin; instead, it recites a "hydrogen peroxide-triacetin solution." Claim 1 provides clear antecedent basis for the term "hydrogen peroxide-triacetin solution." This is the reactant solution that claim 1 contemplates converting into peracetic acid. As such, a skilled artisan would conclude that claim 9 should read "hydrogen peroxide-triacetin solution." The same argument applies equally to claims 10 and 11.

98. This reading is supported by the prosecution history. In the file history for the '449 Patent, the original independent method claim that became issued claim 1 is claim 7, and originally recited a "liquid acetyl precursor" rather than a hydrogen peroxide-triacetin solution. *See* **Ex. J** ('449 Patent Prosecution History), at ESCI 0000476, reproduced in part below.

> 7. A method of generating a non-equilibrium solution of peracetic acid, comprising:
> a. providing water;
> b. introducing a hydrogen peroxide-acetyl precursor solution to the water;
> c. mixing the hydrogen peroxide-acetyl precursor solution and the water to form a mixture;
> d. adding an aqueous source of an alkali metal or earth metal hydroxide to the mixture; and
> e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.

99. At the time, the claims thatwould become claims 9-11 were pending claims 16-18. *See id.* at ESCI 0000477, reproduced in part below.

> 16. The method of claim 7, further comprising allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide and the acetyl precursor into peracetic acid.
>
> 17. The method of claim 16, wherein the time to maximize the conversion of the hydrogen peroxide and the acetyl precursor into peracetic acid is about 30 seconds to about five minutes.
>
> 18. The method of claim 17, further comprising, after step (e), a step of sampling the reaction medium to determine the time required to maximize the amount of hydrogen peroxide and acetyl precursor that are converted into peracetic acid.

100. Subsequently, claim 7 was amended to replace "acetyl precursor" with "triacetin," but dependent claims 16-18 were not so amended. *Id.* at ESCI0000207-208, reproduced in part below.

> 7. (Currently amended) A method of generating a non-equilibrium solution of peracetic acid, comprising:
>
> a. providing water;
> b. introducing a hydrogen peroxide-triacetin ~~acetyl precursor~~ solution to the water;
> c. mixing the hydrogen peroxide-triacetin ~~acetyl precursor~~ solution and the water to form a mixture;
> d. adding an aqueous source of an alkali metal or earth metal hydroxide to the mixture; and
> e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.
>
> …
>
> 16. (original) - The method of claim 7, further comprising allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide and the acetyl precursor into peracetic acid.
>
> 17. (original) - The method of claim 16, wherein the time to maximize the conversion of the hydrogen peroxide and the acetyl precursor into peracetic acid is about 30 seconds to about five minutes.
>
> 18. (original) - The method of claim 17, further comprising, after step (e), a step of sampling the reaction medium to determine the time required to maximize the amount of hydrogen peroxide and acetyl precursor that are converted into peracetic acid.

101. Finally, an Examiner's amendment was issued in an attempt to correct this omission. *Id.* at ESCI0000196, reproduced in part below.

with Audrey A. Millemann on June 17, 2013. The application has been amended as follows:

In claim 16, line 2, after "peroxide", delete "and the acetyl precursor", and insert ---triacetin--

In claim 17, line 2, after "peroxide", delete "and the acetyl precursor", and insert ---triacetin--

In claim 18, line 3, after "peroxide", delete "and the acetyl precursor", and insert ---triacetin--

In claim 19, line 1, after "wherein", delete "the acetyl precursor is triacetin"

Delete claims 1-6, 26-27, 30-31, 34-38 and 40-91.

102. Since claim 7 (now claim 1) was amended to recite a "hydrogen peroxide-triacetin solution," it stands to reason that the Examiner intended to amend the dependent claims to refer to the same structure, i.e. the "hydrogen peroxide-triacetin solution."

103. As such, the phrase "hydrogen peroxide triacetin" in claims 9, 10, and 11 of the '449 Patent should be read as "hydrogen peroxide-triacetin solution," rather than as "hydrogen peroxide and triacetin," as the Defendant contends.

104. In contrast, claim 1 of the '997 Patent is directed not to a hydrogen peroxide-triacetin solution, but to aqueous hydrogen peroxide and triacetin. *See* '997 Patent Claim 1, reproduced below.

> We claim:
> **1**. A method of generating a non-equilibrium solution of peracetic acid, comprising:
> a. providing water;
> b. introducing triacetin and aqueous hydrogen peroxide to the water;
> c. mixing the triacetin and the aqueous hydrogen peroxide with the water to form a mixture;
> d. adding an aqueous source of an alkali metal or earth alkali metal hydroxide to the mixture; and
> e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.

105. Clean Chemistry's proposed construction of "hydrogen peroxide and triacetin" for claims 9-10 of the '997 Patent is better-supported, and is in fact the language adopted by dependent claims 9-10, reproduced below.

> **9**. The method of claim **1**, further comprising allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid.
> **10**. The method of claim **9**, wherein the time to maximize the conversion of the hydrogen peroxide and the triacetin into peracetic acid is about 30 seconds to about five minutes.

The Claim Term Is Not Limited to Triacetin and Includes All Three Acetyl Groups Thereof

106. Dr. Klibanov advanced a narrow reading of this claim language that is divorced from the specification of the Asserted Patents. Dr. Klibanov's proposed interpretation of the claim term restricts it to the conversion of *only* triacetin into peracetic acid and not any of the underlying intermediaries of triacetin: diacetin and monoacetin. *See* **Ex. F** (Klibanov Decl.), ¶ 60 ("A POSA would recognize that plain reading of the claim term as written only recites triacetin, ***not*** diacetin and/or monoacetin.") (emphasis in original).

107. The Asserted Patents state, with stunning frequency and clarity, that all three acetyl groups of triacetin, which includes both diacetin and monoacetin, are used for conversion into PAA:

- "*When triacetin is used as the acetyl precursor and assuming all three acetyl groups are reacted*, about 40.9% to about 85.7% of the triacetin is converted into peracetic acid, and the percent of hydrogen peroxide remaining is about 0.078% to about 1.88%." **Ex. A** ('449 Patent), 6:6-11 (emphasis added); **Ex. B** ('997 Patent), 6:15-19 (emphasis added).
- "*When the acetyl precursor is triacetin and all three acetyl groups are reacted*, then the product of the perhydrolysis reaction is 1,2,3-propanetriol (glycerine). In these methods, the perhydrolysis reaction is rapid and the maximum amount of PAA is generated within about 30 seconds to about five minutes at ambient temperature. *The methods efficiently utilize the acetyl precursor* and the source of hydrogen peroxide. *When triacetin is used, assuming all three acetyl groups are reacted, about 40.9% to about 85.7% of the triacetin is converted into PAA*. The percent of hydrogen peroxide remaining is about 0.078% to about 1.88%. **Ex. A** ('449 Patent), 17:41-50 (emphasis added); **Ex. B** ('997 Patent), 17:41-51 (emphasis added).
- "The percent of the triacetin acetyl donor converted to PAA was calculated, *assuming all three acetyl groups were available for perhydrolysis*." **Ex. A** ('449 Patent), 18:54-56 (emphasis added); **Ex. B** ('997 Patent), 18:54-56 (emphasis added).
- "Upon addition of the NaOH, PAA was immediately generated, with the maximum amount of 0.326% occurring at five minutes, corresponding to a yield of 62.9% *assuming all three acetyl groups of triacetin were available for perhydrolysis*." **Ex. A** ('449 Patent), 20:53-57 (emphasis added); **Ex. B** ('997 Patent), 20:53-57 (emphasis added).
- "Table X summarizes the next set of data and shows the maximum percent of PAA generated, the time after the addition of NaOH that it took to reach the maximum percent of PAA generated, the pH after the addition of the NaOH, the percent of hydrogen peroxide remaining at the time of the maximum percent of PAA, *and the calculated percent of triacetin converted to PAA assuming that all three acetyl groups were available for perhydrolysis*." **Ex. A** ('449 Patent), 20:59-67 (emphasis added); **Ex. B** ('997 Patent), 20:60-67 (emphasis added).
- "Upon addition of the NaOH, PAA was immediately generated, with the maximum amount of 0.331% occurring after just one minute, corresponding to a calculated conversion of triacetin into PAA of 63.8%, *assuming that all three acetyl groups of triacetin were available for perhydrolysis*." **Ex. A** ('449 Patent), 21:54-58 (emphasis added); **Ex. B** ('997 Patent), 21:54-58 (emphasis added).
- "Table XII summarizes the data and shows the maximum percent of PAA generated, the time after the addition of NaOH that it took to reach the maximum percent of PAA generated, the pH after the addition of the NaOH, the percent of hydrogen peroxide remaining at the time of the maximum percent of PAA, and *the calculated percent of triacetin converted to PAA assuming that all three acetyl groups were available for perhydrolysis*." **Ex. A** ('449 Patent), 21:60-67 (emphasis added); **Ex. B** ('997 Patent), 21:60-67 (emphasis added).
- "Table XVI shows the percent of hydrogen peroxide converted overall, the percent of hydrogen peroxide converted to PAA, and *the percent of triacetin converted to PAA (assuming that all three acetyl groups on triacetin are available for conversion to PAA*) for each of the tests in Table XV." **Ex. A** ('449 Patent), 24:15-19 (emphasis added); **Ex. B** ('997 Patent), 24:15-19 (emphasis added).

108. The column headings for each of Tables IX, X, XI, XII, XIII, XIV, and XVI in the Asserted Patents also specify that the percent of triacetin converted into peracetic acid includes all three acetyl groups of triacetin: "% Triacetin Converted to PAA (3 acetyls)." **Ex. A** ('449 Patent), 19:63-64 (Table IX); *id.* at 21:2-4 (Table X); *id.* at 21:46-47 (Table XI); *id.* at 22:3-6 (Table XII); *id.* at 22:45-46 (Table XIII); *id.* at 23:2-5 (Table XIV); *id.* at 24:24-26 (Table XVI); **Ex. B** ('997 Patent), 20:43-44 (Table IX); *id*. at 21:2-5 (Table X); *id*. at 21:46-47 (Table XI); *id.* at 22:2-5 (Table XII); *id*. at 22:44-46 (Table XIII); *id*. at 23:2-5 (Table XIV); *id*. at 24:23-26 (Table XVI).

109. In short, the explicit direction from the specification makes clear to a POSA that the plain and ordinary meaning of triacetin in the claim term would refer to the conversion of triacetin and its underlying intermediaries, diacetin and monoacetin, into peracetic acid. It would be obvious to a POSA that all three acetyl groups of triacetin react with hydrogen peroxide to form peracetic acid. The term is far from indefinite, and Dr. Klibanov's position is not supported by even a cursory reading of the Asserted Patents.

110. Further, Clean Chemistry's FCN comports with the Asserted Patent's plain and ordinary meaning for a POSA of the conversion of triacetin, and all three of its available acetyl groups, into peracetic acid: "In the current reaction scheme associated with this FCS, a mixture of hydrogen peroxide is blended with sodium hydroxide and dilution water. Triacetin is then added to this diluted mixture. *The resulting reaction converts the three available acetyl groups on triacetin into PAA* with a resulting aqueous solution having a PAA purity of greater than 94 percent." **Ex. G** (FCN), 12 (emphasis added).

Time to Maximize

111. The specifications of the Asserted Patents provide a POSA with context on the sufficient time to "maximize" the conversion of the hydrogen peroxide and triacetin into peracetic

acid. A POSA would recognize from the Asserted Patents that testing the reaction mixture during conversion would allow the POSA to determine the sufficient time to maximize the conversion of hydrogen peroxide and triacetin into peracetic acid.

112. The Asserted Patents inform a POSA how to determine when and how conversion of hydrogen peroxide and triacetin is maximized by detailing the effects of temperature, mixing and mole ratios. *See* **Ex. A** ('449 Patent), 15:27-32 (maximizing the conversion of triacetin and hydrogen peroxide into peracetic acid is dependent on "the temperature of the water, the efficiency of the mixing, and the mole ratio of NaOH:hydrogen peroxide:acetyl precursor employed"); **Ex. B** ('997 Patent), 15:27-32.

113. The Asserted Patents explain how a POSA can sample "the reaction medium at various times after the addition of the aqueous source of alkali metal or earth alkali metal hydroxide to determine the time required under existing conditions to maximize the amount of hydrogen peroxide and acetyl precursor that are converted into PAA." **Ex. A** ('449 Patent), 15:41-45; **Ex. B** ('997 Patent), 15:41-45.

114. Further, Examples 9-12 of the Asserted Patents discuss the time for maximum conversion of hydrogen peroxide and triacetin into peracetic acid at different mole ratios. **Ex. A** ('449 Patent), 19:45-24:46; **Ex. B** ('997 Patent), 19:49-24:46.

115. Screenshots of tables from the examples showing the times for maximizing peracetic acid in relation to hydrogen peroxide and triacetin are included below, which provide empirical evidence to a POSA on the sufficient time to maximize the conversion of hydrogen peroxide and triacetin into peracetic acid:

TABLE IX

Time (min)	% PAA Generated	% Hydrogen Peroxide Remaining	% Triacetin Converted to PAA (3 acetyls)
0	0.015	0.437	2.9
1	0.275	0.298	53.1

TABLE IX-continued

Time (min)	% PAA Generated	% Hydrogen Peroxide Remaining	% Triacetin Converted to PAA (3 acetyls)
3	0.312	0.274	60.2
5	0.326	0.258	62.9
11	0.302	0.233	58.3
21	0.246	0.199	47.5

TABLE X

Mole ratio NaOH:TA	Time at Max. PAA (min)	Max % PAA Generated	% Hydrogen Peroxide Remaining	% Triacetin Converted to PAA (3 acetyls)	pH
3:1	3	0.229	0.291	43.8	11.2
4:1	6	0.285	0.251	54.8	11.3
6:1	5	0.326	0.258	62.9	11.6
8:1	3	0.335	0.271	64.7	12.2

TABLE XI

Time (min)	% PAA Generated	% Hydrogen Peroxide Remaining	% Triacetin Converted to PAA (3 acetyls)
1	0.331	0.317	63.8
3	0.330	0.303	63.6
5	0.319	0.303	61.5
10	0.300	0.295	57.8
20	0.256	0.274	49.3

TABLE XII

Mole Ratio Hydrogen Peroxide: Triacetin	Time at Max. PAA (min)	Max % PAA Generated	% Hydrogen Peroxide Remaining	% Triacetin Converted to PAA (3 acetyls)	pH
2:1	3	0.214	0.079	40.9	12.6
4:1	1	0.272	0.195	51.9	12.4
6:1	1	0.331	0.317	63.8	12.3
8:1	3	0.374	0.445	72.0	11.9

TABLE XIII

Time (min)	% PAA Generated	% Hydrogen Peroxide Remaining	% Triacetin Converted to PAA (3 acetyls)
1	0.247	0.207	47.3
3	0.280	0.178	53.6
5	0.292	0.167	55.9
10	0.267	0.142	51.1
20	0.229	0.111	43.8

TABLE XIV

Mole Ratio NaOH:TA	Time at Max. PAA (min)	Max % PAA Generated	% Hydrogen Peroxide Remaining	% Triacetin Converted to PAA (3 acetyls)	pH
3:1	3	0.246	0.202	47.2	11.3
4:1	5	0.292	0.167	55.9	11.6
6:1	3	0.290	0.181	55.6	12.2
8:1	3	0.272	0.195	51.9	12.4

TABLE XV

Test #	Initial Temp. (° F.)	Final Temp. (° F.)	Final pH	Max. % PAA Generated (time, min)	% Hydrogen Peroxide Remaining
1	NM	NM	12.14	1.71 (1)	0.58
2	38	50	12.67	2.1 (4)	0.43
3	44	88	12.77	6.3 (1)	1.18
4	34	92	13.17	7.2 (1)	1.88

NM = not measured

TABLE XVI

Test #	% Hydrogen Peroxide Converted Overall	% Hydrogen Peroxide Converted to PAA (at maximum conversion time)	% Triacetin Converted to PAA (3 acetyls)
1	67.8	88.1	69.7
2	68.8	94.4	85.8
3	71.6	94.3	85.7
4	66.1	88.1	73.8

116. Example 13 from the Asserted Patents then provides detail on the potential methods to determine the rate of reaction and conversion of hydrogen peroxide and triacetin to form peracetic acid, and the potential impacts of temperature on the time for maximum conversion. **Ex. A** ('449 Patent), 25:38-26:13 (noting how "[t]he rate of the reaction between hydrogen peroxide

and triacetin to form PAA is dependent upon the temperature of inlet water," where higher temperatures resulted in shorter maximum conversion times, and that "the time to achieve the maximum conversion of hydrogen peroxide and triacetin into PAA was determined by sampling and analyzing the solution at sample ports"); **Ex. B** ('997 Patent), 25:38-26:13.

117. The intrinsic evidence instructs a POSA of the plain and ordinary meaning of "a sufficient time to maximize the conversion of the hydrogen peroxide and triacetin into peracetic acid," and dictionary definitions of "maximize" do not add anything to the claim language. The limitations of the claim are apparent without the need for any supplementation or rephrasing.

E. "The time to maximize the conversion of the hydrogen peroxide[-]triacetin [solution] into peracetic acid is about 30 seconds to about five minutes" (Patent No. 8,546,449, Claims 10-11)

Envirotech Proposed Construction	Clean Chemistry Proposed Construction
Plain and ordinary meaning.	Indefinite, otherwise should be construed as "the time to achieve the highest possible conversion of the hydrogen peroxide and the triacetin into peracetic acid is about 30 seconds to about five minutes"

118. This claim term appears in claims 10-11 of the '449 Patent.

119. Dr. Klibanov contends that "about" renders the claim indefinite, reiterates his discussion of "maximize," and continues to take the view that the reference to triacetin excludes diacetin and monoacetin.

120. I incorporate by reference my discussions on "about," on "maximize," and on how the Asserted Patents repeatedly describe that all three acetyl groups of triacetin are reacted. *See supra* ¶¶ 79-92 ("about"), ¶¶ 111-117 ("maximize"), and ¶¶ 107-110 (all three acetyl groups).

121. Dr. Klibanov states that my prior statement's reference to the "maximum conversion of hydrogen peroxide *and/or* triacetin" for Claim 10 is inconsistent with and otherwise distorts the claim language. **Ex. F** (Klibanov Decl.), ¶¶ 63-65. This is fundamentally untrue

because when a POSA seeks to maximize a conversion of one or more reactants *into* a product, the ultimate goal is to obtain the maximum amount of product, here peracetic acid. And, when a POSA seeks to maximize the conversion of two reactants of concern, here hydrogen peroxide and triacetin, *into* a product, one of the two reactants will necessarily be exhausted prior to the other unless the reactants are present in an exact ratio down to the molecule, which is not realistic. In other words, every time there is a maximum conversion of triacetin and hydrogen peroxide *into peracetic acid*, the maximum amount of peracetic acid is limited to and governed by whichever of hydrogen peroxide or triacetin is first totally reacted — the "limiting reagent." Thus, when the conversion of both triacetin and hydrogen peroxide into peracetic acid is maximized, only one of the two reactants will constitute the limiting reagent, having the maximum proportion thereof consumed during the reaction.

122. Dr. Klibanov points out that in my prior statement on claim 11 regarding sampling, which is dependent on claim 10, that I did not reference the "and/or" in that statement. But I clearly noted how my "and/or" statement for "the time to maximize the conversion of the hydrogen peroxide triacetin into peracetic acid is about 30 seconds to about five minutes" was for claims "10-11." This was a simple oversight in the language used on claim 11 regarding sampling, and I maintain that the maximum conversion of hydrogen peroxide and/or triacetin into peracetic acid—whether in the context of a time measurement (claim 10) or sampling (claim 11)—is appropriate.

F. "Sampling the reaction medium to determine the time required to maximize the amount of hydrogen peroxide[-]triacetin [solution] that are converted into peracetic acid" (Patent No. 8,546,449, Claim 11)

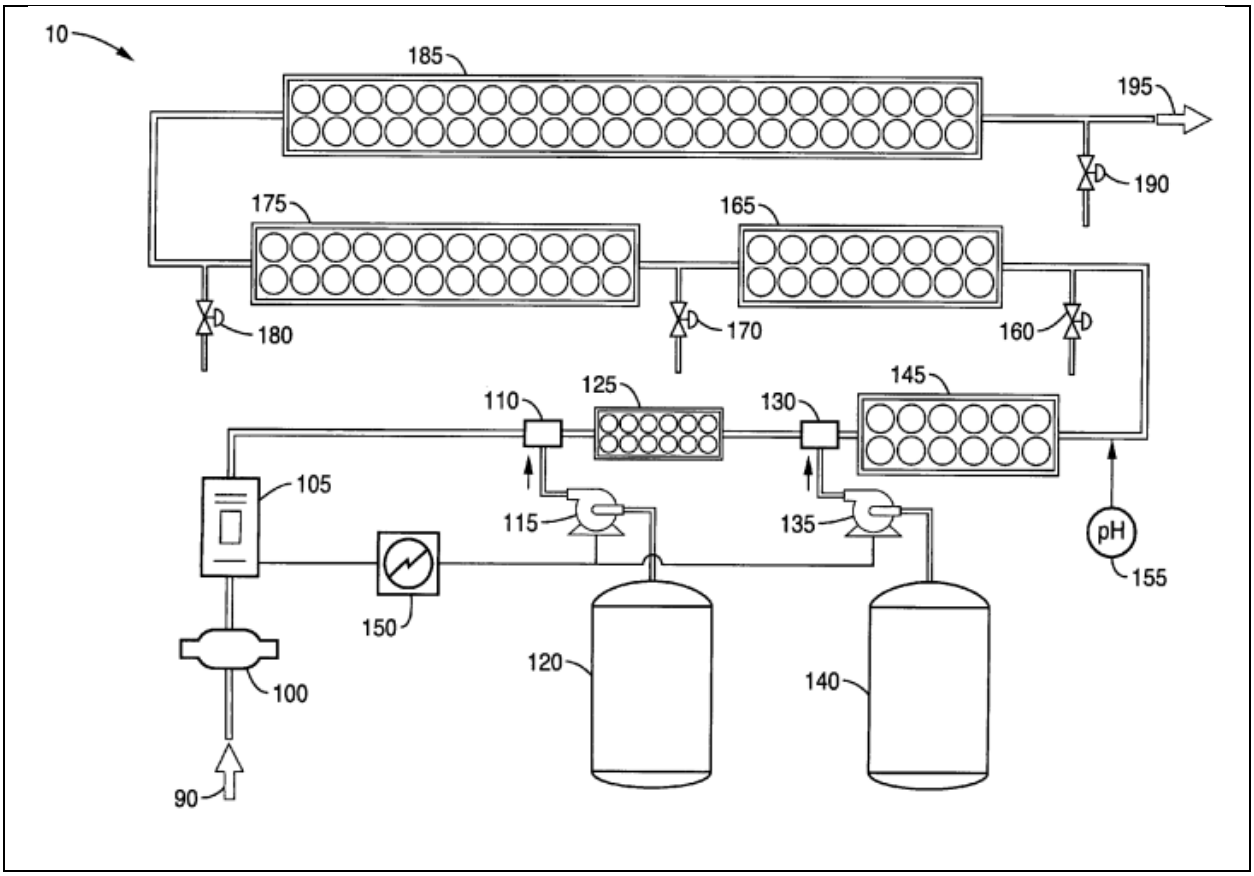
Envirotech Proposed Construction	Clean Chemistry Proposed Construction
Plain and ordinary meaning.	"taking samples of the reaction medium at various times to determine the time required to achieve the highest possible conversion of hydrogen peroxide and triacetin into peracetic acid"

123. The Asserted Patents explain to a POSA how to sample the reaction medium to determine the time required to maximize the amount of hydrogen peroxide and triacetin that are converted into peracetic acid.

124. For instance, Examples 9-12 of the Asserted Patents discuss data from sampling for the time for maximum conversion of hydrogen peroxide and triacetin into peracetic acid at different mole ratios. **Ex. A** ('449 Patent), 19:45-24:46.

125. Example 13 then provides detail on sampling to determine the rate of reaction and conversion of hydrogen peroxide and triacetin to form peracetic acid. **Ex. A** ('449 Patent), 25:38-26:13.

126. The embodiment shown in Example 13 explained to a POSA how "the reaction medium was directed through one or more residence chambers **165**, **175**, and **185** which also contained a packing material to promote turbulence and cause thorough mixing. Residence chambers **165**, **175**, and **185** were designed to be of volumes such that at a total flow rate of one gallon per minute, the reaction medium reached sampling port **170** in one minute, sampling port **180** in two minutes, and sampling port **190** in five minutes, to permit sampling at different time intervals. Thus, depending on the temperature of the inlet water, the time to achieve the maximum conversion of hydrogen peroxide and triacetin into PAA was determined by sampling and analyzing the solution at sample ports **160**, **170**, **180**, and **190**." **Ex. A** ('449 Patent), 25:47-26:8.



127. Further, in response to Dr, Klibanov, I incorporate by reference my discussions on the time to maximize, how the Asserted Patent repeatedly describes that all three acetyl groups of triacetin are reacted, and my rebuttal to Dr. Klibanov's "and/or" discussion. *See supra* ¶¶ 111-117 ("maximize"), ¶¶ 107-110 (all three acetyl groups), and ¶¶ 121-122 ("and/or").

128. A POSA would recognize from the specification that this claim term has its plain and ordinary meaning and refers to taking samples of the reaction medium to determine the amount of time required to maximize the conversion of hydrogen peroxide-triacetin solution into peracetic acid.

G. "The liquid is triacetin defining a hydrogen peroxide-triacetin solution" (Patent No. 8,546,449, Claims 19-23)

Envirotech Proposed Construction	Clean Chemistry Proposed Construction
Plain and ordinary meaning.	Indefinite.

129. I have reviewed the file history of the ’449 Patent, as well as the issued claims for the ’449 Patent.

130. In the file history for the ’449 Patent, the original independent method claim that became issued claim 1 is claim 7, and originally recited a “liquid acetyl precursor” rather than a hydrogen peroxide-triacetin solution. *See* **Ex. J** (’449 Patent Prosecution History), ECSI 0000476.

> 7. A method of generating a non-equilibrium solution of peracetic acid, comprising:
> a. providing water;
> b. introducing a hydrogen peroxide-acetyl precursor solution to the water;
> c. mixing the hydrogen peroxide-acetyl precursor solution and the water to form a mixture;
> d. adding an aqueous source of an alkali metal or earth metal hydroxide to the mixture; and
> e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.

131. At the time, dependent claim 28 then limited the “liquid acetyl precursor” to triacetin. *Id.*

> 8. The method of claim 7, further comprising, prior to step (b), a step of providing the hydrogen peroxide-acetyl precursor solution comprising: introducing a liquid acetyl precursor that is soluble in aqueous hydrogen peroxide to a solution of aqueous hydrogen peroxide; and allowing the liquid acetyl precursor and the solution of aqueous hydrogen peroxide to mix to form the hydrogen peroxide-acetyl precursor solution.
>
> …
>
> 28. The method of claim 8, wherein the liquid acetyl precursor is triacetin defining a hydrogen peroxide-triacetin solution.

132. This dependent claim later became issued claim 19, reciting the phrase "the liquid is triacetin defining a hydrogen peroxide-triacetin solution," which is at issue in this case.

133. Independent method claim 7 was later amended to instead recite a "hydrogen peroxide-triacetin solution" rather than a "liquid acetyl precursor." *See id.* at ECSI 0000206. The claim which would become issued claim 19 was still pending as claim 28 at the time. *See id.* at ECSI 0000210.

> 7. (Currently amended) A method of generating a non-equilibrium solution of peracetic acid, comprising:
>
> a. providing water;
>
> b. introducing a hydrogen peroxide-triacetin ~~acetyl precursor~~ solution to the water;
>
> c. mixing the hydrogen peroxide-triacetin ~~acetyl precursor~~ solution and the water to form a mixture;
>
> d. adding an aqueous source of an alkali metal or earth metal hydroxide to the mixture; and
>
> e. forming a reaction medium comprising a non-equilibrium solution of peracetic acid.
>
> 8. (Currently amended) The method of claim 7, further comprising, prior to step (b), a step of providing the hydrogen peroxide-triacetin ~~acetyl precursor~~ solution comprising: introducing triacetin ~~a liquid acetyl precursor that is soluble in aqueous hydrogen peroxide~~ to a solution of aqueous hydrogen peroxide; and allowing the triacetin ~~liquid acetyl precursor~~ and the solution of aqueous hydrogen peroxide to mix to form the hydrogen peroxide-triacetin ~~acetyl precursor~~ solution.
>
> …
>
> 28. (original) The method of claim 8, wherein the liquid acetyl precursor is triacetin defining a hydrogen peroxide-triacetin solution

134. At this point, claim 28 (i.e. current claim 19) should have been canceled, as its limitations had been incorporated into the independent method claim. Additionally, the claims that depended on claim 28 (i.e. current claims 20-23) should have been amended to depend instead on the independent method claim as appropriate. Instead, an Examiner's amendment was entered, and

the claim was subsequently issued as written, reciting a limitation that was already present in the claim from which it depended. *See id.* at ECSI 0000196.

135. As such, as a POSA, my understanding is that claims 20 and 21 should be interpreted as depending on claim 1.

H. "A non-equilibrium solution of peracetic acid, comprising" (Patent No. 9,730,443; All Claims)

Envirotech Proposed Construction	Clean Chemistry Proposed Construction
The preamble is *not* limiting.	The preamble is limiting.

136. The above-referenced claim phrase is the preamble of claim 1 of the ’443 Patent. For context and easy reference, claim 1 of the ’443 Patent is reproduced below.

> 1. 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.

137. My understanding is that the claim preamble is non-limiting unless it is necessary to give life, meaning, or vitality to the claim, or unless the preamble recites essential steps.

138. In this case, the meaning of the claim is clear without the context of the preamble. The claim lists the components comprising the claimed composition. The preamble also does not recite any steps. A POSA would conclude, without the benefit of the preamble, that the patent claim covers compositions comprising the listed components.

139. As the preamble does not recite essential steps, and is not necessary to give life, meaning, or vitality to the claim, a POSA would conclude that the preamble is not limiting.

I. "A hydrogen peroxide-acetyl precursor solution, comprising" (Patent No. 9,737,072, All Claims)

Envirotech Proposed Construction	Clean Chemistry Proposed Construction
The preamble is *not* limiting.	The preamble is limiting.

140. The above-referenced phrase is the preamble of claim 1 of the ’072 Patent. For context and easy reference, claim 1 of the ’072 Patent is reproduced below.

1. A hydrogen peroxide-acetyl precursor solution, comprising: a. aqueous hydrogen peroxide; b. triacetin; c. a trace amount of peracetic acid; and d. water.

141. As mentioned above, my understanding is that the claim preamble is non-limiting unless it is necessary to give life, meaning, or vitality to the claim, or unless the preamble recites essential steps.

142. In this case, the meaning of the claim is clear without the context of the preamble. The claim lists the components comprising the claimed composition. The preamble also does not recite any steps. A POSA would conclude, without the benefit of the preamble, that the patent claim covers compositions comprising the listed components.

143. As the preamble does not recite essential steps, and is not necessary to give life, meaning, or vitality to the claim, a POSA would conclude that the preamble is not limiting.

J. "Trace amount [of peracetic acid]" (Patent No. 9,737,072, All Claims)

Envirotech Proposed Construction	Clean Chemistry Proposed Construction
Plain and ordinary meaning.	Indefinite.

144. The ’072 Patent recites the phrase “a trace amount of peracetic acid” in claim 1, the only independent claim.

145. Dr. Klibanov stated in his declaration that "the claim phrase 'trace amount' would be perceived by a POSA to be a subjective term of degree, and the specification of the '072 Patent would not provide to him or her any objective basis for determining its meaning." **Ex. F** (Klibanov Decl.), ¶ 84.

146. I previously stated that "a skilled artisan would recognize that "trace amount" refers to an amount corresponding to the lower bound at the limit of detection, which is at least as low as 40 ppb or any other such lower bound of detection." **Ex. K** (Whiteker Jul. 1 Decl.), ¶ 10. Klibanov counters that my "phrase 'or any other such lower bound of detection' is itself indefinite and implies that the lower limit depends on the detection method used by Enviro Tech." **Ex. F** (Klibanov Decl.), ¶ 88.

147. The term "trace amount" necessitates a detection method, and the lower limit of any detection method is the "detection limit." Different detection methods can have different detection limits, but a POSA would understand that the choice of which detection method to use for a particular measurement depends on a variety of factors that include time required for measurement, ease of measurement, and cost of equipment. Here, a POSA would be guided by the '449 Patent's specification identifying two different detection methods, and its further statement that the one of these methods is well suited for instances where there is a low concentration of peracetic acid.

148. The first method discussed is the ceric sulfate-sodium hydroxide method. **Ex. D** ('072 Patent), 7:65-8:37. The second is the modified DPD method. *Id*. at 8:38-67.

149. The specification even notes that "[i]n circumstances *where low concentrations of PAA* were used, the modified DPD method [] was employed." *Id*. at 8:38-40 (emphasis added). The statement that the modified DPD method is well-adapted for measuring low concentrations of

peracetic acid teaches a POSA that the modified DPD method is suitable for detecting "trace" amounts of peracetic acid.

150. The specification also states that the modified DPD method "is a colorimetric method accepted by the EPA," and this acceptance by the EPA is evidence that the testing methodology is well established and could be easily employed by a POSA. *Id*. 8:41-42.

151. The specification then explains to a POSA how to use the modified DPD method to detect peracetic acid and why the test works for detecting peracetic acid: "[the modified DPD method] relies on the ability of PAA to behave like chlorine in that it rapidly and quantitatively oxidizes iodide ion (I^-) into iodine (I_2) that reacts with a color indicator (DPD), which turns the solution a shade of pink, the intensity of which is proportional to the concentration of the PAA. A colorimeter is used that is programmed to measure the intensity (absorbance) of the pink coloration and display the result in terms of ppm as Cl_2. A calculation converts this number into the ppm as PAA, based on the weight ratio of PAA to Cl_2 (76/71=1.07)." *Id*. at 8:43-52.

152. I conducted a quick patent search relating to the modified DPD method and located EnviroTech U.S. Patent No. 7,651,860 (the "'860 Patent"), which notes that "[o]ver the concentration range of 0.05-2.00 ppm, analytical recoveries were close to quantitative in all cases." **Ex. O** ('860 Patent), 5:27-30. From this, a POSA would conclude that the limit of detection is approximately 0.04 ppm.

153. And, even absent the extensive disclosure from the specification, a POSA would understand that a "trace amount" is detectable and quantifiable, and is greater than an amount at "no detectible levels," as evidenced by the definition of "trace" in the *McGraw-Hill Dictionary of Scientific and Technical Terms* (6th ed. 2003) ("McGraw-Hill Dictionary") as "an extremely small but detectable quantity of a substance." **Ex. P** (McGraw-Hill Dictionary), 2169.

154. Further support for "trace amount" having a quantitative, and not indefinite, meaning comes from a patent application from Clean Chemistry. In WO 2014/039929 A1, filed September 7, 2013, Buschmann states that "concentrates having *only trace or no detectible levels* of hydrogen peroxide are preferred." **Ex. Q** (International Patent Application PCT/US2013/058650), ¶ [0100]. This statement shows a POSA would understand that a trace amount is clearly a detectable amount.

155. The foregoing demonstrates a POSA would consider the plain language meaning of a "trace amount" to be a small amount that is detectable with a test—as provided for in the '072 Patent. And, at a minimum, a POSA would recognize that the modified DPD method is a suitable test to determine whether a trace amount of peracetic acid is present, where the detection limit of the test would determine the threshold of the trace amount.

V. RESERVATION OF RIGHTS

156. I reserve the right to supplement my opinions expressed herein in the future in order to respond to any arguments that Clean Chemistry and/or its expert(s) may raise and to consider new information as it becomes available to me.

VI. ATTESTATION

I declare under penalty of perjury that the foregoing is true and correct.

s/Gregory T. Whiteker/
Gregory T. Whiteker, Ph.D.
Dated: August 21, 2025

Appendix 1

Gregory T. Whiteker, Ph.D.

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PROFESSIONAL EXPERIENCE

Independent Chemical Consultant July 2022 – present
WHITEKER SCIENTIFIC CONSULTING LLC

- Expert in route scouting, agrochemicals, homogeneous catalysis, and Green Chemistry.
- Hands-on experience with flow chemistry, precious metals management, computer-aided retrosynthesis planning, and Lean Startup methodology.
- Recipient of 2025 American Chemical Society Peter Dunn Team Award for Green Chemistry & Engineering.

Distinguished Research Fellow (highest level on Dow/Corteva technical ladder) June 2020 – Feb. 2022
CORTEVA AGRISCIENCE, **Process Chemistry,** Indianapolis, IN

- Designed novel asymmetric catalytic manufacturing process from renewable raw material to key chiral intermediate for new fungicide.
- Technical representative on corporate IP strategy team.
- Developed internal Green Chemistry metrics to support launch of Corteva 2030 Sustainability Goals.
- Corteva representative to American Chemical Society Green Chemistry Institute Pharmaceutical Roundtable.

Research Fellow Oct. 2016 – June 2020
DOW AGROSCIENCES, **Process Chemistry,** Indianapolis, IN

- Led multidisciplinary 20 FTE team that developed capabilities for measuring rate of pesticide uptake by plants to optimize efficacy of agrochemical formulations.
- Member of technical review team for Corteva New Business Incubator platform.

Principal Research Scientist Oct. 2012 – Oct. 2016
DOW AGROSCIENCES, **Process Chemistry,** Indianapolis, IN

- Led research team that identified sustainable chemistry inventions for manufacture of Adavelt fungicide.
- Led process research efforts (10 FTEs) for synthesis of 9-membered macrocyclic picolinamide fungicides.

Group Leader Jan. 2010 – Oct. 2012
DOW AGROSCIENCES, **Specialty Synthesis,** Indianapolis, IN

- Led process research for multiple developmental molecules, including Rinskor herbicide, recipient of 2018 EPA Green Chemistry Challenge award and 2018 Agrow award.

Lead Research Specialist June 2005 – Dec. 2009
DOW AGROSCIENCES, Specialty Synthesis, Indianapolis, IN

- Led scale-up activities for Arylex herbicide, 2016 R&D 100 award winner.

Senior Research Specialist Feb. 2001 – June 2005
THE DOW CHEMICAL COMPANY, **Catalyst Discovery group, Corporate R&D,** South Charleston, WV

- Led 8 FTE international R&D effort to discover and develop state-of-art asymmetric hydroformylation catalysts of general use in pharmaceutical synthesis.
- Developed novel olefin hydroaminomethylation route to blockbuster drug, Fexofenadine.

Research Scientist June 1991 – Feb. 2001
UNION CARBIDE CORPORATION, **Catalyst Skill Center,** South Charleston, WV

- Discovered and co-developed commercial, proprietary PhenoxyImine Zr polyolefin catalyst family used in process to manufacture Dow INFUSE block copolymers.
- Invented proprietary half-sandwich ethylene polymerization catalyst family and provided on-site technical support for gas-phase pilot plant and commercial trials.
- Led design and implementation of proprietary high-throughput synthesis and screening capability for heterogeneous catalysis.

EDUCATION

NIH & American Cancer Society Postdoctoral Fellow Nov. 1989 - June 1991
MASSACHUSETTS INSTITUTE OF TECHNOLOGY, Department of Chemistry
Advisor: Professor Stephen J. Lippard
"Enantioselective Reactions of C_2-Symmetric Platinum Complexes with Single and Double-Stranded DNA"

Ph. D. Inorganic Chemistry (minor: Organic Chemistry) Oct. 1989
UNIVERSITY OF WISCONSIN-MADISON, Department of Chemistry
Advisor: Professor Charles P. Casey
"Synthesis, Structure, and Hydroformylation Selectivity of Metal Complexes of Diphosphines with Large Natural Bite Angles"

B.S. Chemistry (with honors) May 1985
EARLHAM COLLEGE, Richmond, IN

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80. "Process for synthesis of picolinamides", *US Patent 12,281,076*, April 22, 2025.
79. "Preparation of halogen analogs of picloram", *US Patent 12,017,993*, June 25, 2024.
78. "Preparation of halogen analogs of picloram", *US Patent 11,401,242*, Aug. 2, 2022.
77. "Process for the preparation of 4-alkoxy-3-hydroxypicolinic acids", *US Patent 10,550,083*, Feb. 4, 2020.
76. "4-((6-(2-(2,4-difluorophenyl)-1,1-difluoro-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl)pyridin-3-yl and processes of preparation" , *US Patent 10,513,506*, Dec. 24, 2019.
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INVITED PRESENTATIONS

16. ACS Green Chemistry Institute Pharmaceutical Roundtable, October 2018
15. Yale University, May 2017
14. Green Chemistry Gordon Research Conference, August 2016
13. Inorganic Reaction Mechanisms Gordon Research Conference, March 2015
12. Purdue University, Dec. 2013
11. Butler University, May 2012
10. Symposium for ACS Award for Service to Inorganic Chemistry, presented to Chuck Casey, ACS National meeting, March 2011
9. Conference on Catalysis of Organic Reactions, April 2010
8. University of Kansas, Center for Environmentally Beneficial Catalysis, January 2005
7. INFORMEX Homogeneous Catalysis Workshop, January 2004
6. Chiral Europe, May 2003
5. Department of Chemistry, West Virginia University, February 2003
4. Frontiers in Catalysis series, University of Wisconsin, February 2002
3. Conference on Catalysis of Organic Reactions, April 2002
2. ACS National Meeting, Chuck Casey symposium, August 2002
1. ACS National meeting, Homogeneous catalysis tutorial session, August 2001

CONFERENCE PRESENTATIONS

10. *Use of Green Chemistry Principles in the Design of Crop Protection Products and Processes*, IUPAC Crop Protection Congress (2019).
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