

EXHIBIT 2023

Enviro Tech v. Clean Chemistry

Declaration of Dr. Alexander M. Klibanov
(Exhibit 09 to Docket No. 34)

EXHIBIT 09

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

**ENVIROTECH CHEMICAL
SERVICES, INC.**

Plaintiff,

v.

CLEAN CHEMISTRY, INC.

Defendant.

Case No. 1:24-cv-01313-ADA

Jury Trial Demanded

**DECLARATION BY DR. ALEXANDER M. KLIBANOV IN SUPPORT OF
DEFENDANT CLEAN CHEMISTRY, INC.'S OPENING
CLAIM CONSTRUCTION BRIEF**

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I. INTRODUCTION

I, Alexander M. Klibanov, Ph.D., of Del Mar, California, declare as follows:

1. I am currently a Professor Emeritus of Chemistry and Bioengineering at the Massachusetts Institute of Technology (“M.I.T.”), where I taught and conducted research for over 40 years. From 2014 to 2019 (and also from 2007 to 2012), I held the Novartis Endowed Chair Professorship in Chemistry at M.I.T. From 2012 to 2014, I held the Roger and Georges Firmenich Endowed Chair Professorship in Chemistry at M.I.T. Prior to that, I was a Professor of Chemistry and a Professor of Bioengineering at M.I.T., positions I held from 1988 and 2000, respectively. From 1979 to 1988, I was an Assistant Professor, then an Associate Professor, and thereafter a Full Professor of Applied Biochemistry in the Department of Applied Biological Sciences (formerly the Department of Nutrition and Food Science) at M.I.T.

2. I obtained my M.S. in Chemistry from Moscow University in Russia in 1971 and Ph.D. in Chemical Enzymology (a branch of Medicinal Chemistry) from the same university in 1974. Thereafter, I was a Research Chemist at Moscow University’s Department of Chemistry for three years. From 1977 to 1979, following my immigration to the United States, I was a Post-Doctoral Associate at the Department of Chemistry, University of California in San Diego.

3. Over the last 50+ years as a practicing chemist, I have extensively researched, published, and lectured in many areas of chemistry, including formulation and medicinal chemistry.

4. During my over 40 years as a M.I.T. professor, I taught numerous undergraduate and graduate courses in various areas of chemistry, including general, organic, physical, and biological chemistry.

5. I have earned numerous prestigious professional awards and honors. For example, I was elected to the U.S. National Academy of Sciences (considered among the highest honors that can be given to an American scientist) and also to the U.S. National Academy of Engineering (considered among the highest honors that can be given to an American engineer). I am also a Founding Fellow of the American Institute for Medical and Biological Engineering and a Corresponding Fellow of the Royal Society of Edinburgh (Scotland's National Academy of Science and Letters). In addition, I have received the Arthur C. Cope Scholar Award, the Marvin J. Johnson Award, the Ipatieff Prize, and the Leo Friend Award, all from the American Chemical Society (the largest professional society in the world), as well as the International Enzyme Engineering Prize.

6. I currently serve on the Editorial or Advisory Boards of over a dozen scientific publications, including "Open Access Academic Books in Chemistry," "Applied Biochemistry and Biotechnology," "Nanocarriers," "Biotechnology and Bioengineering," "Journal of Biological Chemistry and Molecular Pharmacology," "Recent Patents in Biotechnology," "Archives of Medical Biotechnology," "Current Pharmaceutical Biotechnology," "Open Journal of Pharmacology," and "International Journal of Drug Design, Delivery, and Safety."

7. I have published over 315 scientific papers in various areas of chemistry. I am also a named inventor of 33 issued United States patents and of a number of pending ones. I have given over 370 invited lectures, including many distinguished named lectureships, at scientific conferences, universities, and corporations all over the world, many of them dealing with preparation, formulation, stability, stabilization, and evaluation of biologically active compounds, such as biocides. According to a recent Stanford University-led study, the overall impact of my published work places me in the top 0.01% of all scientists in the world.

8. In addition to my research and teaching activities at M.I.T., I have consulted widely for chemical, pharmaceutical, food, and biotechnology companies. Of particular relevance to the present proceedings is my consulting experience with industrial production and applications of peracetic acid (also known as peroxyacetic acid, CH_3COOOH ; abbreviated as “PAA”).

9. I also have founded seven start-up industrial companies and have been on the scientific advisory boards and/or boards of directors of those companies and of many others.

10. As of March 24, 2011 (the priority date of all of the patents-in-suit, also referred to herein as “the Asserted Patents”), I at least met (and indeed exceeded) the professional background and qualifications requirements for a person of ordinary skill in the art (“a POSA”) with respect to the Asserted Patents, as defined below.

11. My *Curriculum vitae*, attached as Appendix 1, summarizes my education and academic experience. Among other things, it lists all my professional publications and issued U.S. patents.

II. LEGAL PRINCIPLES

12. I am not a lawyer or patent scholar, but I have been informed of certain legal principles that are relevant to my analysis herein by Clean Chemistry, Inc.'s counsel (“counsel”). My understanding of these legal principles explained to me by counsel is outlined below in this section of the present Declaration.

A. Priority Date

13. I understand that the Asserted Patents are U.S. Patent Nos. 8,546,449 (the “449 Patent”); 9,363,997 (the “997 Patent”); 9,730,443 (the “443 Patent”); and 9,737,072 (the “072 Patent”). Each of the Asserted Patents has a priority date (or constructive date of the invention,

also called the time of the invention) of March 24, 2011 (as seen in Item (62) on the cover page of each patent). I further understand that the '449 Patent issued from the original parent application (Appl. No. 13/065,553) filed March 24, 2011; the '997 Patent issued from Appl. No. 14/681,938, which was a divisional of a divisional to the original parent application; the '443 Patent issued from Appl. No. 15,063,306, which was a divisional of a divisional of the original parent application; and the '072 Patent issued from Appl. No. 15/063,293, which also was a divisional of a divisional application of the original parent application. All of the Asserted Patents share essentially the same specification.

B. A Person of Ordinary Skill in the Art

14. United States patents, such as the four Asserted Patents, and relevant prior art thereto should be evaluated from the perspective of a hypothetical person of ordinary skill in the art at the time of the invention (“a POSA”).

15. 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.

16. In my opinion, a POSA with respect to the subject matters of all of the patents-in-suit would have had at least a bachelor's degree in chemistry, chemical engineering, or a related discipline, plus a couple of years of practical experience in chemical syntheses, or equivalent knowledge and work experience. I consider myself at least a POSA under this definition.

17. I have considered the issues, and arrived at my conclusions described in this Declaration, from the perspective of such a POSA.

C. Claim Construction

18. Claims of a patent, and terms included in those claims, should be interpreted from the perspective of a POSA. Here, the time of the 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. A claim term (also called a claim limitation) is a specific requirement or restriction within a patent claim that narrows the scope of the patented invention. A patent's claims, its specification, and the file history (collectively referred to as "intrinsic evidence") should be analyzed to arrive at the proper interpretation of a claim term.

20. Sometimes (as in the case of certain claim terms of the Asserted Patents), a patentee can include a particular definition of a claim term in the specification. In such instances, the claim term generally should be construed and interpreted according to the definition provided in the specification, assuming that the definition is of sufficient clarity to otherwise avoid indefiniteness (see below).

21. The patent claim and terms therein should be interpreted in light of the intrinsic evidence, which includes the language of the claim in question and of the other claims in the patent, the specification of the patent, and the relevant prosecution history of the patent. Other evidence, which is considered extrinsic evidence and not in the written record of the patent or its prosecution history, such as relevant technical dictionaries and learned treatises or opinions from technical experts, also may be considered if it is not inconsistent with the intrinsic evidence. However, if the meaning of the claim and its terms is clear from the intrinsic evidence, then there is no reason for a POSA to look into extrinsic evidence.

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. A patent claim is required to particularly point out and distinctly claim the subject matter which the inventor(s) regard 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. A claim is deemed indefinite if it fails to inform, with reasonable certainty, a POSA about the scope of the invention. The legal standard of "reasonable certainty" requires that the claims, when read in light of the specification and prosecution history of the patent, provide clear notice of what is claimed, thereby allowing a POSA to understand the bounds of the claim.

25. As with claim construction, the analysis of indefiniteness primarily involves intrinsic evidence, including the patent’s claims, specification, and prosecution history. When the intrinsic evidence is insufficient to arrive at a definite understanding of the claimed subject matter, such extrinsic evidence 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 POSA.

III. TECHNOLOGY BACKGROUND SUMMARY

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. Because the Asserted Patents all share essentially the same specification and are all divisionals springing from the same original patent application, below I will address the specific claim terms the constructions of which are disputed in this case by the parties, i.e., Clean Chemistry, Inc. ("Clean Chemistry") and Envirotech Chemical Services, Inc. ("Enviro Tech"). The materials I have reviewed in preparing this Declaration are the Asserted Patents, their respective file histories, and the various other documents that are cited throughout this Declaration. The opinions expressed by me herein are with respect to the claim terms as used in each respective claim across all of the Asserted Patents.

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

Clean Chemistry Proposed Construction	Enviro Tech Proposed Construction
Plain and ordinary meaning: steps a to e must be performed <i>sequentially in the same order in which they are recited</i> in the claim	Plain and ordinary meaning: the steps can be performed in <i>any</i> order

29. Claim 1 of the '997 Patent (which is nearly identical to claim 1 of the '449 Patent) is reproduced below, with certain terms indicated by me in bold underline.

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

Step b. of Claim 1 requires introducing ... to ***the*** water, which requires that water is already present. Changing the order of steps a. and b. does not work: one cannot add a hydrogen peroxide-triacetin solution to water if water is not already present (i.e., has not yet been “provid[ed]”). Step c. then requires mixing the two components recited in step b, namely water and a hydrogen peroxide-triacetin solution, to form a mixture. Use of the definite article “the” to

modify both the water and the hydrogen peroxide-triacetin solution in step c. indicates that both are already present (previously recited). Further, step c. forms *a* mixture, and step d. requires adding something to *the* mixture. Changing the order of steps, e.g., such that step c. is performed earlier is not possible – without both the water and the hydrogen peroxide-triacetin solution present, the specified mixture cannot be formed. And changing the order of steps to have step d. performed earlier is also not possible – until step c. is completed, there is no mixture to which the “aqueous source of an alkali metal or earth alkali metal hydroxide” can be added.

30. A POSA would understand that the order of addition of reaction components in process chemistry can be critical in achieving desired reaction results because it can modify reaction kinetics (e.g., reaction rates) through varying the reactant concentrations at a given place in a reaction vessel; moreover, changes in relative concentrations of reactants can impact the number of side reactions or intermediates that may form in the reaction system. Order of addition’s impact on concentrations can also affect the solubility of reaction components and the homogeneity of reaction mixtures. These are fundamental concepts in chemistry that a POSA would bring to any interpretation of a method claim specifying multiple process steps.

31. Enviro Tech has failed to explain how its interpretation that the claimed steps ostensibly “can be performed in any order” is derived from a reading of the claim by a POSA. In Enviro Tech's expert Declaration provided as part of its extrinsic evidence, Enviro Tech’s expert, Dr. Gregory Whiteker, stated that “A skilled artisan would recognize that the reaction is likely initiated by the high pH created by the sodium hydroxide. As such, the order of addition is likely irrelevant to the reaction outcome.” Exhibit 10, Declaration Gregory T. Whiteker, Ph.D., (“Whiteker Decl.”), ¶ 10, p. 2, second row of the table. In my opinion, by using the word “likely” in this phrase Dr. Whiteker undermines any probative value of his statement.

32. The specification of the '997 Patent and '443 Patent contradicts both Enviro Tech's and its expert's positions, stating at column 24, lines 32-34 (underlining added):

The data in Tables XV and XVI indicate that far higher amounts of PAA are possible if the 50% sodium hydroxide solution is the last component of the mixture to be introduced.

Ex. 1, '449 Patent, 24:32-34. Clearly, the order of addition of sodium hydroxide affected the process that is the subject of the patents' disclosure, and Enviro Tech's patent specification teaches that “adding an aqueous source of an alkali metal or earth alkali metal hydroxide” last yielded the best results for at least the exemplified Enviro Tech process.

33. I further note that the first-page Abstracts of *all* the Asserted Patents say as much because the second sentence in each reads in pertinent part (emphases and underlining added):

These methods comprise introducing [“triacetin and aqueous hydrogen peroxide” or “hydrogen peroxide-acetyl precursor solution”] to water, **mixing**, **and then** adding an aqueous source of an alkali metal or earth alkali metal hydroxide.

See, e.g., Ex. 1, '449 Patent, Abstract, p. 1. Even assuming that a POSA might need to consult the extrinsic evidence, I know of none suggesting a different interpretation of the claim besides that proposed by Clean Chemistry that would be reasonable to the POSA. Given the clear support for Defendant Clean Chemistry's construction from the plain claim language, the patent specification's teachings, and the rest of the intrinsic record, it is my opinion that a POSA would interpret claims 1 in question (which are necessarily incorporated in all of the dependent claims) as limited to the specific sequence of steps specified in the claim. To do otherwise would eliminate POSA's reasonable certainty for an understanding of the claim's scope and meaning.

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

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

34. There is no stated definition of the claim phrase “non-equilibrium solution,” or of its parts “non-equilibrium” or “solution,” in the specification of the Asserted Patents. The claims in the '449 Patent are directed to making a "non-equilibrium solution of peracetic acid." The file history of the '449 Patent reveals nothing of substance regarding the meaning of this claim phrase. Enviro Tech has indicated that "a non-equilibrium solution of peracetic acid" has its “plain and ordinary meaning” without providing any definition of the “plain and ordinary meaning,” except to say through Enviro Tech's expert Declaration that "[a] skilled artisan would recognize that a ‘nonequilibrium solution of peracetic acid’ is one which has not yet reached equilibrium. That is, the rates of forward and reverse reactions are not yet equal." Ex. 10, Whiteker Decl., ¶ 10, p. 2, third row of the table.) In other words, it appears Enviro Tech's expert Dr. Whiteker has opined that the reaction is *reversible* and could at some later point reach equilibrium.

35. There are multiple possible chemical reactions (primary and side reactions of reaction intermediates) that can take place in an aqueous system such as that specified in the claims in question. A POSA would understand that the primary product-forming reaction between triacetin and hydrogen peroxide is essentially *irreversible* (i.e., there is essentially no reverse reaction to re-form the starting acetyl group donor triacetin from the reaction product) and hence it cannot reach a genuine state of “equilibrium.” Thus, in the context of using triacetin

as the acetyl group donor in the subject reaction to form PAA, referring to the claimed solution as being a “non-equilibrium” one would appear to a POSA to be misplaced and confusing.

36. Because the undertaken reaction is essentially irreversible with respect to the primary starting reactants triacetin and hydrogen peroxide, ultimately forming glycerol and peracetic acid, the claim term “non-equilibrium” would be non-sensical to a POSA in this context. The reaction of triacetin with hydrogen peroxide to form peracetic acid never can be an equilibrium reaction, i.e., a chemical reaction at equilibrium. While it is possible to speculate that the reference to “non-equilibrium” might be to side reactions in the system, that possibility is not illuminated in any way in the intrinsic record of the Asserted Patents.

37. The use of the term “solution” in this claim phrase would indicate to a POSA that it is a *homogeneous* (i.e., uniform) mixture, rather than a heterogeneous one. Nothing in the patent specification illuminates whether or how the homogeneity is determined, or when a mixture that might begin as a heterogeneous mixture transforms into a homogeneous one (i.e., a liquid solution), or how the homogeneity should be determined empirically. Without such guidance from the intrinsic record, a POSA would not know when a mixture becomes sufficiently homogeneous to constitute the claimed aqueous “solution.”

38. A POSA would understand that there are many ways to assess homogeneity of a mixture, including an aqueous solution, and different degrees of homogeneity that could lead a POSA to conclude whether a mixture remains heterogeneous or has become homogeneous and is thus a solution. Homogeneity is itself a term of degree and depends upon the level of uniformity at which solutes are disbursed within a solvent. If uniformly distributed throughout the solvent at the molecular level, then solutes are considered by a POSA to be in solution with the solvent. If

not uniformly distributed, a POSA would understand that the combination of the solutes and the solvent is a heterogeneous mixture, i.e., is **not** a solution.

39. In the case of the claims in question, there is no guidance in the intrinsic record about the level of uniform distribution of solutes within the solvent that could be acceptable for a reaction mixture to be considered a solution. Without such definitional guidance from the intrinsic record, a POSA cannot ascertain with any reasonable certainty if or when a mixture of the indicated materials becomes a homogeneous mixture/solution within the scope of the claims. Combining this ambiguity with the use of the misplaced claim term “non-equilibrium” further exacerbates confusion for a POSA with regard to a “non-equilibrium solution” as it is used in this context. Based upon these considerations and the state of the intrinsic record, it is my opinion that the claim terms “non-equilibrium solution” (whether it is modified with the indefinite article “a” (as in the case of the '997 Patent) or missing this modifier for whatever reason (as in the case of the '449 Patent)) fails to provide a POSA with an understanding of the meaning and scope of the claims in which it appears with any reasonable degree of certainty; therefore, in my opinion, this claim term is indefinite.

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

Clean Chemistry Proposed Construction	Enviro Tech Proposed Construction
Indefinite	Plain and ordinary meaning

40. The recited claim term “about” is used within various dependent claims in the Asserted Patents as an indefinite term of degree with various differently recited 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 ; said mole ratio of said hydrogen peroxide to said triacetin is about 3.8:1	8,546,449, Claims 3, 20; 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 ; the mole ratio of the sodium hydroxide to the hydrogen peroxide to the triacetin is about 4.2:18:1	8,546,449, Claims 13, 23; 9,363,997, Claim 12
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

41. A POSA would read the claim term “about” in each of these claims as an indefinite term of degree because he or she would not be able to determine the bounds of the recited numerical values and ranges.

42. Nothing in the claims, specifications, or prosecution histories of the Asserted Patents provides a POSA with any guidance as to the upper and/or lower limits of each of the “about” numerical values. Instead, a POSA would recognize that the limits of each of the “about” numerical values would be his/her own subjective assessment regarding how far beyond the recited numerical values the claim term “about” extends the scope of the claims in which it appears.

43. The intrinsic evidence provides a POSA with no guidance for quantifying the bounds of the claims under the claim term of degree “about.” Instead, the specifications of the Asserted Patents either repeat the claim language verbatim or give exemplary values that are precise to the numerical value recited in the claims:

- For example, claims 3 and 20 of the '449 Patent and claim 2 of the '072 Patent recite a “mole ratio of...about 2.98:1 to about 12.48:1.” Compare this to the disclosures in the specification: “The mole ratio...is about 2.98:1 to about 12.84:1” (Ex. 1, '449 Patent, 9:4-5); “The mole ratio...was calculated to be 2.98:1.” (Ex. 1, '449 Patent, 9:57-58); “A formulation...in a mole ratio of 12.84:1.” (Ex. 1, '449 Patent, 10:31-32.)
- Claim 3 of the '072 Patent recites a “mole ratio of...about 3.8:1.” Compare this to the disclosures in the specification: “The mole ratio...about 3.8:1” (Ex. 4, '072 Patent, 9:53); “Thus, the mole ratio...was 3.8:1” (Ex. 4, '072 Patent, 13:14-15, 26:27-28); “For this mole ratio...of 3.8:1” (Ex. 4, '072 Patent, 27:1-2).
- Claims 7 and 22 of the '449 Patent and claim 7 of the '997 Patent recite that “the sodium hydroxide is about 1.82% to about 7.28%.” Compare this to the disclosures in the specification: “the amount of sodium hydroxide is about 1.82% to about 7.28%” (Ex. 1, '449 Patent, 14:64-65); “the amount of sodium hydroxide is about 1.82% to about 7.28%” (Ex. 1, '449 Patent, 16:66-17:1).
- Claim 13 of the '449 Patent and claim 12 of the '997 Patent recite “the mole ratio of...about 4.2:3.8:1.” Compare this to the disclosures in the specification: “a preferred mole ratio of...about 4.2:3.8:1” (Ex. 1, '449 Patent, 14:65-67, 17:1-3);

“Thus, the mole ratio was...4.2:3.8:1” (Ex. 1, '449 Patent, 23:32-34); “The mole ratio...at 4.2:3.8:1” (Ex. 1, '449 Patent, 23:45-47, 23:56-58).

- Claim 2 of the '443 Patent recites “a pH of about 11.2 to about 13.37.” Compare this to the disclosure in the specification: “having a pH of about 11.2 to about 13.37” (Ex. 3, '443 Patent, 6:40-42, 18:25-26); Table X (citing pH ranges between 11.2 and 12.2); “the initial pH measured 11.2” (Ex. 3, '443 Patent 33:40-43); “the same initial pH of 11.2” (Ex. 3, '443 Patent, 33:43-45); Table XVII (citing pH values between 12.62 and 13.37 with varying numbers of significant figures) (Ex. 3, '443 Patent, 33:30-50).
- Claim 3 of the '443 Patent recites “said peracetic acid is about 1% to about 7.1%.” Compare this to the disclosure in the specification: “This method produces solutions with a high level of PAA, from about 1% to about 7.1%” (Ex. 3, '443 Patent, 6:43-45); “The PAA solutions have high levels of PAA, from about 1% to about 7.1%.” (Ex. 3, '443 Patent, 18:24-27); “Further, up to 7.1% PAA was generated...” (Ex. 3, '443 Patent, 24:61-63).
- Claim 2 of the '072 Patent recites “said aqueous hydrogen peroxide is about 23% to about 40%” and claim 3 of the '072 Patent recites “said aqueous hydrogen peroxide is about 27%.” Compare this to the disclosures in the specification: “On the other hand, there are much less stringent requirements for products that contain hydrogen peroxide, and all reporting, permitting and shipping restrictions are lifted for products that contain less than 27% hydrogen peroxide.” (Ex. 4, '072 Patent, 2:20-24); “One such hydrogen peroxide-triacetin solution comprises about 23% to about 40% hydrogen peroxide...” (Ex. 4, '072 Patent, 9:41-43); “A

preferable hydrogen peroxide-triacetin solution comprises about 27.15% hydrogen peroxide...” (Ex. 4, '072 Patent, 9:49-52); “the mixture was 40% hydrogen peroxide” (Ex. 4, '072 Patent, 10:48-52); Table II (showing 40.21% hydrogen peroxide remaining on day 1) (Ex. 4, '072 Patent, 10:58-11:7); “the mixture was 27.15% hydrogen peroxide” (Ex. 4, '072 Patent, 13:10-14).

- Claim 2 of the '072 Patent recites “said triacetin is about 20% to about 53%” and claim 3 of the '072 Patent recites “said triacetin is about 46%.” Compare this to the disclosures in the specification: “about 20% to about 52% triacetin” (Ex. 4, '072 Patent, 9:41-46); “about 45.67% triacetin” (Ex. 4, '072 Patent, 9:48-52); “mixture was...20% triacetin” (Ex. 4, '072 Patent, 10:48-52); “mixture was...45.67% triacetin” (Ex. 4, '072 Patent, 13:10-14); “triacetin (45.76%)” (Ex. 4, '072 Patent, 23:35-38); “contained...45.7% triacetin” (Ex. 4, '072 Patent, 26:24-27).
- Claim 10 of the '449 Patent and claim 10 of the '997 Patent recite “time to maximize the conversion of the hydrogen peroxide triacetin into peracetic acid is about 30 seconds to about five minutes.” Compare this to the disclosures in the specification: “Within about 30 seconds to about five minutes, the amount of hydrogen peroxide and acetyl precursor that are converted into peracetic acid is maximized.” (Ex. 1, '449 Patent, 6:3-6); “the amount of hydrogen peroxide and acetyl precursor that are converted into PAA is maximized within about 30 seconds to about five minutes.” (Ex. 1, '449 Patent, 15:27-32); “Thus, at any given flow rate in the pipe, the first residence chamber is of a volume such that 30 seconds have elapsed since the introduction of 50% NaOH, one minute has

elapsed by the time the flow reaches the sampling port immediately after the second residence chamber, and additional time elapses by the time the flow reaches the remaining sampling ports. Up to four residence chambers and sampling ports may be placed in series such as this to provide the user with about 30 seconds to five minutes of residence time after the introduction of the 50% NaOH. Once the flow of the reaction medium has been established, samples are drawn from all four sampling ports associated with the residence chambers and analyzed for peracetic acid.” (Ex. 1, ’449 Patent, 15:50-63); “PAA is maximized within about 30 seconds to about five minutes.” (Ex. 1, ’449 Patent, 17:17-22); *see also* Ex. 1, ’449 Patent, 25:14-26:13 (sampling ports between “30 seconds,” “one minute,” “two minutes,” “five minutes”).

- Claim 12 of the ’449 Patent and claim 11 of the ’997 Patent recite “wherein the percent of triacetin that is converted into peracetic acid is about 40.9% to about 85.7%.” Compare this to the disclosures in the specification: “about 40.9% to about 85.7% of the triacetin is converted into peracetic acid” (Ex. 1, ’449 Patent, 6:6-10); “about 40.9% to about 85.7% of the triacetin is converted into PAA” (Ex. 1, ’449 Patent, 17:48-51); “a calculated conversion of triacetin into PAA of 63.8%” (Ex. 1, ’449 Patent, 21:53-57).

44. Thus, 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.

45. Furthermore, the values recited in the “about” claims vary widely in numerical precision. For example, some claims recite a different number of significant figures even for the

lower and upper limits of the same range (not to mention for different claim ranges)—e.g. (underlining added), “a pH of about 11.2 to about 13.37” and molar ratios of “about 2.98:1 to about 12.84:1”—and by using different time measures in “seconds” and “minutes”—e.g. (underlining added), “about 30 seconds to about five minutes.” A POSA thus would be unable to determine how far each of these claims reaches. In particular, it would be unclear to a POSA how to determine a reasonably certain measure that would fall within the scope of the claims.

46. For example, a POSA would not know whether a pH of “about 13.37” extends to between 13.36 and 13.38 (± 0.01) or between 13.27 and 13.47 (± 0.1). Likewise, it would be unclear to him/her whether that same measure of extent—e.g., ± 0.01 or ± 0.1 —applies equally to “about 11.2.” With respect to claimed time periods, a POSA would not know the extent of “about 30 seconds” and whether it would include, for instance, ± 0.5 s or ± 5 s. Similar to the example concerning the values of pH, it would be unclear to him/her whether the same extent applies to “about 5 minutes” (i.e., 300 seconds) or whether the use of “minutes” instead of “seconds” provides a different extent.

47. To further illustrate the foregoing indefiniteness arguments, consider claims 2 and 3 of the '072 Patent as an example. The former claim discloses that “the mole ratio of said hydrogen peroxide to said triacetin is about 2.98:1 to about 12.84:1.” Claim 3 (directly dependent from claim 2 and hence incorporating all of its limitations) discloses that the “the mole ratio of said hydrogen peroxide to said triacetin is about 3.8:1.” A POSA would recognize that “2.98” has three significant figures, “12.84” has four significant figures, and “3.8” has two significant figures. In other words, the same claimed parameter (the mole ratio of hydrogen peroxide to triacetin) of the same patent has the claimed number of significant figures that for no apparent reason varies from two to three to four for no apparent reason. In view of this fact,

using the number of significant figures in the claimed mole ratios as a guide, a POSA would recognize the “about 2.98” claimed value to cover the range between 2.975 and 2.285 (i.e., ± 0.005 or $\pm 0.17\%$), the “about 12.84” claimed value to cover the range between 12.835 and 12.845 (i.e., ± 0.005 or $\pm 0.04\%$), and the “about 3.8” claimed value to cover the range between 3.75 and 3.85 (i.e., ± 0.05 or $\pm 1.38\%$). A POSA would understand that in view of the same patent specification (and hence the same measurement methodology for determining the mole ratios) this great disparity in the uncertainty levels of the claimed mole ratios (spanning as much as the 35-fold range: $1.3\%/0.04\% = 35$) makes no scientific sense. Put another way, the meaning of the claim term “about” here varies dramatically from one claim of the same patent to another one that depends from it, and even within the same claim, thereby making the claim term “about” indefinite.

48. Plaintiff’s and its expert Dr. Whiteker’s proposed construction fails to clarify the uncertainty of the claim term “about” in the Asserted Patents. Instead, Dr. Whiteker’s Declaration merely provides a different term of degree to replace “about”: “approximately” or “in close proximity to.” Ex. 10, Whiteker Decl., pg. 3, table rows 5-7. These are merely synonymous with “about” and provide no further quantitative clarity on the extent of measure for how far the claims reach. Dr. Whiteker seems oblivious to the fact that the claimed values recited in the “about” claims vary widely in numerical precision (as reflected by the number of significant figures provided) and fails to discuss how this fact would affect the scopes of the claimed values/ranges. He and Plaintiff fail to point to any additional intrinsic evidence (nor do I see any), other than the disclosures cited above, that provides any further guidance to a POSA on the scope of the claimed numerical values. Based on a POSA’s understanding of the claims in question and the intrinsic evidence as a whole, the extent to which the recited claimed term of

degree “about” expands the recited claim limitations is left to a subjective determination of an individual POSA. Thus, in my opinion, these claim terms are indefinite.

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

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

49. 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.”

50. As an initial matter, I understand that claim 9 (and claims dependent from it) of the '449 Patent should actually recite (emphasis added) “allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide **[and the]** triacetin into peracetic acid” based on the prosecution history of the '449 Patent. Claim 16 of the originally filed '449 Patent, which was eventually issued as claim 9, originally recited “allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide and the acetyl precursor into peracetic acid”:

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.

Ex. 11, '449 Patent File History, March 24, 2011, Claims, originally filed claim 16.

51. Following a restriction requirement, the Patent and Trademark Office Examiner (the “Examiner”) raised claim rejections that while the specification enabled the claims as to triacetin specifically, it failed to enable the scope of the claims as to an acetyl precursor broadly. Ex. 12, ’449 Patent File History, April 1, 2013, Non-Final Rejection, p. 7 (notated p. 6). The Examiner recommended amending the claims to recite “triacetin” in place of “acetyl precursor.” Ex. 12, ’449 Patent File History, April 1, 2013, Non-Final Rejection, p. 7 (notated p. 6).

52. The Applicant then amended claims 7 and 8, deleting “acetyl precursor” and adding “triacetin” in its place, but did not amend remaining claims, such as claims 16-18, that also recited an acetyl precursor:

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 alkali 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.

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.

Ex. 13, '449 Patent File History, May 23, 2013, Amendment & Response to Office Action, pp. 3-5.

53. Following Applicant's amendment, the Examiner issued a Notice of Allowance with an Examiner Amendment amending claims 16-18 to remove the phrase "and the acetyl precursor" and replace it with "-triacetin":

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--

Ex. 14, '449 Patent File History, July 15, 2013, Notice of Allowance & Examiner's Amendment, p. 2. Once the amendments were made and the '449 Patent issued, original claims 16-18 issued as

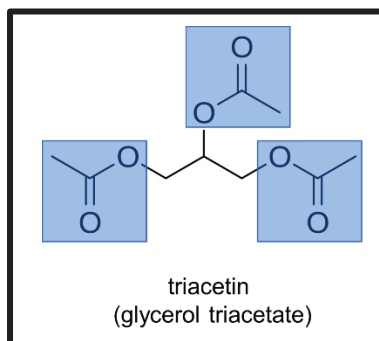
claims 9-11 reciting the term “hydrogen peroxide triacetin.” It is clear that during the amendment process, Examiner and Applicant inadvertently omitted the word(s) “and” / “and the” from the claims when replacing “acetyl precursor” with “triacetin” to overcome the rejection. Original claim 7 of the '449 Patent, issued as claim 1, recited a “hydrogen peroxide-acetyl precursor solution”, and original claim 16, now claim 9, recited “hydrogen peroxide and the acetyl precursor.” Ex. 11, '449 Patent File History, March 24, 2011, Originally filed claims, notated as pg. 62. The Applicant clearly distinguished between the hydrogen peroxide-acetyl precursor solution and, separately, hydrogen peroxide and the acetyl precursor. After the Non-Final Rejection and Applicant’s amendment of “hydrogen peroxide-acetyl precursor solution,” a number of claims still recited “acetyl precursor.” Ex. 13, '449 Patent File History, May 23, 2013, Amendment & Response to Office Action, Claims 16-19, pp. 4-5. The Examiner’s Amendment attempted to rectify these claims that continued to recite “acetyl precursor” and replace it with “triacetin” in order to issue the claims. Ex. 14, '449 Patent File History, July 15, 2013, Notice of Allowance & Examiner’s Amendment, p. 2. In doing so, however, the Examiner appears to have mistakenly removed the terms “and” / “and the” from original claims 16-18 when replacing “acetyl precursor” with “triacetin.” Based on the originally filed claims and subsequent amendments, it would be clear to a POSA that claims 9-12 of the '449 Patent should recite “hydrogen peroxide and triacetin.”

54. Thus, it is my understanding that claim 9 of the '449 Patent should be read as (emphasis added) “allowing the reaction medium sufficient time to maximize the conversion of the hydrogen peroxide **[and the]** triacetin into peracetic acid.”

55. Turning now to the issue of construction of the claims in question, a POSA would understand that the claim term “to maximize” has its plain and ordinary meaning in the claims—

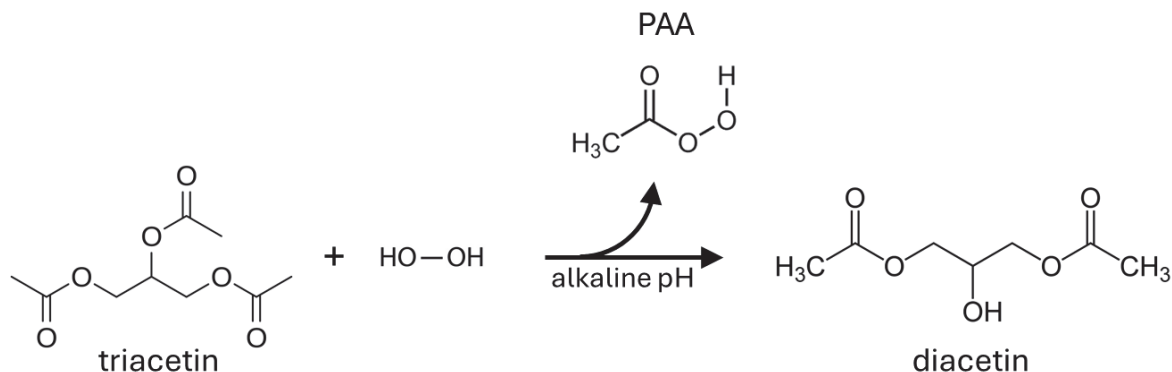
i.e., “to raise to the highest possible degree.” The word “maximize” has a well-understood meaning to a lay-person. For example, Webster’s New World College Dictionary defines “maximize” as “raise to the highest possible degree.” Exhibit 15, *Maximize*, WEBSTER’S NEW WORLD COLLEGE DICTIONARY (4th ed. 2000); Exhibit 16, *Maximize*, COLLINSDICTIONARY.COM (same); *see also* Exhibit 17, *Maximize*, BRITANNICA.COM (“to increase (something) as much as possible”); Exhibit 18, *Maximize*, DICTIONARY.CAMBRIDGE.ORG (“to increase something as much as you can”); Exhibit 19, *Maximize*, DICTIONARY.COM (“to increase to the greatest possible amount or degree”). Here, the claims recite “to maximize the conversion of the hydrogen peroxide [and] triacetin into peracetic acid.” Reading the plain language of these claims, a POSA would understand that “to maximize the conversion” is referring to the conversion of the hydrogen peroxide and triacetin. Thus, a POSA would understand that the proper construction for these terms is “allowing the reaction medium sufficient time to achieve *the highest possible* conversion of the hydrogen peroxide and the triacetin into peracetic acid.”

56. A POSA would recognize that triacetin is a triester of glycerol (also called glycerine) and acetic acid having three acetyl groups in the form of three carboxylic acid ester groups (shown as blue boxes below):

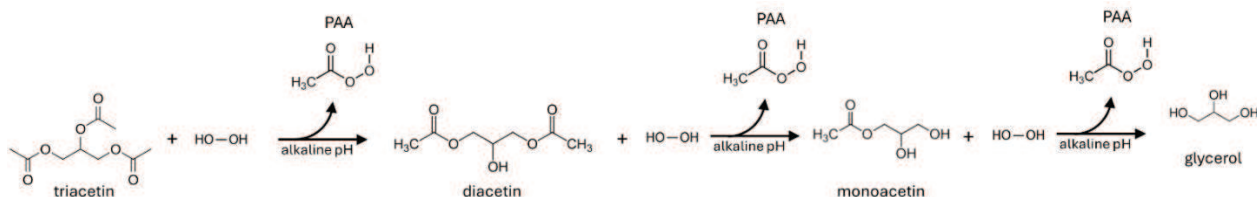


57. A POSA would understand that, under alkaline conditions (i.e., pH > 7), triacetin and hydrogen peroxide (H₂O₂ or HO-OH) chemically react with each other and are consequently

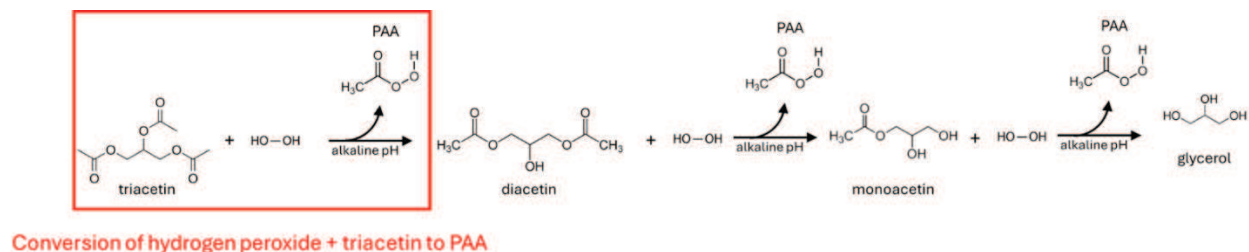
initially converted into peracetic acid (PAA) and diacetin by reaction of one of the three acetyl groups on triacetin, as follows:



58. A POSA would also understand that diacetin can be further converted into another PAA and monoacetin by reaction of one of the two acetyl groups of diacetin and that such monoacetin can be still further converted into yet another PAA and glycerol by reaction of monoacetin's remaining acetyl group. This overall series of de-esterification reactions converting triacetin to diacetin to monoacetin to glycerol and also forming PAA can be depicted as follows:



59. Reading the claim language itself, a POSA would recognize that the terms “conversion” / “amount...converted” refer specifically to the conversion of “hydrogen peroxide (and) *tri*acetin” into peracetic acid (emphasis added). Thus, a POSA would understand the plain meaning of the claims in question to be referring to “maximiz[ing] the conversion of hydrogen peroxide (and) triacetin into peracetic acid” and *not* to the conversion of hydrogen peroxide (and) diacetin or monoacetin into PAA:



60. Dr. Whiteker appears to agree that the claim term in question refers only to the de-esterification of specifically triacetin. He states, for example, that “[a] skilled artisan would recognize that a sufficient time can be determined by testing the reaction mixture during conversion to determine the amount of peracetic acid and *triacetin* present.” Ex. 10, Whiteker Decl., p. 3 (emphasis added). But to the extent that Dr. Whiteker and Plaintiff disagree with this literal interpretation of the claim language and assert instead that diacetin and/or monoacetin are also included in the recited conversion, this view would render the claims in question indefinite. A POSA would recognize that plain reading of the claim term as written only recites triacetin, *not* diacetin and/or monoacetin.

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

Clean Chemistry Proposed Construction	Enviro Tech Proposed Construction
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”	Plain and ordinary meaning

61. This claim term appears in claims 10-11 of the '449 Patent. As explained above in section D, para. 54, it is my opinion that this claim term, in fact, should read “[t]he time to maximize the conversion of the hydrogen peroxide [and the] triacetin into peracetic acid is about 30 seconds to about five minutes” in view of an error in amending the claims during prosecution.

62. In my opinion, this claim is indefinite as described above in section C, para. 45, at least because it recites (emphasis added) “*about* 30 seconds to *about* five minutes.” And the claim language “to maximize the conversion of the hydrogen peroxide (and) triacetin into peracetic acid” should be construed as set forth in section D, paras. 55-56 above—i.e., “to achieve the highest possible conversion of the hydrogen peroxide and the triacetin into peracetic acid.”

63. Dr. Whiteker opines that “[a] skilled artisan would recognize that this [claim] limitation applies when a particular reaction mixture reaches maximum conversion of hydrogen peroxide *and/or* triacetin at a time point between, or in close proximity to, 30 seconds and 5 minutes.” Ex. 10, Whiteker Decl., p. 3 (emphasis added). In my opinion, this Dr. Whiteker’s position renders the claim term in question indefinite.

64. Dr. Whiteker’s use of the phrase “and/or” is not consistent with the claim scope. As explained in section D, para. 54, above, based on the prosecution history of the Asserted Patents, the claim term should read “hydrogen peroxide and the triacetin.” This understanding is further bolstered by the plain reading of the claim which requires (emphasis added) “the conversion of hydrogen peroxide triacetin *into peracetic acid*.” While Dr. Whiteker appears to ignore this requirement of the claim, to a POSA the claim language here clearly requires the maximum conversion of hydrogen peroxide and triacetin into peracetic acid.

65. In my opinion, Dr. Whiteker’s proposed construction distorts the plain meaning of the claim language in question, such that the claim could only require maximum conversion of the hydrogen peroxide *or* of the triacetin. This would improperly zero in on the maximum conversion of hydrogen peroxide *alone*. As explained above in section D, para. 58, however, a POSA would understand that triacetin and hydrogen peroxide chemically react with each other

and consequently are converted into peracetic acid (PAA) and diacetin. The diacetin thus formed can then react with the hydrogen peroxide and convert into PAA and monoacetin. The monoacetin thus formed can then further react with the hydrogen peroxide and convert into PAA and glycerol. Therefore, a POSA would understand that the hydrogen peroxide can continue reacting with diacetin and then with monoacetin and be converted into PAA in the solution. The maximum conversion of hydrogen peroxide is, therefore, not limited to the conversion of hydrogen peroxide and triacetin into PAA, but also includes the subsequent conversion of hydrogen peroxide in its reactions with diacetin or monoacetin into PAA.

66. A POSA would understand the plain meaning of the claim in question to refer to the conversion of both hydrogen peroxide and triacetin. He or she would not interpret the claim language in the manner proposed by Dr. Whiteker, which would also include the conversion of diacetin and monoacetin, as this would be inconsistent with the plain meaning of the claim term and render the claim indefinite.

67. Notably, claim 11 of the '449 Patent, which depends from claim 10, recites “sampling the reaction medium to determine the time required to maximize the amount of hydrogen peroxide triacetin that are converted into peracetic acid.” Dr. Whiteker contends that “[a] skilled artisan would recognize that this refers to taking samples of the reaction medium to determine the amount of time required to maximize the conversion of both hydrogen peroxide *and* triacetin into peracetic acid.” Ex. 10, Whiteker Decl., p. 3 (emphasis added). Dr. Whiteker thus inexplicably takes inconsistent positions with regard to claims 10 and 11 of the '449 Patent because he seems to acknowledge in his proposal for claim 11 that the maximum conversion of “hydrogen peroxide triacetin” refers to the maximum conversion of both hydrogen peroxide and triacetin.

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

Clean Chemistry Proposed Construction	Enviro Tech Proposed Construction
“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”	Plain and ordinary meaning

68. As explained in section D, paras. 55-56 above, “*to maximize* the amount of hydrogen peroxide triacetin that are converted into peracetic acid” means “*to achieve the highest possible* conversion of hydrogen peroxide and triacetin into peracetic acid.”

69. For this claim term, Dr. Whiteker contends that “[a] skilled artisan would recognize that this refers to taking samples of the reaction medium to determine the amount of time required to maximize the conversion of both hydrogen peroxide and triacetin into peracetic acid.” Ex. 10, Whiteker Decl., p. 3. I understand that he, therefore, agrees that “sampling the reaction medium” refers to “taking samples of the reaction medium.” Dr. Whiteker’s proposal also implies that he agrees that the taking of these samples must occur at various time points, so that a POSA would be able to “determine the time required” to maximize, or achieve the highest possible, conversion of hydrogen peroxide and triacetin into peracetic acid.

70. Further, as explained above with regard to claim 10 of the '499 Patent, Dr. Whiteker properly acknowledges that the claim term “the conversion of hydrogen peroxide triacetin into peracetic acid” refers to “the conversion of both hydrogen peroxide *and* triacetin into peracetic acid.” This statement in the context of claim 11 of the '449 Patent, however, is contrary to the statement made by him with respect to claim 10, which claim 11 directly depends from, where he omits the requirement of the conversion of hydrogen peroxide and triacetin *into*

peracetic acid. Specifically, Dr. Whiteker asserts that the substantively identical claim language in claim 10—“the conversion of the hydrogen peroxide triacetin into peracetic acid”—instead referred to (emphasis added) “conversion of hydrogen peroxide *and/or* triacetin” with no mention of peracetic acid. Accordingly, Dr. Whiteker’s statements regarding claim 11 only highlight that his opinions regarding claim 10 are incorrect because they inconsistently interpret the meaning of the same recited claim language, which I understand from counsel is improper.

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

Clean Chemistry Proposed Construction	Enviro Tech Proposed Construction
Indefinite	Plain and ordinary meaning

71. Enviro Tech's expert Declaration submitted with its Preliminary Claim constructions did not address, or seek to define, this claim phrase; to my knowledge, Enviro Tech has not otherwise provided any definition of its “plain and ordinary meaning.”

72. Reading the claims in question, I note there is no antecedent basis for the word "liquid." Claim 19 depends from claim 2, which in turn depends from claim 1. Ex. 1, '449 Patent, 34:48 through 36:15. Neither claim 1 nor claim 2 of the '449 Patent recites the word "liquid." Further, to a POSA the phrasing "*triacetin* defin[es] a hydrogen peroxide-*triacetin* solution" (emphases added) would be non-sensical and unclear—one component is supposed to both define a composition as a solution and define that solution as containing itself and another component.

73. Turning to the '449 Patent specification for some possible guidance or clarification, I find that it would provide no enlightenment to a POSA as to the meaning of this

non-sensical phrase; in other words, a POSA would have no way to interpret the claim phrase in absence of further guidance from the intrinsic record, for which I see none.

74. Based upon my reading of the intrinsic record and understanding of the knowledge of a POSA, it is my opinion that this claim phrase would not provide to a POSA any reasonable certainty as to the meaning and scope of the claims in which the phrase resides in the Asserted Patents, thereby making those claims indefinite.

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

Clean Chemistry Proposed Construction	Enviro Tech Proposed Construction
The preamble is limiting	The preamble is <i>not</i> limiting

75. The above-referenced claim phrase is the preamble of claim 1 of the '449 Patent and may impact the scope and validity of that claim 1 and all claims depending therefrom. For context and easy reference, claim 1 of the '443 Patent is reproduced below.

Claim 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.

76. In my review of the intrinsic record of the '443 Patent, I see nothing that would suggest to a POSA that the preamble in this claim is non-limiting.

77. A POSA would understand that at some proportions and/or at some relative amounts, the components identified and listed in claim 1 can exist separately or, if brought together could in some circumstances form a mixture that is **not** a solution.

78. As used in this claim, the term “solution” would be interpreted by a POSA, having the benefit of the specification of the '443 Patent and its file history, as a liquid in a homogeneous state, as distinct from heterogeneous mixtures of substances and from the listed components standing alone and not in an admixture with one another. Without being brought together as a combination, components a. through f. of the claim would be substances standing alone. But if brought together, they exist as a mixture that is either heterogeneous or homogeneous if in a liquid state. Once a homogeneous mixture, they would be a solution, as the claim term “solution” would be understood by a POSA reading the '443 Patent in the context of its specification and file history. To disregard the words in the preamble would be to disregard any requirement that the individual components in the list of ingredients have been brought together to form a mixture or a combination, which would be a non-sensical result. Thus, in my opinion, the preamble’s limitations are necessary for a POSA to understand with any reasonable certainty the meaning and scope of claim 1 of the '443 Patent and its dependent claims.

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

Clean Chemistry Proposed Construction	Enviro Tech Proposed Construction
The preamble is limiting	The preamble is not limiting

79. The above-referenced phrase is the preamble of claim 1 of the '072 Patent, and it may affect the scope and validity of that patent’s claims 1-3. For context and easy reference, claim 1 of the '072 Patent is reproduced below.

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

80. Nothing in the intrinsic record would suggest to a POSA that the preamble in this claim is non-limiting.

81. The preamble is properly considered by Clean Chemistry to be limiting due to the presence of the claim term *solution* for the same reasons as set forth above with respect to the preamble of claim 1 of the '443 Patent. In my opinion, this preamble must be construed as limiting in order to provide a reasonable certainty to a POSA about the meaning and scope of the claim.

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

Clean Chemistry Proposed Construction	Enviro Tech Proposed Construction
Indefinite	Plain and ordinary meaning

82. The above-referenced claim phrase appears in claim 1 of the '072 Patent, and it may affect the scope and validity of its claims 1-3.

83. I first note that the dependent claims would not assist a POSA with interpretation of the claim term "trace amount" in independent claim 1 because they are only directed to the molar ratios and concentrations of triacetin and hydrogen peroxide. Peracetic acid is never mentioned in any of the two dependent claims.

84. 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. There is no discussion in the '072 Patent specification of the desirability or non-desirability of the presence of peracetic acid in the claimed solutions, nor of the desired or optimal amounts of peracetic acid in the claimed solutions.

85. The specification of the '072 Patent does state that "a trace amount of PAA ... is formed within the first day of preparing the hydrogen peroxide-acetyl precursor solution." Ex. 4, '072 Patent, 9:45-46 and 50-52. However, Examples 1 and 7 report **zero** peracetic acid in the hydrogen peroxide-triacetin solutions on the first day. Ex. 4, '072 Patent, 9:66 to 10:20, as well as 13:10-30; Tables I and VII. No other discussion of the term "trace amount" is found in the patent specification.

86. If the claims of the '072 Patent were to be interpreted by a POSA as encompassing solutions containing **no** peracetic acid, then the claim phrase "trace amount of peracetic acid" would be effectively read out of the claims and ignored, and I see no reason why a POSA would read claim 1 in such a way.

87. Notably, there are disclosures of peracetic acid concentrations in the '072 Patent specification, which indicates at column 6, lines 42-43, "a high level of PAA, from about 1% to about 7.1%" and which is reiterated at column 18, lines 13-14: "high levels of PAA, from about 1% to about 7.1%."¹ From these statements in the '072 Patent specification, a POSA would most likely infer that if an amount of about 1% or more is expressly called a "high level" of peracetic

¹ The specification of the '072 Patent expressly defines "%" as "mean[ing] weight percent, except when referring to the percent converted." Ex. 4 '072 Patent, 7:58-59. Since the above-quoted phrases do not refer to the percent converted, the "%" therein is weight percent.

acid by the patentees, then a trace (or low, or moderate) amount of peracetic acid is some amount that is less than "about 1%" of peracetic acid. However, what quantitatively is a "low," "moderate," or "trace" amount within the broad range of 0 to 1%, was left undefined by the patentees and, in my opinion, would be uncertain to a POSA.

88. Enviro Tech's expert Declaration states 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. 10, Whiteker Decl., p. 7, ¶ 10, first row of the table. In my opinion, Dr. Whiteker's 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. 10, Whiteker Decl., p. 7, ¶ 10, first row of the table. While the specification the '072 Patent mentions multiple detection methods and specifies that one method, namely the modified DPD method (Ex. 4, '072 Patent, 8:38-53), can be used when "low" (otherwise undefined) peracetic acid concentrations are involved, the Examples of the patent use a different method, namely ceric sulfate-sodium thiosulfate titration. Ex. 4, '072 Patent, 7:65 to 8:27. Furthermore, no guidance is given to a POSA in the patent specification regarding which one to use or what amount or range of amounts of PAA needs to be detected to be considered a "trace amount."

89. The intrinsic record thus would have left a POSA without guidance as to what does and does not constitute a "trace amount." In my opinion, in light of the intrinsic evidence, the claim phrase "trace amount" is incapable of providing reasonable certainty to a POSA as to the meaning or scope of the claim; therefore, it is indefinite.

V. RESERVATION OF RIGHTS

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

VI. ATTESTATION

91. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Date: August 4, 2025

/Alexander M. Klibanov/

Alexander M. Klibanov, Ph.D.

Curriculum vitae of Dr. Alexander M. Klibanov

Nationality: Naturalized U.S. Citizen (1983)

Education: 1974 Ph.D. in Chemical Enzymology, Moscow University
1971 M.S. in Chemistry, Moscow University

Honors:

2015 Tau Beta Pi's Leonardo Da Vinci Lecturer, MIT

2007-11 and 2014 Novartis Chair Endowed Professorship, MIT

2012-13 Roger and Georges Firmenich Endowed Professorship, MIT

2011 MIT Biological Engineering Senior Class Faculty Award

2006 Distinguished GRUM Lecturer in Drug Discovery & Development, University of Montreal (Canada)

2004 UNAM Distinguished Lecturer, National University of Mexico (Mexico City)

2001 Walter Enz Lecturer in Pharmaceutical Chemistry, University of Kansas

2001 Elected a Corresponding Fellow of the Royal Society of Edinburgh (Scotland's National Academy of Science and Letters)

2000 Merck Distinguished Lecturer, Rutgers University

2000 Top 20 Biotechnology & Bioengineering Papers of the Last Forty Years

1998 Robert Lutz Lecturer, University of Virginia

1996 Perkin-Elmer Distinguished Lecturer, University of Pittsburgh

1995 Elected to the National Academy of Sciences of the U.S.A.

1995 Nathan O. Kaplan Memorial Lecturer in Biological Chemistry, University of California at San Diego

1994 R.W. Johnson PRI Lecturer, Pharmaceutical Research Institute

1994 Warren McCabe Lecturer, North Carolina State University

1993 Elected to the National Academy of Engineering of the U.S.A.

1993 Arthur C. Cope Scholar Award of the American Chemical Society

1993 Biotechnology Divisional Lectureship Award of the Institute of Food Technologists

1992 Charles Sabat Lecturer, Rutgers University

1992 Elected a Founding Fellow of the American Institute for Medical and Biological Engineering

1992 Louis C. Jordy Research Scholar Lecturer, Drew University

1991 International Enzyme Engineering Award

1991 Marvin J. Johnson Award of the American Chemical Society

1990 Monsanto Lecturer, Ohio State University

1990 NRC Distinguished Lecturer, Academia Sinica (Taiwan)

1989 Ipatieff Prize of the American Chemical Society

1989 Backer Lecturer, Groningen University (Holland)

1988 Dow Lecturer, University of Ottawa (Canada)

1987 Distinguished Scholar Lecturer, Hope College

1986 Leo Friend Award of the American Chemical Society

1984 Who's Who in Frontier Science and Technology

1984 Sohio Lecturer, Case Western Reserve University

1982 American Men and Women of Science

1981-1983 Henry L. Doherty Career Development Professorship, MIT

1975 U.S.S.R. Ministry of Higher Education Prize

Professional Experience:

2019-present Novartis Chair Professor Emeritus of Chemistry and Bioengineering, MIT

2014-2019 Novartis Chair Professor of Chemistry and Bioengineering, MIT

2012-2013 Roger and Georges Firmenich Professor of Natural Products Chemistry
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2007-2011 Novartis Chair Professor of Chemistry and Bioengineering, MIT

2000-2019 Professor of Bioengineering
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1988-2019 Professor of Chemistry
Department of Chemistry, MIT

1987-1988 Professor of Applied Biochemistry
Department of Applied Biological Sciences, MIT

1983-1987 Associate Professor of Applied Biochemistry
Department of Applied Biological Sciences (formerly Department of Nutrition and Food Science), MIT

1979-1983 Assistant Professor of Applied Biochemistry
Department of Nutrition and Food Science, MIT

1977-1979 Postdoctoral Associate, Department of Chemistry University of California at San Diego

1974-1977 Research Chemist
Department of Chemistry, Moscow University

Current Journal Editorial/Advisory Boards:

"Biocatalysis and Biotransformation", "Applied Biochemistry and Biotechnology", "Open Chemistry Journal", "Biotechnology Progress", "Biotechnology & Bioengineering", "Microbial Biotechnology", "Open Journal of Pharmacology", "Nanocarriers", "Journal of Antivirals and Antiretrovirals", "Open Access Academic Books in Chemistry", "Journal of Biological Chemistry and Molecular Pharmacology", "Archives of Natural Products and Medicinal Chemistry", "Recent Patents in Biotechnology", "Current Pharmaceutical Biotechnology", and "Archives of Medical Biotechnology", "International Journal of Drug Design, Delivery and Safety"

Professional Societies:

U.S. National Academy of Sciences, U.S. National Academy of Engineering, American Chemical Society, American Institute for Medical and Biological Engineering

Current Research Interests:

Drug synthesis and modification	Medicinal and formulation chemistry
Protein and nucleic acid delivery	Antimicrobial polymers
Enzymes as catalysts in organic syntheses	
Stabilization and formulation of macromolecular pharmaceuticals	

Publications:

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Invited Lectures:

1. Gordon Conference on Immobilized Enzymes, Complexes, and Cells (Plymouth, NH). August 1978.
2. 5th International Conference on Enzyme Engineering (Henniker, NH). August 1978.
3. Miles Laboratories (Elkhart, IN). February 1980.
4. Gordon Conference on Immobilized Species (Henniker, NH). August 1980.
5. Novo Laboratories (Wilton, CT). October 1980.
6. Corning Glass Works Co. (Corning, NY). October 1980.
7. Stauffer Chemical Co. (Dobbs Ferry, NY). December 1980.
8. DuPont Experimental Station (Wilmington, DE). January 1981.
9. Dow Chemical Co. (Wayland, MA). April 1981.
10. Cetus Corp. (Berkeley, CA). April 1981.
11. Exxon Research & Engineering Co. (Linden, NJ). April 1981.
12. Meeting of the American Solar Energy Society (Philadelphia, PA). May 1981.
13. 6th International Conference on Enzyme Engineering (Kashikojima, Japan). September 1981.
14. Genex Corp. (Rockville, MD). October 1981.
15. ILP Symposium for Senior Executives (London, England). November 1981.
16. California Institute of Technology (Pasadena, CA). December 1981.
17. Symposium of the American Society for Microbiology (Atlanta, GA). March 1982.
18. Kodak Research Center (Rochester, NY). March 1982.
19. Repligen Corp. (Cambridge, MA). April 1982.
20. Symposium on the Biological Basis of New Developments in Biotechnology

(Minneapolis, MN). May 1982.

21. Meeting of the Biochemical Society (Oxford, England). July 1982.
22. Meeting of the American Chemical Society (Kansas City, MO). September 1982.
23. Rotenburger Symposium on Enzyme Technology (Kassel, Germany). September 1982.
24. Genetics Institute (Boston, MA). September 1982.
25. Meeting of the American Institute of Chemical Engineers (Los Angeles, CA). November 1982.
26. G.D. Searle Co. (Chicago, IL). October 1982.
27. Halcon International Research Center (Montvale, NJ). October 1982.
28. International Workshop on Immobilized Enzymes and Cells (Bangkok, Thailand). December 1982.
29. Amoco Research Center (Naperville, IL). January 1983.
30. University College London (London, England). May 1983.
31. International Conference on Biotechnology Biotech '83 (London, England). May 1983.
32. Tufts University Workshop on Immobilized Enzymes and Proteins (Medford, MA). June 1983.
33. Gordon Conference on Organic Reactions and Processes (New Hampton, NH). July 1983.
34. Symposium "Biocatalysis: New Discoveries and Uses", Meeting of the American Society for Industrial Microbiology (Sarasota, FL). August 1983.
35. Monsanto Co. (St. Louis, MO). September 1983.

36. Pasteur Biosciences '83 Conference (Paris, France). September 1983.
37. 7th International Conference on Enzyme Engineering (White Haven, PA). September 1983.
38. University of Iowa (Iowa City, IA). October 1983.
39. CPC Moffett Technical Center (Summitt-Argo, IL). December 1983.
40. General Foods Co. (Dobbs Ferry, NY). December 1983.
41. U.S. National Bureau of Standards (Gaithersburg, MD). April 1984.
42. Millipore Corp. (Bedford, MA). April 1984.
43. Technical University of Munich (Munich, F.R.G.). May 1984.
44. Danish Academy of Technical Sciences (Copenhagen, Denmark). May 1984.
45. Novo International Biotechnology Symposium (Copenhagen, Denmark). May 1984.
46. CRA Scientific Conference (St. Charles, IL). June 1984.
47. Gordon Conference on Immobilized Species in Biotechnology (Plymouth, NH). August 1984.
48. Meeting of the American Chemical Society (Philadelphia, PA). August 1984.
49. International Biotechnology Conference Biotech '84 (Washington, DC). September 1984.
50. Staley Manufacturing Co. (Decatur, IL). October 1984.
51. Case Western Reserve University (Cleveland, OH). October 1984.
52. IMC Corp. (Terre Haute, IN). October 1984.
53. Syracuse University (Syracuse, NY). November 1984.
54. National University of Mexico (Mexico City, Mexico). November 1984.

55. National Starch & Chemical Corp. (Bridgewater, NJ). November 1984.
56. Mead Corp. (Chillicothe, OH). November 1984.
57. Hebrew University of Jerusalem (Jerusalem, Israel). November 1984.
58. U.S. Army Chemical R&D Center (Aberdeen Proving Ground, MD). December 1984.
59. Allied Corp. (Morristown, NJ). December 1984.
60. Bristol Laboratories (Syracuse, NY). January 1985.
61. University of Rochester (Rochester, NY). January 1985.
62. G.D. Searle Co. (Chicago, IL). February 1985.
63. Wellcome Research Laboratories (Research Triangle Park, NC). February 1985.
64. UCLA Symposium on Protein Structure, Folding and Design (Keystone, CO). April 1985.
65. International Conference on Application of Biocatalysts in Organic Synthesis (Noordwijkerhout, Holland). April 1985.
66. Guido Donegani Research Institute (Novara, Italy). April 1985.
67. Hoffmann-LaRoche Co. (Basel, Switzerland). April 1985.
68. Pittsburgh-Cleveland Catalysis Society Meeting (Pittsburgh, PA). May 1985.
69. Ethyl Corp. (Baton Rouge, LA). May 1985.
70. Stony Brook Symposium on Protein Engineering (Stony Brook, NY). May 1985.
71. Amgen Corp. (Thousand Oaks, CA). June 1985.
72. Gordon Conference on Applied Microbiology (New London, NH). August 1985.
73. International Congress of Biochemistry (Amsterdam, Holland). August 1985.
74. IUPAC Congress (Manchester, England). September 1985.

75. International Enzyme Engineering Conference (Helsingor, Denmark). September 1985.
76. Biotechnica '85 (Hannover, West Germany). October 1985.
77. Biotec 85 (Dusseldorf, West Germany). October 1985.
78. Smith Kline & French Co. (Philadelphia, PA). November 1985.
79. Exxon Corporate Research (Anandale, NJ). December 1985.
80. Pennsylvania State University (University Park, PA). December 1985.
81. Georgetown University (Washington, DC). February 1986.
82. Columbia University (New York, NY). February 1986.
83. Upjohn Co. (Kalamazoo, MI). February 1986.
84. UNIDO Workshop on Biotechnology (Trieste, Italy). March 1986.
85. Eniricherche (Monterotondo, Italy). March 1986.
86. EEC Biomolecular Engineering Meeting (Compiègne, France). April 1986.
87. ACS Conference on Chemical Aspects of Biotechnology (Gaithersburg, MD). May 1986.
88. Biotech '86 Europe International Conference (London, England). May 1986.
89. IUPAC International Symposium on Organic Chemistry in Technological Perspective (Jerusalem, Israel). June 1986.
90. University of Tel-Aviv (Ramat-Aviv, Israel). June 1986.
91. Annual Meeting of the Canadian Biochemical Society (Guelph, Canada). June 1986.
92. International Symposium on Biologically Engineered Polymers (Cambridge, England). July 1986.
93. TNO Institute of Applied Chemistry (Zeist, The Netherlands). August 1986.

94. IUPAC International Symposium on the Chemistry of Natural Products (The Hague, The Netherlands). August 1986.
95. American Chemical Society National Meeting (Anaheim, CA). September 1986.
96. Catalytica Annual Science and Technology Symposium (San Jose, CA). September 1986.
97. International Conference on Enzyme Engineering (Cambridge, England). September 1986.
98. Ohio State University (Columbus, OH). October 1986.
99. Michigan State University (Lansing, MI). October 1986.
100. Biotechnology Process Engineering Symposium (Cambridge, MA). October 1986.
101. University of Delaware (Newark, DE). November 1986.
102. American Red Cross Blood Research Institute (Bethesda, MD). November 1986.
103. International Symposium on Biocatalysis in Non-Aqueous Solvents (Wageningen, The Netherlands). December 1986.
104. University of Trondheim (Trondheim, Norway). December 1986.
105. Colgate-Palmolive Research Center (Piscataway, NJ). January 1987.
106. International Paper Co. (Tuxedo Park, NY). January 1987.
107. University of Massachusetts (Amherst, MA). February 1987.
108. American Society for Microbiology Biocatalysis Symposium (Atlanta, GA). March 1987.
109. Hope College (Holland, MI). March 1987.
110. Pfizer Corporate Research Center (Groton, CT). April 1987.
111. OBBS Symposium on Protein Engineering (Ottawa, Canada). April 1987.

112. University of Texas (Austin, TX). April 1987.
113. Florida Catalysis Conference (Palm Coast, FL). May 1987.
114. PPG Industries (Barberton, OH). May 1987.
115. Abbott Laboratories (North Chicago, IL). May 1987.
116. American Oil Chemists Society Symposium on Lipases (New Orleans, LA). May 1987.
117. Argonne National Laboratory (Argonne, IL). June 1987.
118. Canadian Chemical Conference (Quebec City, Canada). June 1987.
119. Squibb Co. (New Brunswick, NJ). June 1987.
120. FEBS Annual Meeting (Ljubljana, Yugoslavia). July 1987.
121. L'Oreal Research Institute (Paris, France). July 1987.
122. International Symposium on Biointeractions (Cambridge, England). July 1987.
123. Eli Lilly Co. (Indianapolis, IN). August 1987.
124. Upjohn Co. (Kalamazoo, MI). September 1987.
125. International Enzyme Engineering Conference (Santa Barbara, CA). October 1987.
126. Shell Development Co. (Houston, TX). October 1987.
127. DuPont Experimental Station (Wilmington, DE). October 1987.
128. University of Helsinki (Helsinki, Finland). November 1987.
129. International Conference on Bioreactors and Biotransformations (Gleneagles, Scotland). November 1987.
130. Sandoz Co. (Basel, Switzerland). November 1987.
131. University of Waterloo (Waterloo, Canada). December 1987.

132. Norwegian Biochemical Society Annual Meeting (Bejito, Norway). January 1987.
133. Rutgers University (New Brunswick, NJ). February 1988.
134. University of Ottawa (Ottawa, Canada). February 1988.
135. Boston Biomedical Research Institute (Boston, MA). March 1988.
136. Princeton University (Princeton, NJ). March 1988.
137. Royal Society of Chemistry Meeting (Kent, England). April 1988.
138. Stanford University (Stanford, CA). May 1988.
139. University of Graz (Graz, Austria). May 1988.
140. Belgian Organic Chemistry Symposium (Ghent, Belgium). May 1988.
141. Dow Chemical Co. (Midland, MI). May 1988.
142. Michigan State University (Lansing, MI). May 1988.
143. American Chemical Society Meeting (Toronto, Canada). June 1988.
144. Proctor & Gamble Co. (Cincinnati, OH). June 1988.
145. International Congress of Biochemistry (Prague, Czechoslovakia). July 1988.
146. International Biotechnology Symposium (Paris, France). July 1988.
147. Gordon Conference on Catalysis (Newport, RI). August 1988.
148. Conference on Biocatalytic Synthesis of Organic Compounds (Saratoga, NY). August 1988.
149. International Symposium on Thermodynamics Applied to Biological Systems (Santa Margherita, Italy). September 1988.
150. Cornell University (Ithaca, NY). September 1988.
151. Eastman Kodak Co. (Kingsman, TN). September 1988.

152. Symposium on Biotechnology Challenges in the Food Industry (Williamsburg, VA). October 1988.
153. University of California at Irvine (Irvine, CA). October 1988.
154. UCSF Symposium on Protein and Drug Design (San Francisco, CA). October 1988.
155. Boston University (Boston, MA). October 1988.
156. Wayne State University (Detroit, MI). November 1988.
157. Kyoto Symposium on Frontiers in Biocatalysis (Kyoto, Japan). November 1988.
158. Rohm & Haas Co. (Spring House, PA). January 1989.
159. Block Drug Co. (Jersey City, NJ). January 1989.
160. State University of New York (Albany, NY). March 1989.
161. Scripps Clinic and Research Foundation (La Jolla, CA). April 1989.
162. Texas A&M University (College Station, TX). May 1989.
163. University of Texas (Austin, TX). May 1989.
164. International Congress of Food Engineering (Cologne, F.R.G.). May 1989.
165. University of Groningen (Groningen, The Netherlands). June 1989.
166. Gordon Conference on Enzymes, Coenzymes, and Metabolic Pathways (Meridan, NH). July 1989.
167. American Peptide Symposium (La Jolla, CA). July 1989.
168. International Symposium on Prospects in Protein Engineering (Haren, The Netherlands). August 1989.
169. Connaught Laboratories (Toronto, Canada). September 1989.
170. University of Georgia (Athens, GA). October 1989.
171. Spanish National Congress of Biochemistry (Alicante, Spain). October 1989.

172. Symposium on Receptor- and Enzyme- Based Drug Design (Chapel Hill, NC). October 1989.
173. Wesleyan University (Middletown, CT). November 1989.
174. University of Wisconsin (Madison, WI). February 1990.
175. Merck Sharp & Dohme Research Laboratories (Rahway, NJ). February 1990.
176. International Symposium on Biochemical Engineering (Stuttgart, F.R.G.). March 1990.
177. University of Geneva (Geneva, Switzerland). March 1990.
178. University of Lausanne (Lausanne, Switzerland). March 1990.
179. University of Bern (Bern, Switzerland). March 1990.
180. University of Fribourg (Fribourg, Switzerland). March 1990.
181. International Conference on Protein Stability (Cambridge, England). March 1990.
182. AFRC Institute of Food Research (Reading, England). March 1990.
183. Lehigh University (Bethlehem, PA). April 1990.
184. Biotechnology Research Institute (Montreal, Canada). April 1990.
185. Ohio State University (Columbus, OH). April 1990.
186. Pharmaceutical Manufacturers Association Annual Meeting (St. Louis, MO). April 1990.
187. International Conference on Industrial Use of Enzymes (Chicago, IL). May 1990.
188. Korea Advanced Institute of Science and Technology (Seoul, Korea). June 1990.
189. Academia Sinica and National Taiwan University (Taipei, Taiwan). June 1990.
190. Gordon Conference on Biocatalysis (Plymouth, NH). June 1990.

191. IUPAC Conference on Organic Synthesis (Helsinki, Finland). July 1990.
192. International Conference on Solution Chemistry (Ottawa, Canada). August 1990.
193. Gordon Conference on Biomolecular Recognition (Plymouth, NH). August 1990.
194. University of Naples (Naples, Italy). September 1990.
195. International Conference on Water and Life (Crans-sur-Sierre, Switzerland). September 1990.
196. International Symposium on Thermodynamic Basis of Protein Structure and Function (Kansas City, MO). October 1990.
197. Johns Hopkins University (Baltimore, MD). October 1990.
198. Institute of Medicine Workshop on Microheterogeneity of Biological Macromolecules (Arlington, VA). November 1990.
199. U.S.-Japan Biotechnology Conference (Honolulu, HI). January 1991.
200. Ciba-Geigy Corp. (Summit, NJ). February 1991.
201. City University of New York (New York, NY). March 1991.
202. Rensselaer Polytechnic Institute (Troy, NY). March 1991.
203. Bristol-Myers Squibb Co. (Wallingford, CT). April 1991.
204. British Biochemical Society Meeting (Reading, England). April 1991.
205. University of California at Berkeley (Berkeley, CA). April 1991.
206. California Institute of Technology (Pasadena, CA). April 1991.
207. Merck, Sharp & Dohme Research Laboratories (West Point, PA). May 1991.
208. Bristol-Myers Squibb Research Institute (Princeton, NJ). May 1991.
209. International Conference on Biocatalysis (Orlando, FL). June 1991.

- 210. U.S. Army Research, Development and Engineering Center (Natick, MA). July 1991.
- 211. Gordon Conference on Natural Products (Plymouth, NH). July 1991.
- 212. Lederle-Praxis Biologicals Co. (Sanford, NC). July 1991.
- 213. International Biochemistry Congress (Jerusalem, Israel). August 1991.
- 214. American Chemical Society Meeting (New York, NY). August 1991.
- 215. International Enzyme Engineering Conference (Kona, HI). September 1991.
- 216. University of Lowell (Lowell, MA). October 1991.
- 217. Rutgers University (Piscataway, NJ). November 1991.
- 218. International Symposium on Enzymes in Organic Synthesis (New Delhi, India). January 1992.
- 219. International BioSymposium Nagoya '92 (Nagoya, Japan). January 1992.
- 220. International Symposium on Biomolecules in Organic Solvents (Taxco, Mexico). February 1992.
- 221. Rockefeller University (New York, NY). March 1992.
- 222. Symposium on Molecular Chirality of the Pharmaceutical Society of Japan (Tokyo, Japan). April 1992.
- 223. Conference on Enzymes in Organic Chemistry of the Dutch Chemical Society (Wageningen, The Netherlands). April 1992.
- 224. International Symposium on Bioprocessing of Coal (Clearwater Beach, FL). May 1992.
- 225. Exxon Workshop on New Leads in Coal Depolymerization (Montgomery, TX). May 1992.
- 226. Italian Symposium on Biochemical Biotechnology (Capri, Italy). June 1992.
- 227. Gordon Conference on Biocatalysis (Meriden, NH). July 1992.

- 228. FEBS Meeting (Dublin, Ireland). August 1992.
- 229. International Biotechnology Symposium (Washington, DC). August 1992.
- 230. International Symposium Bio Japan '92 (Yokohama, Japan). August 1992.
- 231. Texas College of Osteopathic Medicine (Fort Worth, TX). October 1992.
- 232. Rutgers University (Newark, NJ). October 1992.
- 233. Schering-Plough Co. (Bloomfield, NJ). November 1992.
- 234. International Symposium ISOPOW -V: *Properties of Water in Foods* (Peniscola, Spain). November 1992.
- 235. Carlsberg Laboratory (Copenhagen, Denmark). November 1992.
- 236. International Food Technology Conference (The Hague, The Netherlands). November 1992.
- 237. Singapore Institute of Standards and Industrial Research (Singapore). November 1992.
- 238. Drew University (Madison, NJ). December 1992.
- 239. Northeastern University (Boston, MA). January 1993.
- 240. Ciba Corning Diagnostics Corp. (Irvine, CA). January 1993.
- 241. University of Kansas (Lawrence, KS). January 1993.
- 242. 6th International Symposium on Recent Advances in Drug Delivery Systems (Salt Lake City, UT). February 1993.
- 243. Pennsylvania State University (University Park, PA). March 1993.
- 244. Northwestern University (Evanston, IL). March 1993.
- 245. International Symposium on Technologies for the Production of Enantiomerically Pure Chemicals (Amelia Island, FL). March 1993.
- 246. Gordon Conference on Bioanalytical Sensors (Ventura, CA). March 1993.

247. Pharmaceutical Manufacturers Association Analytical R&D/Pharmaceutical Development Subsections Joint Annual Meeting (Lake Buena Vista, FL). April 1993.
248. University of Massachusetts Symposium on Breakthrough Technologies: *Paradigms for a New Century* (Amherst, MA). May 1993.
249. Parke-Davis Corp. (Ann Arbor, MI). May 1993.
250. NutraSweet Co. (Mt. Prospect, IL). June 1993.
251. IGT/GRI Workshop on Novel Concepts for the Production of Regio- and Stereospecific Compounds (Chicago, IL). June 1993.
252. Northeast Regional Meeting of the American Chemical Society (Boston, MA). June 1993.
253. Institute of Food Technologists' Biotechnology Meeting (Chicago, IL). July 1993.
254. Annual Meeting of Department of Energy's Biological and Chemical Technology Research Program Principal Investigators (Tiburon, CA). July 1993.
255. Allied-Signal Corp. (Des Plaines, IL). July 1993.
256. American Chemical Society Meeting (Chicago, IL). August 1993.
257. University of Illinois at Urbana-Champaign (Urbana, IL). September 1993.
258. International Enzyme Engineering Conference (Deauville, France). September 1993.
259. Queens College (Flushing, NY). November 1993.
260. Exxon Chemical Research Meeting (Galveston, TX). November 1993.
261. Hoffmann-LaRoche Co. (Nutley, NJ). December 1993.
262. U.S.-Japan Symposium on Drug Delivery (Maui, HI). December 1993.
263. North Dakota State University (Fargo, ND). February 1994.
264. Annual Meeting of the American Institute for Medical and Biological

- Engineering (Washington, DC). March 1994.
265. Rhone-Poulenc Rorer Symposium on Visions in Chemistry (Collegeville, PA). May 1994.
266. International Flavors & Fragrances R&D (Union Beach, NJ). May 1994.
267. Istituto degli Ormoni (Milan, Italy). June 1994.
268. Gordon Conference on Enzymes, Coenzymes, and Metabolic Pathways (Meriden, NH). July 1994.
269. Annual Meeting of Department of Energy's Biological and Chemical Technology Research Program Principal Investigators (Denver, CO). July 1994.
270. William S. Johnson Symposium in Organic Chemistry (Stanford, CA). October 1994.
271. R.W. Johnson Pharmaceutical Research Institute (Spring House, PA). October 1994.
272. International Congress of Biochemical Engineering (Mexico City, Mexico). October 1994.
273. National University of Mexico (Mexico City, Mexico). October 1994.
274. DuPont Merck Pharmaceutical Co. (Deepwater, NJ). December 1994.
275. Symposium on Therapeutic Protein Production and Processing (Cambridge, MA). January 1995.
276. International Symposium on Biocatalysts for Flavor Production, BioFlavour '95 (Dijon, France). February 1995.
277. Institut Pasteur (Paris, France). February 1995.
278. Florida State University (Tallahassee, FL). March 1995.
279. Abbott Laboratories (North Chicago, IL). March 1995.
280. University of Maryland, Baltimore County (Baltimore, MD). March 1995.

281. University of California at San Diego (La Jolla, CA). April 1995.
282. Great Lakes Regional Meeting of the American Chemical Society (LaCrosse, WI). June 1995.
283. Gordon Conference on Bioorganic Chemistry (Andover, NH). June 1995.
284. Annual Meeting of Department of Energy's Biochemical and Chemical Technology Research Principal Investigators (Albuquerque, NM). July 1995.
285. International Symposium "Biocatalysis-95" (Suzdal, Russia). August 1995.
286. International Enzyme Engineering Conference (San Diego, CA). October 1995.
287. Symposium on Biomacromolecules: *From 3-D Structure to Applications* (Pasco, WA). October 1995.
288. Enzymol International Inc. (Columbus, OH). December 1995.
289. International Symposium PacifiChem '95 (Honolulu, HI). December 1995.
290. 3rd U.S.-Japan Symposium on Drug Delivery (Maui, HI). December 1995.
291. New England Section of the Society for Industrial Microbiology (Cambridge, MA). February 1996.
292. Brown University (Providence, RI). February 1996.
293. University of Pittsburgh (Pittsburgh, PA). February 1996.
294. Food Research Institute (Reading, England). March 1996.
295. International Symposium Chiral USA '96 (Boston, MA). May 1996.
296. BP Catalyst Colloquium (Uxbridge, England). June 1996.
297. International Symposium on Homogeneous Catalysis (Princeton, NJ). August 1996.
298. Juan March Foundation's International Workshop on Novel Biocatalysts (Madrid, Spain). March 1997.
299. University of Kentucky (Lexington, KY). April 1997.

300. Gordon Conference on Organic Reactions and Processes (Henniker, NH). August 1997.
301. Novo Nordisk Symposium on Protein Stability (Klampenborg, Denmark). August 1997.
302. International Enzyme Engineering Conference (Beijing, China). October 1997.
303. Biogen Inc. (Cambridge, MA). December 1997.
304. INBIO Europe'98 Conference on Advances in Industrial Biocatalysis (Amsterdam, The Netherlands). February 1998.
305. International Symposium on Stability and Stabilization of Biocatalysts (Córdoba, Spain). April 1998.
306. International Symposium on Protein Structure, Stability and Folding: *Fundamental and Medical Aspects* (Moscow, Russia). June 1998.
307. International Conference on Protein Stabilization (Leeds, England). June 1998.
308. University of Virginia (Charlottesville, VA). September 1998.
309. Danish Biotechnology Conference (Vejle, Denmark). May 1999.
310. International Conference on Biocatalysis and Biotransformation Biotrans '99 (Giardini Naxos, Italy). September 1999.
311. Annual Meeting of the American Association of Pharmaceutical Scientists (New Orleans, LA). November 1999.
312. Brandeis University (Waltham, MA). November 1999.
313. Rutgers University (Piscataway, NJ). March 2000.
314. Chiral USA 2000 Conference (Boston, MA). May 2000.
315. Land O'Lakes Conference on Solid-State Reactivity in Pharmaceutical Systems (Merrimac, W I). June 2000.
316. Agouron Pharmaceuticals Inc. (San Diego, CA). July 2000.

- 317. U.S. Patent and Trademark Office Technology Fair (Arlington, VA). July 2000.
- 318. 23rd Gulf Coast Chemistry Conference (Pensacola, FL). September 2000.
- 319. Avon Products (Suffern, NY). November 2000.
- 320. Procter & Gamble Co. (Cincinnati, OH). November 2000.
- 321. Flamel Technologies (Venissieux, France). December 2000.
- 322. BioVision 2001 International Conference (Lyon, France). February 2001.
- 323. 9th Baxter Science and Technology Symposium (Hyland, IL). May 2001.
- 324. International Symposium on Applications of Enzymes in Chemical and Biological Defense (Orlando, FL). May 2001.
- 325. International Conference on Applied Biocatalysis (Trondheim, Norway). June 2001.
- 326. PPG Industries (Allison Park, PA). August 2001.
- 327. University of Kansas (Lawrence, KS). August 2001.
- 328. Alkermes Inc. (Cambridge, MA). October 2001.
- 329. 6th U.S.-Japan Symposium on Drug Delivery Systems (Maui, HI). December 2001.
- 330. Acambis Inc. (Cambridge, MA). January 2002.
- 331. Baxter BioScience Co. (Duarte, CA). January 2002.
- 332. International Symposium on Challenges in Drug Discovery and Development in the 21st Century (Kolkata, India). March 2002.
- 333. National Institute of Standards and Technology (Gaithersburg, MD). April 2002.
- 334. Albany Molecular Research, Inc. (Mt. Prospect, IL). April 2002.
- 335. Institute for International Research Conference on Protein and Peptide Formulation Strategies for Drug Development and Delivery (San Francisco, CA). August 2002.

- 336. R&D Management Council Meeting of the Technical Association of the Pulp and Paper Industry (Cambridge, MA). November 2002.
- 337. DuPont Central R&D Center (Wilmington, DE). December 2002.
- 338. *ACTIVEPack* 2003 Conference (Ponte Verde Beach, FL). February 2003.
- 339. International Symposium on Industrial Applications of Biocatalysis: *Chemical Development Issues* (Boston, MA). September 2003.
- 340. U.S. Army Workshop on Self-Decontaminating Materials and Multifunctional Coatings (Arlington, VA). October 2003.
- 341. British Royal Society Meeting on Biocatalysis in Alternative Media (London, England). December 2003.
- 342. National Autonomous University of Mexico (Mexico City, Mexico). March 2004.
- 343. Healthcare Research Initiative Workshop on the Effect of Radiofrequency Radiation on Pharmaceutical Product Quality (Cambridge, MA). June 2004.
- 344. Rensselaer Biotechnology Symposium on Biological Discoveries That Will Change the World (Troy, NY). September 2004.
- 345. Barnett International Conference: *The Consequences of Aggregation in Drug Development, Immunology, Quality Control, and Disease Genesis* (Philadelphia, PA). September 2004.
- 346. 4th Annual IBC Conference on Formulation Strategies for Protein Therapeutics (Boston, MA). October 2004.
- 347. U.S. Army Edgewood Chemical Biological Center (Aberdeen Proving Ground, MD). August 2005.
- 348. World Congress on Synthetic Receptors (Salzburg, Austria). September 2005.
- 349. International Conference “Celebrating 30 Years of Robert Langer’s Science” (Cambridge, MA). July 2006.
- 350. University of Montreal (Montréal, Québec, Canada). October 2006.
- 351. The Boeing Company Research Center (Everett, WA). December 2006.

- 352. Instrumentation Laboratory (Lexington, MA). December 2006.
- 353. Acambis Inc. (Cambridge, MA). January 2007.
- 354. 6th International Symposium on Industrial Microbiology and Biotechnology (Cambridge, MA). August 2007.
- 355. Scientific Conference on Chemical & Biological Defense Research (Timonium, MD). November 2007.
- 356. MIT Research and Development Conference (Cambridge, MA). November 2007.
- 357. Nanotech '2008 International Conference (Boston, MA). June 2008.
- 358. Materials Research Society Symposium (Boston, MA). December 2008.
- 359. Johnson & Johnson Research Briefing at MIT (Cambridge, MA). January 2009.
- 360. 3rd Annual Lyophilization Conference: *Ensuring Optimum Formulations for Pharmaceuticals and Biologics* (Boston, MA). February 2010.
- 361. DSM Corporate Research Center (Geleen, The Netherlands). June 2010.
- 362. Merck Serono Pharmaceutical Co. (Darmstadt, Germany). June 2010.
- 363. NanoFormulations '2010 International Conference (Stockholm, Sweden). June 2010.
- 364. Covidien Surgical Devices and Vascular Therapies Divisions (Cambridge, MA). October 2010.
- 365. World Lyophilization Summit (Cambridge, MA). May 2011.
- 366. Alvogen (Cambridge, MA). March 2012.
- 367. Colgate-Palmolive Co. (Cambridge, MA). April 2012.
- 368. FDA Parenteral Drug Association Glass Quality Conference (Washington, DC). June 2012.
- 369. University of Puerto Rico (Humacao, Puerto Rico). January 2013.

- 370. International Conference on Creating and Leveraging Intellectual Property in Developing Countries (Durban, South Africa – *via teleconference*). November 2013.
- 371. Northwestern University (Evanston, IL). April 2015.
- 372. FDA and Parenteral Drug Association Joint Regulatory Conference (Washington, DC). September 2016.
- 373. Annual Partnership Opportunities in Drug Delivery (PODD) Conference (Boston, MA). October 2017.