

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Clean Chemistry, Inc.,
Petitioner,

v.

Enviro Tech Chemical Services, Inc.,
Patent Owner

Review no.: IPR2025-01458

U.S. Patent No. 9,737,072

Issued: August 22, 2017

Filed: March 7, 2016

Inventors: Michael S. Harvey and Jonathan N. Howarth

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

Declaration of Dr. Alexander M. Klibanov for U.S. Patent No. 9,737,072

CLEAN CHEMISTRY EXH 1008
IPR2025-01458

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I. Introduction

I, Dr. Alexander Klibanov, 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 the U.S. Patent No. 9,737,072 (“the ‘072 Patent”)), I at least met (and indeed exceeded) the background and qualifications requirements of a person of ordinary skill in the art (“a POSA”) with respect to the ‘072 Patent, 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’s counsel (“counsel”). My understanding of these legal principles explained by counsel is outlined below in this section of the present Declaration.

A. Priority Date

13. The ‘072 Patent has a priority date (or constructive date of invention) of March 24, 2011 (as seen in Item (62) on the cover page of the ‘072 Patent). I understand that the ‘072 Patent is a divisional application (from Appln. No. 14/019,296, now the U.S. Patent No. 9,370,180), which is itself a divisional application of another patent application (Appln. No. 13/065,553, now the U.S. Patent No. 8,546,449), and that the ‘072 Patent has the same priority date as the U.S. Patent No. 8,546,449 (i.e., March 24, 2011, as noted above).

B. A Person of Ordinary Skill in the Art

14. United States patents and prior art 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 creativity. He or she is presumed to be familiar with all publicly available relevant prior art at the time of the invention of the patent in question (here, the ‘072 Patent).

16. In my opinion, a POSA with respect to the subject matter of the ‘072 Patent 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 the ‘072 Patent is a divisional of a divisional, for which the earliest filing date is March 24, 2011, as explained above. Exhibit 1002.

19. 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 '072 Patent), a patentee can include a particular definition of a claim term in the patent specification. In such instances, the claim generally should be interpreted according to that definition provided in the patent specification.

21. The patent claim 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, also may be considered if it is not inconsistent with the intrinsic evidence. However, if the meaning of the claim is clear from the intrinsic evidence, then there is no reason for a POSA to look into extrinsic evidence.

D. Anticipation

22. A patent claim is considered to be anticipated by the prior art when each and every limitation of the claim is found in a single prior art reference either expressly or inherently, where inherently means that the feature is not explicitly stated but is necessarily present.

23. A prior art reference that teaches a specific value for a variable or a specific range of values within a claimed range anticipates the claimed range.

24. A prior art reference that teaches a specific range of values for a variable, which range overlaps with a claimed range for that variable, also anticipates the claimed range if there is no criticality to the claimed range (such as unexpectedly superior results).

E. Obviousness

25. Relevant factual considerations for an obviousness analysis include (1) the scope and content of the prior art; (2) differences between the prior art and the patent claims; and (3) the level of skill possessed by a hypothetical person of ordinary skill in the art at the time of the invention.

26. Obviousness of a patent claim can be based on either a single prior art reference or a combination of two or more of such references that disclose all of the features of the claim, whether expressly or inherently.

27. If a prior art reference discloses fewer than all limitations of a patent claim, the claim may still be obvious if the differences between the subject matter of the claim and the prior art reference would have been obvious to a POSA at the time of the invention.

28. Also, a patent claim that recites a specific range of values of a variable can be rendered obvious by prior art that teaches a range that encompasses, or

overlaps with, the recited range of values, unless the recited range demonstrates some criticality, such as unexpectedly superior results.

29. A patent claim that recites a combination of known elements combined according to known methods that produces predictable results is probably obvious.

30. However, an obviousness determination of a patent claim should not be based on the benefit of hindsight gained from the disclosure of the patent under consideration.

III. Summary of Conclusions

31. Based on my professional knowledge and experience, as well as on my review of the intrinsic evidence and of the prior art as of the constructive time of the invention (March 24, 2011), I have concluded that Claims 1 through 3 of the '072 Patent (i.e., all the claims of this patent) are anticipated by, and/or obvious over, at least the prior art cited below in this Declaration.

IV. Technology Background

A. My Experience Relevant to the Technology of the Alleged Invention of the '072 Patent

32. I am familiar with peracetic acid synthesis, in part due to having been a long-term consultant to E. I. du Pont de Nemours and Company (DuPont) starting in the early 1990s. The subject matter for which I was a consultant at DuPont dealt, among other things, with methods for synthesizing peracetic acid using perhydrolase enzymes, such as lipases.

B. Summary of the Technology

33. Peracetic acid (CH_3COOOH or $\text{CH}_3\text{-C(=O)-O-OH}$, often abbreviated as PAA) is a common name for peroxyacetic acid, which is a small organic acid known for its disinfectant (i.e., microbe-killing) properties. Interest in use of peracetic acid began increasing in the 1990s.

34. Peracetic acid is typically prepared from an acetyl source and an appropriate oxidant. Acetyl sources include acetic acid, acetaldehyde, tetraacetyl ethylene diamine (TAED), diacetin (glycerin(e)/glycerol diacetate), and triacetin (glycerin(e)/glycerol triacetate). Suitable oxidants include hydrogen peroxide (H_2O_2) or inorganic compounds that provide H_2O_2 in water, such as sodium perborate and sodium percarbonate. Hydrogen peroxide is often the preferred oxidant.

35. While initial efforts to make peracetic acid industrially centered on oxidation of acetic acid, since the early 2000s, the focus has changed to use of acetyl sources having more than one acetyl group per molecule, with TAED and especially triacetin often being preferred.

V. Overview of the '072 Patent (Exhibit 1001)**A. Summary of the '072 Patent**

36. The '072 Patent contains the total of three claims, of which Claim 1 is independent and Claims 2 and 3 depend, directly or indirectly, respectively, from

Claim 1. Exhibit 1001, column 34, line 57, to column 35, line 4. According to its Abstract, the '072 Patent describes methods for generating peracetic acid (PAA) from aqueous hydrogen peroxide, triacetin, water, and an aqueous source of an alkali metal or earth alkali metal hydroxide. Exhibit 1001, Item (57).

37. The '072 Patent describes “liquid compositions for use in generating non-equilibrium solutions of PAA.” Exhibit 1001, column 5, lines 24-25. These liquid compositions are described as “hydrogen peroxide-acetyl precursor solutions,” which “comprise a solution of aqueous hydrogen peroxide, a liquid acetyl precursor that is soluble in aqueous hydrogen peroxide, a trace amount of peracetic acid, and water.” Exhibit 1001, column 5, lines 25-29. The '072 Patent indicates that a “preferable acetyl precursor is triacetin, which displays an unexpectedly high solubility in hydrogen peroxide.” Exhibit 1001, column 5, lines 29-31.

38. As part of the description of the method for making the hydrogen peroxide-triacetin solutions, the '072 Patent states that “The mole ratio of hydrogen peroxide:triacetin is about 2.98:1 to about 12.84:1.” Exhibit 1001, column 9, lines 24-25. This mole (or molar) ratio range is also recited in Claim 2 of the '072 Patent. The concentration ranges recited in Claim 2 of the '072 Patent are discussed in column 9, lines 39-46:

When triacetin is used as the liquid acetyl precursor, the solution that is formed is a hydrogen peroxide-triacetin solution. One such hydrogen

peroxide-triacetin solution comprises about 23% to about 40% hydrogen peroxide (from 50% aqueous hydrogen peroxide), about 20% to about 52% triacetin, water, and a trace amount of PAA that is formed within the first day of preparing the hydrogen peroxide-acetyl precursor solution.

39. Examples 1 through 6 of the '072 Patent describe the preparation of hydrogen peroxide-triacetin solutions (i.e., hydrogen peroxide-acetyl precursor solutions). The molar ratios of hydrogen peroxide to triacetin, as well as the concentrations of hydrogen peroxide and triacetin in the solutions prepared in Examples 1-6, correspond to, or fall within, the ranges subsequently recited in Claim 2 of the '072 Patent. Exhibit 1001, column 9, line 64, to column 13, line 6.

40. A POSA would have understood that the hydrogen peroxide to triacetin molar ratio value and their respective weight percent concentration values recited in Claim 3 of the '072 Patent are discussed in column 9, lines 48-53:

A preferable hydrogen peroxide-triacetin solution comprises about 27.15% hydrogen peroxide (from 50% aqueous hydrogen peroxide), about 45.67% triacetin, water, and a trace amount of PAA that is formed within the first day of preparing the hydrogen peroxide-acetyl precursor solution. The mole ratio of hydrogen peroxide:triacetin is about 3.8:1.

41. Example 7 of the '072 Patent also describes the preparation of a hydrogen peroxide-triacetin solution. The molar ratio of hydrogen peroxide to triacetin, as well as the concentrations of hydrogen peroxide and triacetin in the solution prepared in Example 7, correspond to the values recited in Claim 3. Exhibit 1001, column 13, lines 7-53.

B. Summary of the Prosecution History of the '072 Patent (Exhibit 1005)

42. I have reviewed the file (or prosecution) history of the '072 Patent.

43. The application for the '072 Patent was filed on March 7, 2016. The application as filed had six claims. Exhibit 1005, Pages 81-82.

44. In an Office Action dated November 4, 2016, the Patent and Trademark Office ("PTO") Examiner set forth a Restriction Requirement with four Groups of claims. Exhibit 1005, Pages 121-122. The Restriction Requirement from the Office Action is summarized in the table below.

Group	Claims	Claimed subject matter
I	1-3	hydrogen peroxide-acetyl precursor solution
II	4	method of preparing a hydrogen peroxide-acetyl precursor solution
III	5	a non-equilibrium solution of peracetic acid made by a specified method
IV	6	an on-site non-equilibrium peracetic acid generation system

45. In a Response filed on November 30, 2016, the Applicants provisionally elected Group I, Claims 1-3. Exhibit 1005, Pages 130-131.

46. A non-final Office Action was issued on February 13, 2017, indicating that Claims 1-3 are prosecuted and Claims 4-6 are withdrawn from further consideration. In the Office Action, Claims 1-3 were provisionally rejected for obviousness-type double patenting over Claims 1-3 of co-pending Application No. 15/063,306 (“the ‘306 application”; now the U.S. Patent No. 9,730,443). Exhibit 1005, Pages 136-138; Exhibit 1005.

47. The PTO rejection stated that the conflicting claims were not patentably distinct, because the rejected claims are directed to “a hydrogen peroxide-acetyl precursor solution comprising hydrogen peroxide, peracetic acid, triacetin, and water,” and the ‘306 application claims “a non-equilibrium solution of peracetic acid comprising peracetic acid, hydrogen peroxide, triacetin, 1,2,3-propanetriol [i.e., glycerin(e) or glycerol] and alkali metal or earth alkali metal hydroxide, and water.” Exhibit 1005, Page 137 (underlining in original).

48. In a Response filed on March 7, 2017, the Applicants filed a Terminal Disclaimer over the ‘306 application. Exhibit 1005, Pages 148-149.

49. On May 9, 2017, the PTO Examiner issued a Notice of Allowance, allowing Claims 1-3 and cancelling Claims 4-6 by an Examiner’s Amendment. Exhibit 1005, Pages 178-179.

50. The '072 Patent then issued on August 22, 2017.

VI. Claim Construction

51. From my review of the claims, specification, and file history of the '072 Patent, it appears that the claim term “water” would have had its plain and ordinary meaning well familiar to a POSA. The other claim terms of the '072 Patent are discussed below.

A. “Hydrogen peroxide-acetyl precursor”

52. Claim 1 of the '072 Patent recites “[a] hydrogen peroxide-acetyl precursor solution” in the preamble. This claim phrase “hydrogen peroxide-acetyl precursor” of Claim 1 is defined in the patent specification. Specifically, the '072 Patent specification states that “[w]hen triacetin is used as the liquid acetyl precursor, the solution that is formed is a hydrogen peroxide-triacetin solution.” Exhibit 1001, column 9, lines 39-41. Therefore, with triacetin as the liquid acetyl precursor, the Claim 1’s preamble phrase “[a] hydrogen peroxide-acetyl precursor solution” would have been understood by a POSA to mean “a hydrogen peroxide-triacetin solution.”

B. “[A]queous hydrogen peroxide”

53. The claim phrase “aqueous hydrogen peroxide” is not expressly defined in the specification of the '072 Patent, but as a POSA would have understood, this phrase refers to the presence of hydrogen peroxide in the claimed hydrogen

peroxide-acetyl precursor solution. This understanding is supported by the ‘072 Patent specification, which states that “[a] preferable hydrogen peroxide-triacetin solution comprises about 27.15% hydrogen peroxide (from 50% aqueous hydrogen peroxide).” Exhibit 1001, column 9, lines 48-50.

C. “Triacetin”

54. The claim term “triacetin” is not expressly defined in the specification of the ‘072 Patent, but it is a common name for glycerin(e) (also referred to as glycerol) triacetate, i.e., the triester of glycerol with acetic acid. This understanding is supported by the ‘072 Patent specification, which states that “[w]hen the acetyl precursors [*sic*] is triacetin, the product of the perhydrolysis reaction [i.e., the complete triester cleavage mediated by hydrogen peroxide] is 1,2,3-propanetriol (glycerine).” Exhibit 1001, column 15, lines 63-65.

D. “Peracetic acid”

55. Claim 1 of the ‘072 Patent recites the term “peracetic acid,” which is expressly defined in the patent specification: “The terms ‘PAA’ and ‘peracetic acid’ mean peroxyacetic acid or peracetic acid, and/or the conjugate base of peracetic acid (the peracetate ion).” Exhibit 1001, column 7, lines 55-57.

E. “Trace amount”

56. The phrase “a trace amount of peracetic acid” found in Claim 1 of the ‘072 Patent is not expressly defined in the specification of the ‘072 Patent and would

have seemed vague to a POSA. However, the patent specification repeatedly refers to “solutions with a high level of PAA [i.e., peracetic acid], from about 1% to about 7.1%” or “solutions hav[ing] high levels of PAA, from about 1% to about 7.1%.” Exhibit 1001, column 6, lines 42-43, and column 18, lines 13-14, respectively. A POSA would have recognized that the terms “a high level” or “high levels” of peracetic acid in this context are the opposite of the term “a trace amount” of peracetic acid (which term is repeatedly used in the ‘072 Patent specification: column 5, lines 28-29; column 9, lines 9, 44, and 50-51). Therefore, if peracetic acid amounts of “about 1%” or greater are expressly called by the patentees “high,” then it stands to reason that “trace amount[s]” of peracetic acid are those containing some amount that is less than “about 1%” of peracetic acid.

VII. Overview of Two Selected Prior Art References

A. WO 2011/017095 A2 (“Stauffer”; Exhibit 1012)

57. WO 2011/017095 A2 has priority dates of July 27, 2009, July 26, 2010, and July 27, 2010, thus making this international patent application a prior art with respect to the ‘072 Patent. Exhibit 1012, Page 1, Items (30) and (22). Stauffer’s Abstract indicates that the patent application disclosure relates to “[i]n-situ enzymatic preparation of peracid-based removable antimicrobial coating compositions and their methods of use for controlling microorganisms at various loci.”

58. One aspect of the invention in WO 2011/017095 A2 is:
an antimicrobial composition comprising components which comprise:
a) a film-forming water soluble or water-dispersible agent;
b) an inert solvent;
c) a carboxylic acid ester substrate;
d) a peroxygen source;
e) an enzyme catalyst having perhydrolase activity; and
f) a rheology modifier
wherein, upon combining said components, a peroxyacid is formed.

Exhibit 1012, Page 4, lines 1-9.

59. Relevant to this aspect of the WO 2011/017095 A2 invention is its Example 4, in which several ingredients were combined to form a mixture that included “triacetin” and “hydrogen peroxide”; and where small amounts of “peracetic acid” were subsequently formed. Exhibit 1012, Pages 63-64.

60. The Applicant in WO 2011/017095 A2 is DuPont. Exhibit 1012, Page 1. In reference to my consulting work for DuPont mentioned above, I was not directly involved in this particular aspect of using enzymes for making peracetic acid, and thus I am not listed as an inventor on this patent application.

B. JP 2006-045147 A (“Okano”; Exhibit 1013)

61. JP 2006-045147 A was filed on August 6, 2004, and published on February 16, 2006, thus making this Japanese patent application prior art with respect to the ‘072 Patent. Exhibit 1013, Page 1, Items (22) and (43). According to Okano’s Abstract, its disclosure is directed to “a sterilizing cleaner composition for hard surfaces.” The Abstract further states that the composition contains:

water and an organic peracid obtained by reacting (A) an ester of a polyhydric alcohol and an organic acid with (B1) hydrogen peroxide in a specific molar ratio in water at a pH of 8 to 12, and having a pH of 1 or more and less than 7 at 25°C.

Exhibit 1013, Page 1.

62. In its Disclosure of Invention, Okano explains that component (A) is “an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group,” and that “hydrogen peroxide” is “referred to as component (B1)”. Exhibit 1013, paragraph 0008.

63. Okano further states that “triacetin is preferable” as “component (A)”. Exhibit 1013, paragraph 0014.

64. Indeed, Example 1 of Okano uses triacetin as component (A), along with hydrogen peroxide (component (B1)), to form “the organic peroxy acid,” i.e.,

peroxyacetic acid (or peracetic acid, PAA) here, in water. Exhibit 1013, paragraph 0057.

65. Regarding molar ratios of the components, Okano discloses that the “organic peracid” composition is “obtained by reacting component (A) and component (B1) in water in a molar ratio of (A)/(B1) = 1/10 to 20/1.” Exhibit 1013, paragraph 0015.

66. For concentrations (expressed in percent by weight (“wt%”)), Okano in paragraph 0035 states:

The amount of component (A) in the composition for producing sterilizing cleaner is preferably 20 to 90 wt%, further 30 to 90 wt%, and even more preferably 40 to 80 wt%, and the amount of component (B1) is preferably 1 to 30 wt%, more so 5 to 25 wt%, and even more preferably 10 to 25 wt%.

Exhibit 1013, Pages 11-12.

VIII. Specific Grounds for Invalidity of the ‘072 Patent

A. Grounds 1a-1b: WO 2011/017095 A2 (“Stauffer”) Anticipates and/or Renders Obvious Claim 1 of the ‘072 Patent

1. Ground 1a - WO 2011/017095 A2 anticipates Claim 1

67. In Example 4 of Stauffer, several ingredients are combined: a sodium bicarbonate buffer, deionized (“DI”) water, Turpinal[®] SL (a trade name for the

chelating agent etidronic acid), triacetin, an aqueous solution of Elvanol[®] 51-04,¹ aqueous hydrogen peroxide, and *T. neapolitana* perhydrolase enzyme (a biological catalyst). Exhibit 1012, Page 63, lines 8-17. Three experimental runs were performed: one with neither an enzyme nor Elvanol[®] 51-04, one with the enzyme but without Elvanol[®] 51-04, and one with both the Elvanol[®] 51-04 and the enzyme present. Exhibit 1012, Page 63, lines 26-32. In all three runs, peracetic acid was detected even after 1 minute, with 114 ppm (i.e., parts per million) being the minimum amount of PAA detected. Exhibit 1012, Page 64, Table 1.

68. Therefore, Example 4 of Stauffer discloses to a POSA aqueous mixtures of triacetin and hydrogen peroxide with small amounts (in the hundreds or thousands of ppm) of peracetic acid (PAA) formed therein. Exhibit 1012, Pages 63-64.

69. In Example 5 of Stauffer, another set of three experimental runs was performed with similar ingredients, including water, triacetin, and aqueous hydrogen peroxide, except that the polyol was a mixture of Elvanol[®] 51-04, PEG (i.e., polyethylene glycol)-300, and Silwet[®] L-77 (a trade name for the trisiloxane ethoxylate surfactant). Exhibit 1012, Page 64, lines 14-24. In all three runs, peracetic

¹ Elvanol[®] 51-04 is a “partially hydrolyzed [] polyvinyl alcohol, 88% grade.” Exhibit 1012, Page 56, lines 24-25.

acid (PAA) was detected even after 1 minute, with 114 ppm being the minimum amount of PAA detected. Exhibit 1012, Page 65, Table 2.

70. Therefore, Example 5 of Stauffer discloses to a POSA aqueous mixtures of triacetin and hydrogen peroxide with small amounts (in the hundreds or thousands of ppm) of peracetic acid formed therein. Exhibit 1012, Pages 64-65.

71. The solutions in Examples 4 and 5 of Stauffer thus contain all of the components listed in Claim 1 of the '072 Patent: "aqueous hydrogen peroxide", "triacetin", "water", and 114 ppm or more of "peracetic acid", which is commonsensically "a trace amount of peracetic acid". Under the other possible interpretation (see above) of the claim term "a trace amount of peracetic acid" as less than a 1% solution of peracetic acid, 114 ppm is undeniably less than 1% (1 wt% = 10,000 ppm). Therefore, Claim 1 of the '072 Patent is anticipated by Stauffer.

2. Ground 1b - Claim 1 is obvious over WO 2011/017095 A2

72. By its disclosures in Examples 4 and 5, Stauffer makes it obvious to a POSA that peracetic acid is present in a solution comprising water, triacetin, and aqueous hydrogen peroxide. A POSA would have understood that peracetic acid will be present, and in amounts of less than 1%, because Stauffer shows that PAA is formed in hydrogen peroxide-triacetin aqueous compositions that contain an enzyme with or without a polyol, as well as in an experiment containing neither an enzyme

nor a polyol, in amounts under 1%. Exhibit 1012, Pages 63-65 (Examples 4 and 5; Tables 1 and 2).

B. Grounds 2a-2d: JP 2006-045147 A (“Okano”) Anticipates and/or Renders Obvious Claims 1-3 of the ‘072 Patent

1. Claim 1 of the ‘072 Patent

a. Ground 2a - JP 2006-045147 A Anticipates Claim 1

73. In its Example 1, Okano discloses combining triacetin, aqueous hydrogen peroxide, and water, along with an alkaline aqueous solution containing sodium hydroxide and organic phosphonic acid. Exhibit 1013, paragraph 0057.

74. Paragraph 0059 of Okano is directed to “ Measurement of Organic Peroxy Acid Concentration” for sterilizing cleaner composition (I) and states that “an organic peroxy acid concentration (as peracetic acid concentration) was found using the following formula” and immediately thereafter refers to “[o]rganic peroxyacid (peracetic acid) concentration (%)” in the formula. Exhibit 1013, Page 20. Paragraph 0057 (Example 1) is entitled “Preparation of Sterilizing Cleaner Composition (I).”

75. The four components (a. through d.) listed in Claim 1 of the ‘072 Patent are thus expressly present in the solution of Example 1 of Okano. Specifically, the mixture formed in Okano’s Example 1 contained triacetin, aqueous hydrogen peroxide, and water, and an organic peracid was formed therein. Furthermore, the

organic peracid formed in Example 1 of Okano was necessarily peracetic acid because component (A) was triacetin.

76. Therefore, Example 1 of Okano discloses to a POSA mixtures in water of triacetin and aqueous hydrogen peroxide with small amounts of peracetic acid. Exhibit 1013, paragraphs 0057 and 0059.

b. Ground 2b - Claim 1 is obvious over JP 2006-045147 A

77. By its express disclosures, especially in Example 1, Okano makes it obvious to a POSA that peracetic acid is present in a mixture comprising water, triacetin, and aqueous hydrogen peroxide.

78. A POSA would have understood that peracetic acid will be present in such a solution because Okano shows that peracetic acid is necessarily formed in hydrogen peroxide-triacetin aqueous solutions. Exhibit 1013, paragraphs 0057 and 0059 (Pages 19-20).

2. Claims 2-3 of the '072 Patent

a. Ground 2c - JP 2006-045147 A Anticipates Claims 2-3

79. Dependent Claims 2 and 3 of the '072 Patent recite additional features beyond those of independent Claim 1: molar (mole) ratios of hydrogen peroxide to triacetin, as well as wt% concentrations of both hydrogen peroxide and triacetin in the claimed solution. Claim 2 recites ranges for these features, while Claim 3 recites specific values for these features.

i. Molar (mole) ratios

80. In Claim 2 of the '072 Patent, the “mole” ratio of hydrogen peroxide to triacetin is “about 2.98:1 to about 12.84:1.”

81. In Claim 3 of the '072 Patent, the “mole” ratio of hydrogen peroxide to triacetin is “about 3.8:1.”

82. The molar ratios in Okano are disclosed as component (A) over component (B1). To directly compare the values disclosed in Okano with the molar ratios recited in Claims 2 and 3 of the '072 Patent, the $(A)/(B1) = 1/10$ to $20/1$ in Okano needs to be inverted to $(B1)/(A)$, which is $10/1$ to $1/20$. To make the direct comparison easier, the lower, $1/20$ numerical ratio in Okano can be expressed as $0.05:1$.² Thus, in Okano the molar ratio of component (B1) to component (A), or of hydrogen peroxide to triacetin, is $0.05:1$ to $10:1$.

83. This hydrogen peroxide to triacetin molar ratio in Okano, $0.05:1$ to $10:1$, greatly overlaps with the corresponding molar ratio range recited in Claim 2 of the '072 Patent (i.e., “about 2.98:1 to about 12.84:1”).

84. The hydrogen peroxide to triacetin molar ratio disclosed in Okano, $0.05:1$ to $10:1$, clearly encompasses the molar ratio value recited in Claim 3 of the '072 Patent (i.e., “about 3.8:1”).

² This conversion is performed by dividing both 20 and 1 by 20. $20 \div 20 = 1$; $1 \div 20 = 0.05$.

ii. Concentrations

85. Claims 2 and 3 of the '072 Patent also specify concentrations (in wt%) for both hydrogen peroxide and triacetin.

a) Hydrogen peroxide concentrations

86. In Claim 2 of the '072 Patent, the concentration range of aqueous hydrogen peroxide is “about 23% to about 40%.”³

87. In Claim 3 of the '072 Patent, the concentration of aqueous hydrogen peroxide is “about 27%.”

88. Okano, in its paragraph 0035, states that “the amount of component (B1) [i.e., the concentration of hydrogen peroxide] is preferably 1 to 30 wt%.” Exhibit 1013, Page 12.

89. The “preferabl[e]” 1 to 30% concentration range taught in Okano for hydrogen peroxide, component (B1), thus greatly overlaps the hydrogen peroxide concentration range recited in Claim 2 of the '072 Patent (“about 23% to about 40%”). Moreover, the “about 23% to about 40%” claimed in Claim 2 of the '072 Patent also overlaps with even still “more preferabl[e]” and narrower 5 to 25% and 10 to 25% hydrogen peroxide concentration ranges disclosed in Okano. And the “preferabl[e]” hydrogen peroxide concentration range of Okano clearly

³ According to the specification of the '072 Patent, “[t]he terms ‘percent’ and ‘%’ mean weight [i.e., “wt”] percent, except when referring to the percent converted.” Exhibit 1001, column 7, lines 58-59.

encompasses the hydrogen peroxide concentration value recited in Claim 3 of the ‘072 Patent (“about 27%”).

b) Triacetin concentrations

90. In Claim 2 of the ‘072 Patent, the triacetin concentration range is “about 20% to about 53%.”

91. In Claim 3 of the ‘072 Patent, the triacetin concentration is “about 46%.”

92. Okano, in its paragraph 0035, states that “[t]he amount of component (A) [i.e., the concentration of triacetin] in the composition for producing sterilizing cleaner is preferably 20 to 90 wt%.” Exhibit 1013, Page 12.

93. The “preferabl[e]” concentration range taught in Okano for component (A), triacetin, namely 20 to 90% by weight, clearly encompasses the triacetin concentration range claimed in Claim 2 of the ‘072 Patent (“about 20% to about 53%”). Moreover, the “about 20% to about 53%” triacetin concentration range claimed in Claim 2 of the ‘072 Patent greatly overlaps with even still “more preferabl[e]” and narrower 30 to 90% and 40 to 80% triacetin concentration ranges disclosed in Okano. Similarly the “preferabl[e]” 20 to 90% triacetin concentration range disclosed in Okano clearly encompasses the triacetin concentration value in Claim 3 of the ‘072 Patent (“about 46%”). In fact, this “about 46%” triacetin concentration value claimed in Claim 3 of the ‘072 Patent is also clearly

encompassed by even still “more preferabl[e]” and narrower 30 to 90% and 40 to 80% triacetin concentration ranges disclosed in Okano.

iii. Molar ratios + concentrations

94. For ease of reference, the ranges and values discussed above are also set forth in the following Table (where all percentages are wt% and the claim term “about” modifying all the ranges and values claimed in Claims 2 and 3 of the ‘072 Patent is omitted for brevity):

	Molar/mole ratio H ₂ O ₂ :triacetin	H ₂ O ₂ concentration	Triacetin concentration	Water content
Okano	0.05:1 to 10:1	1% to 30%	20% to 90%	1% to 25%
Claim 2	2.98:1 to 12.84:1	23% to 40%	20% to 53%	7% to 57%*
Claim 3	3.8:1	27%	46%	27%*

* Calculated.

95. Okano discloses a water content for the first composition for producing a sterilizing cleaner, stating that “[i]n order to suppress reaction between component (A) and component (B) during storage and maintain stability when the composition is in a liquid form, the water content in the liquid composition is preferably 1 to 25 wt%, more preferably 5 to 20 wt%, and even more preferably 5 to 15 wt%.” Exhibit 1013, paragraph 0051.

96. While not explicitly claimed in the '072 Patent, the water content can be calculated as the remainder from the concentration values recited for hydrogen peroxide and triacetin in Claims 2 and 3. The results are shown above in the last column of the Table. The broadest water content range taught in Okano greatly overlaps with the range implicit in Claim 2 of the '072 Patent, and the water content value implicit in Claim 3 of the '072 Patent is quite close to the upper end of the broadest water content range taught in Okano. (The water content calculations for Claims 2 and 3 of the '072 Patent assume that the “trace amount” of peracetic acid is below 1 wt%, i.e., is small enough to have only a negligible effect on the calculations.)

97. The “preferabl[e]” ranges and values from Okano listed in the Table are for the first composition for producing a sterilizing cleaner disclosed in Okano. The ranges and values for the second composition of Okano for producing a sterilizing cleaner are quite similar: the molar ratio range is the same, and the hydrogen peroxide and triacetin concentration ranges are even broader (0.1% to 50% for H₂O₂ and 0.1% to 90% for triacetin). Exhibit 1013, paragraphs 0037 and 0038. Because Okano recommends packaging components (A) and (B1) separately for the second composition, the first composition would have been deemed by a POSA to be more relevant, although the overall conclusion would have been the same regardless. Exhibit 1013, paragraph 0043.

98. As established above for Claim 1 of the '072 Patent, Okano discloses to a POSA solutions containing triacetin, hydrogen peroxide, water, and at least trace amounts of peracetic acid. Okano also discloses that these aqueous solutions can contain the hydrogen peroxide and triacetin at specific molar ratios and specific weight concentration ranges that overlap with, or encompass, the ranges claimed in Claim 2 of the '072 Patent and the corresponding values claimed in Claim 3 of the '072 Patent, respectively. Therefore, Okano anticipates Claims 2 and 3 of the '072 Patent.

99. Because the “preferabl[e]” ranges expressly disclosed in Okano both overlap with all of the ranges claimed in Claim 2 of the '072 Patent and also encompass all of the values claimed in Claim 3 of the '072 Patent, Claims 2 and 3 of the '072 Patent are anticipated by JP 2006-045147 A.

b. Ground 2d - Claims 2 and 3 are obvious over JP 2006-045147 A

100. By its express disclosures, especially in Example 1, Okano makes it obvious to a POSA that peracetic acid is present in a mixture comprising water, triacetin, and aqueous hydrogen peroxide. A POSA would have understood that peracetic acid will be present in such an aqueous solution because Okano shows that peracetic acid is necessarily formed in hydrogen peroxide-triacetin aqueous solutions. Exhibit 1013, paragraphs 0057 and 0059 (Pages 19-20).

101. In addition, the ranges for the molar ratios of hydrogen peroxide to triacetin, the ranges for the hydrogen peroxide concentration, and the ranges for the triacetin concentration disclosed in Okano overlap with, or encompass, the ranges and values claimed in Claims 2 and 3 of the '072 Patent, thereby making Claims 2 and 3 of the '072 Patent obvious in view of Okano.

IX. Reservation of Rights

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

X. Attestation

I declare that all statements made herein of my own knowledge are true to the best of my knowledge and that all statements made on information and belief are believed by me to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: 08/25/2025



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***Curriculum vitae* of Dr. Alexander M. Klibanov**

Nationality: Naturalized U.S. Citizen (1983)

Education: 1974 Ph.D. in Chemical Enzymology, Moscow University

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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,
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2004 UNAM Distinguished Lecturer, National University of Mexico (Mexico
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2001 Walter Enz Lecturer in Pharmaceutical Chemistry, University of Kansas

2001 Elected a Corresponding Fellow of the Royal Society of Edinburgh
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2000 Merck Distinguished Lecturer, Rutgers University

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

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1996 Perkin-Elmer Distinguished Lecturer, University of Pittsburgh

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- 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
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Professional Experience:

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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	

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12. Gresser, J.D., Trantolo, D.J., Langer, R., Lewandrowski, K.-U., Klibanov, A.M., Wise, D.L. Resorbable interbody spinal fusion devices. U.S. Patent No. 6,241,771; June 5, 2001.

13. Trantolo, D.J., Langer, R., Klibanov, A.M., Wise, D.L. Buffered resorbable internal fixation devices and methods for making material therefor. U.S. Patent No. 6,419,945; July 16, 2002.
14. Gresser, J.D., Trantolo, D.J., Langer, R., Lewandrowski, K.-U., Klibanov, A.M., Wise, D.L. Method of making biodegradable interbody spinal fusion devices. U.S. Patent No. 6,548,002; April 15, 2003.
15. Klibanov, A.M. Nonaqueous solutions and suspensions of macromolecules for pulmonary delivery. U.S. Patent No. 6,660,715; December 9, 2003.
16. Tiller, J.C., Lewis, K., Liao, C.-J., Klibanov, A.M. Antimicrobial polymeric surfaces. U.S. Patent No. 7,151,139; December 19, 2006.
17. Hirsh, J.C., Fleming, A.B., Rariy, R.V., Klibanov, A.M. Abuse-deterrent drug formulations. U.S. Patent No. 7,771,707; August 10, 2010.
18. Hirsh, J.C., Fleming, A.B., Rariy, R.V., Klibanov, A.M. Abuse-deterrent drug formulations. U.S. Patent No. 8,449,909; May 28, 2013.
19. Rariy, R.V., Fleming, A.B., Hirsh, J.C., Klibanov, A.M. Abuse-deterrent pharmaceutical compositions of opioids and other drugs. U.S. Patent No. 8,557,291; October 15, 2013.
20. Hirsh, J., Fleming, A.B., Rariy, R.V., Klibanov, A.M. Abuse-deterrent drug formulations. U.S. Patent No. 8,758,813; June 24, 2014.
21. Hirsh, J.C., Klibanov, A.M., Swager, T.M., Buchwald, S.L., Lo, W.Y., Fleming, A.B., Rariy, R.V. Abuse-deterrent pharmaceutical compositions of opioids and other drugs. U.S. Patent No. 9,044,398; June 2, 2015.
22. Schaer, T.P., Stewart, S., Klibanov, A.M. Antibacterial coatings that inhibit biofilm formation on implants. U.S. Patent No. 9,089,407; July 28, 2015.
23. Rariy, R.V., Fleming, A.B., Hirsh, J.C., Klibanov, A.M. Abuse-deterrent pharmaceutical compositions of opioids and other drugs. U.S. Patent No. 9,248,195; February 2, 2016.
24. Rariy, R.V., Fleming, A.B., Hirsh, J., Klibanov, A.M. Abuse-deterrent pharmaceutical compositions of opioids and other drugs. U.S. Patent No. 9,592,200; March 14, 2017.

25. Haldar, J., An, D., Álvarez de Cienfuegos, L., Chen, J., Klivanov, A.M. Polymeric coatings that inactivate viruses and bacteria. U.S. Patent Appl. Publ. No. 2010/0136072; June 3, 2010.
26. Pedersen, M., Stanley, M., Gouin, S., Klivanov, A.M, Hsu, B.B. Antimicrobial quat coating on fabrics. PCT Intl. Appl. W O 2012/06561, 2012.
27. Haldar, J., Alvarez de Cienfuegos, L., Klivanov, A.M., Chen, J. Bi-functional polymer-attached inhibitors of influenza virus. PCT Intl. Appl. WO 2009/032605, 2012.
28. Klivanov, A.M., Su, E. Neat liquid pharmaceutical formulations. U.S. Patent No. 9,731,026; August 15, 2017.
29. Hirsh, J.C., Fleming, A.B., Rariy, R.V., Klivanov, A.M. Abuse-deterrent pharmaceutical compositions. U.S. Patent No. 9,763,883; September 19, 2017.
30. Larson, A.M., Weight, A.K., Love, K., Crane, A., Langer, R.S., Klivanov, A.M. Liquid pharmaceutical formulations for injection comprising thiamine pyrophosphate 1-(3-aminopropyl)-2-methyl-1H-imidazole and uses thereof. U.S. Patent No. 9,913,905; March 13, 2018.
31. Larson, A.M., Love, K., Weight, A.K., Crane, A., Langer, R.S., Klivanov, A.M. Liquid pharmaceutical formulations for injection comprising procaine and uses thereof. U.S. Patent No. 9,925,263; March 27, 2018.
32. Larson, A.M., Love, K., Weight, A.K., Crane, A., Langer, R.S., Klivanov, A.M. Liquid pharmaceutical formulations for injection comprising Yellow 5 Orange G and uses thereof. U.S. Patent No. 10,179,172; March 27, 2018.
33. Schaer, T.P., Stewart, S., Klivanov, A.M. Antibacterial coatings that inhibit biofilm formation on implants. U.S. Patent No. 10,500,317; December 10, 2019.
34. Hirsh, J.C., Fleming, A.B., Rariy, R.V., Klivanov, A.M. Abuse-deterrent drug formulations. U.S. Patent No. 10,525,052; January 7, 2020.
35. Abrams, R., Klivanov, A.M., Langer, R., Fredrickson, G. Pharmaceutical container with pH protective layer deposited by atomic layer deposition. U.S. Patent No. 12,109,173; October 8, 2024.

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.
31. Tufts University Workshop on Immobilized Enzymes and Proteins (Medford, MA). June 1983.
32. Gordon Conference on Organic Reactions and Processes (New Hampton, NH). July 1983.
33. Symposium "Biocatalysis: New Discoveries and Uses", Meeting of the American Society for Industrial Microbiology (Sarasota, FL). August 1983.
34. Monsanto Co. (St. Louis, MO). September 1983.
35. Pasteur Biosciences '83 Conference (Paris, France). September 1983.

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

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

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

93. Catalytica Annual Science and Technology Symposium (San Jose, CA). September 1986.
94. International Conference on Enzyme Engineering (Cambridge, England). September 1986.
95. Ohio State University (Columbus, OH). October 1986.
96. Michigan State University (Lansing, MI). October 1986.
97. Biotechnology Process Engineering Symposium (Cambridge, MA). October 1986.
98. University of Delaware (Newark, DE). November 1986.
99. American Red Cross Blood Research Institute (Bethesda, MD). November 1986.
100. International Symposium on Biocatalysis in Non-Aqueous Solvents (Wageningen, The Netherlands). December 1986.
101. University of Trondheim (Trondheim, Norway). December 1986.
102. Colgate-Palmolive Research Center (Piscataway, NJ). January 1987.
103. International Paper Co. (Tuxedo Park, NY). January 1987.
104. University of Massachusetts (Amherst, MA). February 1987.
105. American Society for Microbiology Biocatalysis Symposium (Atlanta, GA). March 1987.
106. Hope College (Holland, MI). March 1987.
107. Pfizer Corporate Research Center (Groton, CT). April 1987.
108. OBBS Symposium on Protein Engineering (Ottawa, Canada). April 1987.
109. University of Texas (Austin, TX). April 1987.
110. Florida Catalysis Conference (Palm Coast, FL). May 1987.
111. PPG Industries (Barberton, OH). May 1987.
112. Abbott Laboratories (North Chicago, IL). May 1987.

113. American Oil Chemists Society Symposium on Lipases (New Orleans, LA). May 1987.
114. Argonne National Laboratory (Argonne, IL). June 1987.
115. Canadian Chemical Conference (Quebec City, Canada). June 1987.
116. Squibb Co. (New Brunswick, NJ). June 1987.
117. FEBS Annual Meeting (Ljubljana, Yugoslavia). July 1987.
118. L'Oreal Research Institute (Paris, France). July 1987.
119. International Symposium on Biointeractions (Cambridge, England). July 1987.
120. Eli Lilly Co. (Indianapolis, IN). August 1987.
121. Upjohn Co. (Kalamazoo, MI). September 1987.
122. International Enzyme Engineering Conference (Santa Barbara, CA). October 1987.
123. Shell Development Co. (Houston, TX). October 1987.
124. DuPont Experimental Station (Wilmington, DE). October 1987.
125. University of Helsinki (Helsinki, Finland). November 1987.
126. International Conference on Bioreactors and Biotransformations (Gleneagles, Scotland). November 1987.
127. Sandoz Co. (Basel, Switzerland). November 1987.
128. University of Waterloo (Waterloo, Canada). December 1987.
129. Norwegian Biochemical Society Annual Meeting (Bejito, Norway). January 1987.
130. Rutgers University (New Brunswick, NJ). February 1988.
131. University of Ottawa (Ottawa, Canada). February 1988.
132. Boston Biomedical Research Institute (Boston, MA). March 1988.

133. Princeton University (Princeton, NJ). March 1988.
134. Royal Society of Chemistry Meeting (Kent, England). April 1988.
135. Stanford University (Stanford, CA). May 1988.
136. University of Graz (Graz, Austria). May 1988.
137. Belgian Organic Chemistry Symposium (Ghent, Belgium). May 1988.
138. Dow Chemical Co. (Midland, MI). May 1988.
139. Michigan State University (Lansing, MI). May 1988.
140. American Chemical Society Meeting (Toronto, Canada). June 1988.
141. Proctor & Gamble Co. (Cincinnati, OH). June 1988.
142. International Congress of Biochemistry (Prague, Czechoslovakia). July 1988.
143. International Biotechnology Symposium (Paris, France). July 1988.
144. Gordon Conference on Catalysis (Newport, RI). August 1988.
145. Conference on Biocatalytic Synthesis of Organic Compounds (Saratoga, NY). August 1988.
146. International Symposium on Thermodynamics Applied to Biological Systems (Santa Margherita, Italy). September 1988.
147. Cornell University (Ithaca, NY). September 1988.
148. Eastman Kodak Co. (Kingsman, TN). September 1988.
149. Symposium on Biotechnology Challenges in the Food Industry (Williamsburg, VA). October 1988.
150. University of California at Irvine (Irvine, CA). October 1988.
151. UCSF Symposium on Protein and Drug Design (San Francisco, CA). October 1988.
152. Boston University (Boston, MA). October 1988.
153. Wayne State University (Detroit, MI). November 1988.

154. Kyoto Symposium on Frontiers in Biocatalysis (Kyoto, Japan). November 1988.
155. Rohm & Haas Co. (Spring House, PA). January 1989.
156. Block Drug Co. (Jersey City, NJ). January 1989.
157. State University of New York (Albany, NY). March 1989.
158. Scripps Clinic and Research Foundation (La Jolla, CA). April 1989.
159. Texas A&M University (College Station, TX). May 1989.
160. University of Texas (Austin, TX). May 1989.
161. International Congress of Food Engineering (Cologne, F.R.G.). May 1989.
162. University of Groningen (Groningen, The Netherlands). June 1989.
163. Gordon Conference on Enzymes, Coenzymes, and Metabolic Pathways (Meridan, NH). July 1989.
164. American Peptide Symposium (La Jolla, CA). July 1989.
165. International Symposium on Prospects in Protein Engineering (Haren, The Netherlands). August 1989.
166. Connaught Laboratories (Toronto, Canada). September 1989.
167. University of Georgia (Athens, GA). October 1989.
168. Spanish National Congress of Biochemistry (Alicante, Spain). October 1989.
169. Symposium on Receptor- and Enzyme- Based Drug Design (Chapel Hill, NC). October 1989.
170. Wesleyan University (Middletown, CT). November 1989.
171. University of Wisconsin (Madison, WI). February 1990.
172. Merck Sharp & Dohme Research Laboratories (Rahway, NJ). February 1990.
173. International Symposium on Biochemical Engineering (Stuttgart, F.R.G.). March 1990.

174. University of Geneva (Geneva, Switzerland). March 1990.
175. University of Lausanne (Lausanne, Switzerland). March 1990.
176. University of Bern (Bern, Switzerland). March 1990.
177. University of Fribourg (Fribourg, Switzerland). March 1990.
178. International Conference on Protein Stability (Cambridge, England). March 1990.
179. AFRC Institute of Food Research (Reading, England). March 1990.
180. Lehigh University (Bethlehem, PA). April 1990.
181. Biotechnology Research Institute (Montreal, Canada). April 1990.
182. Ohio State University (Columbus, OH). April 1990.
183. Pharmaceutical Manufacturers Association Annual Meeting (St. Louis, MO). April 1990.
184. International Conference on Industrial Use of Enzymes (Chicago, IL). May 1990.
185. Korea Advanced Institute of Science and Technology (Seoul, Korea). June 1990.
186. Academia Sinica and National Taiwan University (Taipei, Taiwan). June 1990.
187. Gordon Conference on Biocatalysis (Plymouth, NH). June 1990.
188. IUPAC Conference on Organic Synthesis (Helsinki, Finland). July 1990.
189. International Conference on Solution Chemistry (Ottawa, Canada). August 1990.
190. Gordon Conference on Biomolecular Recognition (Plymouth, NH). August 1990.
191. University of Naples (Naples, Italy). September 1990.

192. International Conference on Water and Life (Crans-sur-Sierre, Switzerland). September 1990.
193. International Symposium on Thermodynamic Basis of Protein Structure and Function (Kansas City, MO). October 1990.
194. Johns Hopkins University (Baltimore, MD). October 1990.
195. Institute of Medicine Workshop on Microheterogeneity of Biological Macromolecules (Arlington, VA). November 1990.
196. U.S.-Japan Biotechnology Conference (Honolulu, HI). January 1991.
197. Ciba-Geigy Corp. (Summit, NJ). February 1991.
198. City University of New York (New York, NY). March 1991.
199. Rensselaer Polytechnic Institute (Troy, NY). March 1991.
200. Bristol-Myers Squibb Co. (Wallingford, CT). April 1991.
201. British Biochemical Society Meeting (Reading, England). April 1991.
202. University of California at Berkeley (Berkeley, CA). April 1991.
203. California Institute of Technology (Pasadena, CA). April 1991.
204. Merck, Sharp & Dohme Research Laboratories (West Point, PA). May 1991.
205. Bristol-Myers Squibb Research Institute (Princeton, NJ). May 1991.
206. International Conference on Biocatalysis (Orlando, FL). June 1991.
207. U.S. Army Research, Development and Engineering Center (Natick, MA). July 1991.
208. Gordon Conference on Natural Products (Plymouth, NH). July 1991.
209. Lederle-Praxis Biologicals Co. (Sanford, NC). July 1991.
210. International Biochemistry Congress (Jerusalem, Israel). August 1991.
211. American Chemical Society Meeting (New York, NY). August 1991.
212. International Enzyme Engineering Conference (Kona, HI). September 1991.

213. University of Lowell (Lowell, MA). October 1991.
214. Rutgers University (Piscataway, NJ). November 1991.
215. International Symposium on Enzymes in Organic Synthesis (New Delhi, India). January 1992.
216. International BioSymposium Nagoya '92 (Nagoya, Japan). January 1992.
217. International Symposium on Biomolecules in Organic Solvents (Taxco, Mexico). February 1992.
218. Rockefeller University (New York, NY). March 1992.
219. Symposium on Molecular Chirality of the Pharmaceutical Society of Japan (Tokyo, Japan). April 1992.
220. Conference on Enzymes in Organic Chemistry of the Dutch Chemical Society (Wageningen, The Netherlands). April 1992.
221. International Symposium on Bioprocessing of Coal (Clearwater Beach, FL). May 1992.
222. Exxon Workshop on New Leads in Coal Depolymerization (Montgomery, TX). May 1992.
223. Italian Symposium on Biochemical Biotechnology (Capri, Italy). June 1992.
224. Gordon Conference on Biocatalysis (Meriden, NH). July 1992.
225. FEBS Meeting (Dublin, Ireland). August 1992.
226. International Biotechnology Symposium (Washington, DC). August 1992.
227. International Symposium Bio Japan '92 (Yokohama, Japan). August 1992.
228. Texas College of Osteopathic Medicine (Fort Worth, TX). October 1992.
229. Rutgers University (Newark, NJ). October 1992.
230. Schering-Plough Co. (Bloomfield, NJ). November 1992.
231. International Symposium ISOPOW -V: *Properties of Water in Foods* (Peniscola, Spain). November 1992.

- 232. Carlsberg Laboratory (Copenhagen, Denmark). November 1992.
- 233. International Food Technology Conference (The Hague, The Netherlands). November 1992.
- 234. Singapore Institute of Standards and Industrial Research (Singapore). November 1992.
- 235. Drew University (Madison, NJ). December 1992.
- 236. Northeastern University (Boston, MA). January 1993.
- 237. Ciba Corning Diagnostics Corp. (Irvine, CA). January 1993.
- 238. University of Kansas (Lawrence, KS). January 1993.
- 239. 6th International Symposium on Recent Advances in Drug Delivery Systems (Salt Lake City, UT). February 1993.
- 240. Pennsylvania State University (University Park, PA). March 1993.
- 241. Northwestern University (Evanston, IL). March 1993.
- 242. International Symposium on Technologies for the Production of Enantiomerically Pure Chemicals (Amelia Island, FL). March 1993.
- 243. Gordon Conference on Bioanalytical Sensors (Ventura, CA). March 1993.
- 244. Pharmaceutical Manufacturers Association Analytical R&D/Pharmaceutical Development Subsections Joint Annual Meeting (Lake Buena Vista, FL). April 1993.
- 245. University of Massachusetts Symposium on Breakthrough Technologies: *Paradigms for a New Century* (Amherst, MA). May 1993.
- 246. Parke-Davis Corp. (Ann Arbor, MI). May 1993.
- 247. NutraSweet Co. (Mt. Prospect, IL). June 1993.
- 248. IGT/GRI Workshop on Novel Concepts for the Production of Regio- and Stereospecific Compounds (Chicago, IL). June 1993.
- 249. Northeast Regional Meeting of the American Chemical Society (Boston, MA). June 1993.

250. Institute of Food Technologists' Biotechnology Meeting (Chicago, IL). July 1993.
251. Annual Meeting of Department of Energy's Biological and Chemical Technology Research Program Principal Investigators (Tiburon, CA). July 1993.
252. Allied-Signal Corp. (Des Plains, IL). July 1993.
253. American Chemical Society Meeting (Chicago, IL). August 1993.
254. University of Illinois at Urbana-Champaign (Urbana, IL). September 1993.
255. International Enzyme Engineering Conference (Deauville, France). September 1993.
256. Queens College (Flushing, NY). November 1993.
257. Exxon Chemical Research Meeting (Galveston, TX). November 1993.
258. Hoffmann-LaRoche Co. (Nutley, NJ). December 1993.
259. U.S.-Japan Symposium on Drug Delivery (Maui, HI). December 1993.
263. North Dakota State University (Fargo, ND). February 1994.
260. Annual Meeting of the American Institute for Medical and Biological Engineering (Washington, DC). March 1994.
261. Rhone-Poulenc Rorer Symposium on Visions in Chemistry (Collegeville, PA). May 1994.
262. International Flavors & Fragrances R&D (Union Beach, NJ). May 1994.
263. Istituto degli Ormoni (Milan, Italy). June 1994.
264. Gordon Conference on Enzymes, Coenzymes, and Metabolic Pathways (Meriden, NH). July 1994.
265. Annual Meeting of Department of Energy's Biological and Chemical Technology Research Program Principal Investigators (Denver, CO). July 1994.

266. William S. Johnson Symposium in Organic Chemistry (Stanford, CA). October 1994.
267. R.W. Johnson Pharmaceutical Research Institute (Spring House, PA). October 1994.
268. International Congress of Biochemical Engineering (Mexico City, Mexico). October 1994.
269. National University of Mexico (Mexico City, Mexico). October 1994.
270. DuPont Merck Pharmaceutical Co. (Deepwater, NJ). December 1994.
271. Symposium on Therapeutic Protein Production and Processing (Cambridge, MA). January 1995.
272. International Symposium on Biocatalysts for Flavor Production, BioFlavour '95 (Dijon, France). February 1995.
273. Institut Pasteur (Paris, France). February 1995.
274. Florida State University (Tallahassee, FL). March 1995.
275. Abbott Laboratories (North Chicago, IL). March 1995.
276. University of Maryland, Baltimore County (Baltimore, MD). March 1995.
277. University of California at San Diego (La Jolla, CA). April 1995.
278. Great Lakes Regional Meeting of the American Chemical Society (LaCrosse, W I). June 1995.
279. Gordon Conference on Bioorganic Chemistry (Andover, NH). June 1995.
280. Annual Meeting of Department of Energy's Biochemical and Chemical Technology Research Principal Investigators (Albuquerque, NM). July 1995.
281. International Symposium "Biocatalysis-95" (Suzdal, Russia). August 1995.
282. International Enzyme Engineering Conference (San Diego, CA). October 1995.
283. Symposium on Biomacromolecules: *From 3-D Structure to Applications* (Pasco, W A). October 1995.

284. Enzymol International Inc. (Columbus, OH). December 1995.
285. International Symposium PacifiChem '95 (Honolulu, HI). December 1995.
286. 3rd U.S.-Japan Symposium on Drug Delivery (Maui, HI). December 1995.
287. New England Section of the Society for Industrial Microbiology (Cambridge, MA). February 1996.
288. Brown University (Providence, RI). February 1996.
289. University of Pittsburgh (Pittsburgh, PA). February 1996.
290. Food Research Institute (Reading, England). March 1996.
291. International Symposium Chiral USA '96 (Boston, MA). May 1996.
292. BP Catalyst Colloquium (Uxbridge, England). June 1996.
293. International Symposium on Homogeneous Catalysis (Princeton, NJ). August 1996.
294. Juan March Foundation's International Workshop on Novel Biocatalysts (Madrid, Spain). March 1997.
295. University of Kentucky (Lexington, KY). April 1997.
296. Gordon Conference on Organic Reactions and Processes (Henniker, NH). August 1997.
297. Novo Nordisk Symposium on Protein Stability (Klampenborg, Denmark). August 1997.
298. International Enzyme Engineering Conference (Beijing, China). October 1997.
299. Biogen Inc. (Cambridge, MA). December 1997.
300. INBIO Europe'98 Conference on Advances in Industrial Biocatalysis (Amsterdam, The Netherlands). February 1998.
301. International Symposium on Stability and Stabilization of Biocatalysts (Córdoba, Spain). April 1998.

302. International Symposium on Protein Structure, Stability and Folding: *Fundamental and Medical Aspects* (Moscow, Russia). June 1998.
303. International Conference on Protein Stabilization (Leeds, England). June 1998.
304. University of Virginia (Charlottesville, VA). September 1998.
305. Danish Biotechnology Conference (Vejle, Denmark). May 1999.
306. International Conference on Biocatalysis and Biotransformation Biotrans '99 (Giardini Naxos, Italy). September 1999.
307. Annual Meeting of the American Association of Pharmaceutical Scientists (New Orleans, LA). November 1999.
308. Brandeis University (Waltham, MA). November 1999.
309. Rutgers University (Piscataway, NJ). March 2000.
310. Chiral USA 2000 Conference (Boston, MA). May 2000.
311. Land O'Lakes Conference on Solid-State Reactivity in Pharmaceutical Systems (Merrimac, W I). June 2000.
312. Agouron Pharmaceuticals Inc. (San Diego, CA). July 2000.
313. U.S. Patent and Trademark Office Technology Fair (Arlington, VA). July 2000.
314. 23rd Gulf Coast Chemistry Conference (Pensacola, FL). September 2000.
315. Avon Products (Suffern, NY). November 2000.
316. Procter & Gamble Co. (Cincinnati, OH). November 2000.
317. Flamel Technologies (Venissieux, France). December 2000.
318. BioVision 2001 International Conference (Lyon, France). February 2001.
319. 9th Baxter Science and Technology Symposium (Hyland, IL). May 2001.
320. International Symposium on Applications of Enzymes in Chemical and Biological Defense (Orlando, FL). May 2001.

321. International Conference on Applied Biocatalysis (Trondheim, Norway). June 2001.
322. PPG Industries (Allison Park, PA). August 2001.
323. University of Kansas (Lawrence, KS). August 2001.
324. Alkermes Inc. (Cambridge, MA). October 2001.
325. 6th U.S.-Japan Symposium on Drug Delivery Systems (Maui, HI). December 2001.
326. Acambis Inc. (Cambridge, MA). January 2002.
327. Baxter BioScience Co. (Duarte, CA). January 2002.
328. International Symposium on Challenges in Drug Discovery and Development in the 21st Century (Kolkata, India). March 2002.
329. National Institute of Standards and Technology (Gaithersburg, MD). April 2002.
330. Albany Molecular Research, Inc. (Mt. Prospect, IL). April 2002.
331. Institute for International Research Conference on Protein and Peptide Formulation Strategies for Drug Development and Delivery (San Francisco, CA). August 2002.
332. R&D Management Council Meeting of the Technical Association of the Pulp and Paper Industry (Cambridge, MA). November 2002.
333. DuPont Central R&D Center (Wilmington, DE). December 2002.
334. *ACTIVE*Pack 2003 Conference (Ponte Verde Beach, FL). February 2003.
335. International Symposium on Industrial Applications of Biocatalysis: *Chemical Development Issues* (Boston, MA). September 2003.
336. U.S. Army Workshop on Self-Decontaminating Materials and Multifunctional Coatings (Arlington, VA). October 2003.
337. British Royal Society Meeting on Biocatalysis in Alternative Media (London, England). December 2003.

338. National Autonomous University of Mexico (Mexico City, Mexico). March 2004.
339. Healthcare Research Initiative Workshop on the Effect of Radiofrequency Radiation on Pharmaceutical Product Quality (Cambridge, MA). June 2004.
340. Rensselaer Biotechnology Symposium on Biological Discoveries That Will Change the World (Troy, NY). September 2004.
341. Barnett International Conference: *The Consequences of Aggregation in Drug Development, Immunology, Quality Control, and Disease Genesis* (Philadelphia, PA). September 2004.
342. 4th Annual IBC Conference on Formulation Strategies for Protein Therapeutics (Boston, MA). October 2004.
343. U.S. Army Edgewood Chemical Biological Center (Aberdeen Proving Ground, MD). August 2005.
344. World Congress on Synthetic Receptors (Salzburg, Austria). September 2005.
345. International Conference “Celebrating 30 Years of Robert Langer’s Science” (Cambridge, MA). July 2006.
346. University of Montreal (Montréal, Québec, Canada). October 2006.
347. The Boeing Company Research Center (Everett, W A). December 2006.
348. Instrumentation Laboratory (Lexington, MA). December 2006.
349. Acambis Inc. (Cambridge, MA). January 2007.
350. 6th International Symposium on Industrial Microbiology and Biotechnology (Cambridge, MA). August 2007.
351. Scientific Conference on Chemical & Biological Defense Research (Timonium, MD). November 2007.
352. MIT Research and Development Conference (Cambridge, MA). November 2007.
353. Nanotech ‘2008 International Conference (Boston, MA). June 2008.

- 354. Materials Research Society Symposium (Boston, MA). December 2008.
- 355. Johnson & Johnson Research Briefing at MIT (Cambridge, MA). January 2009.
- 356. 3rd Annual Lyophilization Conference: *Ensuring Optimum Formulations for Pharmaceuticals and Biologics* (Boston, MA). February 2010.
- 357. DSM Corporate Research Center (Geleen, The Netherlands). June 2010.
- 358. Merck Serono Pharmaceutical Co. (Darmstadt, Germany). June 2010.
- 359. NanoFormulations '2010 International Conference (Stockholm, Sweden). June 2010.
- 360. Covidien Surgical Devices and Vascular Therapies Divisions (Cambridge, MA). October 2010.
- 361. World Lyophilization Summit (Cambridge, MA). May 2011.
- 362. Alvogen (Cambridge, MA). March 2012.
- 363. Colgate-Palmolive Co. (Cambridge, MA). April 2012.
- 364. FDA Parenteral Drug Association Glass Quality Conference (Washington, DC). June 2012.
- 365. University of Puerto Rico (Humacao, Puerto Rico). January 2013.
- 366. International Conference on Creating and Leveraging Intellectual Property in Developing Countries (Durban, South Africa – *via teleconference*). November 2013.
- 367. Northwestern University (Evanston, IL). April 2015.
- 368. FDA and Parenteral Drug Association Joint Regulatory Conference (Washington, DC). September 2016.
- 369. Annual Partnership Opportunities in Drug Delivery (PODD) Conference (Boston, MA). October 2017.