UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.

Petitioner

v.

HALE BIOPHARMA VENTURES, LLC

Patent Owner

Case: IPR2019-00451

U.S. Patent No. 9,763,876 B2

DECLARATION OF NICHOLAS A. PEPPAS, Sc.D.

IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

OF U.S. PATENT NO. 9,763,876

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I, Dr. Nicholas A. Peppas, do hereby make the following declaration:

I. PRELIMINARY STATEMENT

1. I have agreed to provide expert testimony in support of Aquestive, Inc.'s Petition for *Inter Partes* Review of U.S. Patent No. 9,763,876 B2, entitled "Administration of Benzodiazepine Compositions" ("the '876 Patent").

2. I have been asked to provide my opinion in regards to the state of technology relevant to the '876 Patent's disclosure and its claims based on knowledge existing prior to March 27, 2009, prior to June 14, 2011, and prior to December 13, 2011.

3. I have been asked to provide my opinion regarding whether one of ordinary skill in the art at the relevant time would have understood that certain prior art references, alone or in combination, disclose or teach each of the elements and limitations recited in the claims of the '876 Patent. I have also been asked to provide my opinion regarding whether a person of ordinary skill in the art (a "POSITA") would have been motivated or had a rationale or reason to modify or combine those certain prior art references to arrive at the elements recited in the claims of the '876 Patent. In my opinion, the

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references discussed below disclose or teach each of the elements and limitations recited in the claims of the '876 Patent, and a POSITA would have had a strong rationale to combine the references.

4. I am being compensated for my time working on this case at my customary rate of $650.00 per hour for all work performed on the case. My compensation is not in any way related to the outcome of the case. I have no financial interest in this proceeding, and the potential for any future financial benefit is unaffected by the content of my testimony or the outcome of this proceeding. I have reviewed the '876 Patent and am familiar with it.

II. BASIS FOR OPINIONS GIVEN

5. In forming my opinion, I have relied on my own education, work experiences and knowledge and my review of the following documents:

EXHIBIT NO.	EXHIBIT DESCRIPTION
1001	U.S. Patent No. 9,763,876, *Administration Of Benzodiazepine Compositions*, filed October 29, 2014 ('876 Patent)

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1002	File History for '876 Patent, Ser. No. 14/527,613 ('876 FH) 1002 Part 1 - Pages 1-270 1002 Part 2 - Pages 271-530
1003	U.S. Patent No. 8,895,546, *Administration Of Benzodiazepine Compositions*, filed June 13, 2012 ('546 Patent)
1004	File History for '546 Patent, Ser. No. 13/495,942 ('546 FH) 1004 Part 1 – Pages 1-350 1004 Part 2 – Pages 351-700 1004 Part 3 – Pages 701-1050 1004 Part 4 – Pages 1051-1400 1004 Part 5 – Pages 1401-1750 1004 Part 6 – Pages 1751-2100 1004 Part 7 – Pages 2101-2450 1004 Part 8 – Pages 2451-2681
1005	Provisional Patent Application No. 61/497,017, filed June 14, 2011 ('017 Provisional)
1006	Provisional Patent Application No. 61/570,110, filed December 13, 2011 ('110 Provisional)
1007	File History for Non-Provisional Patent Application Serial No. 12/413,439, filed March 27, 2009 ('439 FH) 1007 Part 1 – Pages 1-400 1007 Part 2 – Pages 401-800 1007 Part 3 – Pages 801-1200 1007 Part 4 – Pages 1201-1600 1007 Part 5 – Pages 1601-2000 1007 Part 6 – Pages 2001-2400 1007 Part 7 – Pages 2401-2800 1007 Part 8 – Pages 2801-3200 1007 Part 9 – Pages 3201-3488

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1008	Provisional Patent Application No. 61/040,558, filed March 28, 2008 (‘558 Provisional)
1009	Cartt et al., WO 2009/121039, *Administration Of Benzodiazepine Compositions*, published October 1, 2009, International Filing Date March 27, 2009 (PCT/US2009/038696) (Cartt‘039)
1010	U.S. Patent Application Publication No. US 2009/0258865, *Administration of Benzodiazepine Compositions*, Serial No. 12/413,439 (Cartt‘865)
1011	Meezan et al., U.S. Patent Application Publication No. US 2006/0046962, *Absorption Enhancers for Drug Administration*, Serial No. 11/127,786, published March 2, 2006 (Meezan‘962)
1012	Jamieson et al., U.S. Patent Application Publication No. US 2008/0070904, *Pharmaceutical Compositions of Benzodiazepines and Method of Use Thereof*, Serial No. 11/897,028, published March 20, 2008 (Jamieson)
1013	Sonne, U.S. Patent No. 6,193,985, *Tocopherol Compositions For Delivery Of Biologically Active Agents*, issued February 27, 2001 (Sonne)
1014	Gwozdz et al., WO 2009/120933, *Pharmaceutical Solutions And Method For Solubilizing Therapeutic Agents*, published October 1, 2009, International Filing Date March 27, 2009 (PCT/US2009/038518) (Gwozdz)
1015	Cartt et al., U.S. Patent Application Publication No. US 2008/0279784, *Nasal Administration Of Benzodiazepines*, Serial No. 12/116,842, published November 13, 2008 (Cartt‘784)

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1016	Kee et al., U.S. Patent No. 5,369,095, *Compositions And Method Comprising Substituted Glycosides As Mucus Membrane Permeation Enhancers*, issued November 29, 1994 (Kee)
1017	Cartt et al., WO 2008/137960, *Nasal Administration Of Benzodiazepines*, published November 13, 2008, International filing date May 7, 2008 (PCT/US2008/062961) (Cartt‘960)
1018	Tenta, U.S. Patent No. 3,949,072, *Seborrheic Keratosis Treatment*, issued April 6, 1976 (Tenta)
1019	Ueda et al., U.S. Patent No. 4,657,901, *Pharmaceutical Composition*, issued April 14, 1987 (Ueda)
1020	Meezan et al., U.S. Patent No. 5,661,130, *Absorption Enhancers For Drug Administration*, issued August 26, 1997 (Meezan‘130)
1021	Merkus, U.S. Patent Application Publication No. US 2005/0153956, Serial No. 11/034,474, published July 14, 2005 (Merkus)
1022	Liversidge et al., U.S. Patent Application Publication No. US 2006/0198896, Serial No. 11/354,249, published September 7, 2006 (Liversidge)
1023	Ritschel, *Handbook of Basic Pharmacokinetics*, Chapter 36 (Bioavailability and Bioequivalence), Drug Intelligence Publications, Illinois, 1992 (Ritschel)
1024	Osborne et al., *Skin Penetration Enhancers Cited in the Technical Literature*, Pharmaceutical Technology, November 1997 (Osborne)

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1025	Lindhardt et al., *Electroencephalographic effects and serum concentrations after intranasal and intravenous administration of diazepam to healthy volunteers*, Blackwell Science Ltd Br J Clin Pharmacol, 52, 521-527, 2001 (Lindhardt)
1026	Kibbe, editor, *Handbook of Pharmaceutical Excipients*, Third Edition (2000), American Pharmaceutical Association, Washington DC (Kibbe)
1027	Illum, *Nasal drug delivery-possibilities, problems and solutions*, Journal of Controlled Release 87 (2003) 187-198 (Illum)
1028	Ivaturi et al., *Pharmacokinetics and tolerability of intranasal diazepam and midazolam in healthy adult volunteers*, Acta Neurol Scand. 2009 Nov;120(5):353-7. doi: 10.1111/j.1600-0404.2009.01170.x. Epub 2009 May 14 (Ivaturi)
1029	O'Dell et al., *School nurses' experience with administration of rectal diazepam gel for seizures*, J Sch Nurs., June 2007, 23(3):166-9 (O'Dell)
1030	Gizurarson et al., *Intranasal Administration of Diazepam Aiming at the Treatment of Acute Seizures: Clinical Trials in Healthy Volunteers*, Biological and Pharmaceutical Bulletin, Volume 22 (1999) Issue 4 Pages 425-427 (Gizurarson)
1031	Rowe et al., editors, *Handbook of Pharmaceutical Excipients*, Fourth Edition (2003), Monographs for "Alcohol" (i.e., ethanol), "Alpha Tocopherol", "Benzyl Alcohol", "Glycerin", "Olive Oil", "Polyethylene Glycol", "Propylene Glycol", "Sesame Oil", and

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	"Triacetin", American Pharmaceutical Association, Washington DC (Rowe)
1032	Edman [II] et al., *Microspheres as a nasal delivery system for peptide drugs*, Journal of Controlled Release, Vol. 21 (1992) 165-172 (Edman II)
1033	French et al., *Pharmacopeial Standards and Specifications for Bulk Drugs and Solid Oral Dosage Forms*, Journal of Pharmaceutical Sciences, December 1967, Vol. 56(12):1622-1641 (French)
1034	Edman [I] et al., *(D) Routes of Delivery: Case Studies - (1) Nasal delivery of peptide drugs*, Advanced Drug Delivery Reviews, 8 (1992) 165-177 (Edman I)
1035	Davis, *Delivery of peptide and non-peptide drugs through the respiratory tract*, Pharmaceutical Science & Technology Today, Vol. 2, No. 11 November 1999, pages 450-456 (Davis)
1036	Deshmukh et al., *Lorazepam in the Treatment of Refractory Neonatal Seizures*, Am J Dis Child. 1986;140(10):1042-1044 (Deshmukh)
1037	Colombo, *Mucosal Drug Delivery, Nasal*, pp. 592-605, Vol 2, Encyclopedia of Controlled Drug Delivery (Mathiowitz, editor), John Wiley & Sons, 1999 (Colombo)
1038	Bara, U.S. Patent Application Publication No. US/2006/0178290, Serial No. 10/563,967, published August 10, 2006 (Bara)

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1039	Behl et al., *Effects of physicochemical properties and other factors on systemic nasal drug delivery*, Advanced Drug Delivery Reviews 29 (1998) 89–116 (Behl)
1040	File History for EP 128 01372.9, based on WO 2012/174158 and PCT/US2012/042311 1040 Part 1 - Pages 1-250 1040 Part 2 - Pages 251-500 1040 Part 3 – Pages 501-662
1041	(*this Declaration*)
1042	PDR 54th Edition 2000, DIASTAT® (diazepam rectal gel); MIACALCIN® (Calcitonin Nasal Spray); VALIUM® (diazepam injection), Physicians' Desk Reference.
1043	Knoester, et al., *Pharmacokinetics and pharmacodynamics of midazolam administered as a concentrated intranasal spray. A study in healthy volunteers*, Br J Clin Pharmacol. 2002 May;53(5):501-7.
1044	USP NF 2003, The United States Pharmacopeia, The National Formulary, United States Pharmacopeial Convention, Inc. ("USP/NF 2003").
1045	Maitani, et al., *Design of ocular/lacrimal and nasal systems through analysis of drug administration and absorption*, Journal of Controlled Release, Volume 49, Issues 2–3, 15 December 1997, Pages 185-192.
1046	Provisional Patent Application No. 61/040,281, *Pharmaceutical Solutions and Method for Solubilizing Therapeutics Agents*, filed March 28, 2008, Gwozdz, (Gwozdz '281 Provisional)

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1047	Gwozdz Assignment of Provisional in Non-Provisional Case, dated April 21, 2008, recorded September 23, 2010 (Gwozdz Assignment).
1048	Kagatani, et al., U.S. Patent No. 4,690,952, *Pharmaceutical Compositions for Nasal administration Comprising Calcitonin and an Absorption-Promoting Substance*, issued September 1, 1987 (Kagatani).
1049	Cartt'784 Assignment, dated March 6, 2012, recorded March 29, 2012 (Cartt'784 Assignment)
1050	Table of Various Diazepam Solutions Described in or Modified From Sonne's Example 11 ("DS11")

III. BACKGROUND AND QUALIFICATIONS

6. I am the Cockrell Family Regents Chair (i.e., Chaired Professor) in Engineering at the University of Texas at Austin with appointments in the Departments of Chemical Engineering, Biomedical Engineering of the Cockrell College of Engineering, and the Division of Molecular Pharmaceutics and Drug Delivery of the College of Pharmacy of the University of Texas at Austin since January 1, 2003. I am also a tenured full professor with a joint appointment in the Department of Pediatrics at the Dell Medical School of the same University. From September 2009 to

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August 2015, I was also the Chairman of the Biomedical Engineering Department in the same University.

7. Previously, I was the Showalter Distinguished Professor of Chemical and Biomedical Engineering at Purdue University, in West Lafayette, Indiana, with joint appointments in the School of Chemical Engineering and in the Department of Biomedical Engineering. I joined Purdue University in 1976.

8. I have degrees in chemical engineering from the National Technical University of Athens, Greece (Dipl. Eng., 1971) and the Massachusetts Institute of Technology - MIT (Sc.D., 1973).

9. I did one year of postdoctoral work with Professors Clark Colton, Kenneth Smith and Robert Lees at the Arteriosclerosis Center of the Massachusetts Institute of Technology (1975-76).

10. I am an elected member of the (US) National Academy of Engineering, the (US) National Academy of Medicine, the American Academy of Arts and Sciences, the National Academy of Inventors, the Academy of Engineering, Medicine and Sciences of Texas, the Chinese Academy of Medicine, the National Academy of Pharmacy of France, the Royal Academy of Pharmacy

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of Spain, the Academy of Athens, Greece and the International Academy of Medical and Biological Engineering.

11. I have received honorary doctorate degrees from the University of Ghent, Belgium (1999), the University of Parma, Italy (1999), the University of Athens (2000), and the University of Ljubljana, Slovenia (2012), granted by their respective Faculties of Pharmacy. The doctorate from the University of Parma also carries the title "Doctor of Pharmacy". I have also received an honorary doctorate (in Chemical Engineering) from the University of Patras (2015) and the National Technical University of Athens (2017).

12. I have served as a Visiting Professor at the Faculty of Pharmacy of the University of Geneva, Switzerland (Fall 1982), the Department of Chemical Engineering of the California Institute of Technology (Spring 1983), the Faculty of Pharmacy of the University of Paris-Sud (Fall 1986), the Department of Pharmacy of the University of Parma, Italy (Fall 1987), the School of Pharmacy of the Hoshi University of Tokyo, Japan (Spring 1994), the School of Pharmacy of the Hebrew University of Jerusalem, Israel (Spring 1994), the Departments of Pharmacy and Materials Science of the University of Naples, Italy (May 1996), the Department of Pharmacy of the

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Free University of Berlin, Germany (January-March 2001), the Department of Pharmacy of the Complutense University of Madrid, Spain (March-May 2001) and the Department of Materials Science of the Nanyang Technological Institute of Singapore (2006).

13. My teaching assignments at the University of Texas in the past ten years have been courses on “Polymer Science and Engineering”, “Advances in Biomedical Engineering”, “Advances in Biomaterials Science and Engineering”, “Bionanotechnology”, “Kinetics and Reaction Engineering”, and “Mass Transfer”.

14. Starting in 1979, I developed and taught, along with Professors Robert Langer of MIT, Frank Szoka of the University of California at San Francisco and others, the course “Advances in Controlled Release Technology” offered every summer at MIT. This is a five-day course offered to industrial and university researchers who do not have a sufficient background in the preparation and characterization of drug delivery systems such as tablets, films, capsules and microspheres, and related pharmaceutical systems. The past summer (2018) was the 40th year I taught this course.

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15. My research contributions have been in several areas of drug and protein delivery including therapeutic agents for treatment of diabetes, cancer, autoimmune diseases and cardiovascular problems, biomaterials, bionanotechnology, mass transfer, kinetics and reaction engineering, polymers and biomedical engineering.

16. Since 1979, I have also worked on the design, development and investigation of the pharmaceutical and medical applications of bioadhesive and mucoadhesive polymers and drug delivery formulations based on mucoadhesive polymers. I have published numerous papers on the design and use of mucoadhesive polymers and I have participated in the development of a number of products that incorporated mucoadhesive materials in order to function as adhesives.

17. For over forty years I have been involved with the preparation, characterization and evaluation of the behavior of hydrophilic polymers and their crosslinked networks known as hydrogels used in controlled release devices, especially in controlled delivery of drugs, peptides and proteins. My laboratory pioneered the use of these polymer carriers in drug delivery applications and I have extensive experience in formulation, preparation and

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testing of polymer formulations, including sustained release formulations. I received the 2012 National Academy of Engineering Founders Award in recognition of this pioneering work in the field of drug delivery. The National Academy of Engineering citation for the Founders Award lists "For contributions to biomedical and drug delivery applications of polymer networks and hydrogels and for leadership in the bioengineering community".

18. I am the author of approximately 1,400 publications, 450 abstracts, and approximately 35 issued or pending US and international patents.

19. I am the coauthor or coeditor of 37 books and volumes, including the three-volume monograph "Hydrogels in Medicine and Pharmacy" (CRC Press, 1987).

20. I am the Editor-in-Chief of "Regenerative Biomaterials", Deputy Editor of the journal "Science Advances", the journal "Biomedical Microdevices" and the Biomedical Engineering Book Series of Cambridge University Press.

21. I sit on the editorial boards of numerous journals, including the "Journal of Controlled Release", "Advanced Drug Delivery Reviews", "International Journal of Pharmaceutics", "Journal of Applied Polymer Science", "Journal

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of Biomedical Materials Research", "Journal of Biomaterials Science", "Journal of Drug Delivery Science and Technology", "European Journal of Pharmaceutics and Biopharmaceutics", and "Nanomedicine".

22. From 2008-2016, I was the President of the 26,000-member International Union of Societies of Biomaterials Science and Engineering.

23. Since 1981, I have been one of the leaders of the 4,000-member Controlled Release Society. I guided it as its President in 1987-88, and organized the 1985 (Geneva) and 1993 (Washington) meetings of the Society as well as many other conferences and workshops. The Controlled Release Society is the world's leading Society for technical information in the field of controlled release; it is a leading group addressing controlled release and bioadhesive controlled release systems. In July 2017 I received the CRS Distinguished Service Award.

24. Since 1975 I have been also active in the Society for Biomaterials. I was elected as President-elect in April 2002 and I took over as its President in April 2003 by automatic succession. The Society for Biomaterials is the world's premier scientific and technical organization for the dissemination

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of knowledge related to biomaterials for medical devices, and polymers in pharmaceutical technology.

25. I am Past Chair of the Engineering section of the American Association for the Advancement of Science (AAAS).

26. I have received numerous US and international awards that are awarded by the leading world organizations of scientific and technical excellence. These include the 2012 Founders Award of the National Academy of Engineering, the 2010 Acta Biomaterialia Gold Medal; the 2010 Maurice-Marie Janot Award, of the French and German Pharmaceutical Associations APGI and APV; the 2018 Distinguished Pharmaceutical Scientist Award of the American Association of Pharmaceutical Scientists (AAPS, the highest research recognition of the most important pharmaceutical association of the USA); the 2002 Dale Wurster Award in Pharmaceutics also from AAPS; the 2002 Eurand Award for Life Achievements in Oral Drug Delivery (the highest scientific recognition in oral delivery by the Controlled Release Society); the 2010 Distinguished Achievement Award of the Biomedical Engineering Society; the 2010 Acta Biomaterialia Gold Medal; the 2010 Distinguished Scientist of the Southern Universities Research Association;

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the 2008 Pierre Galletti Award of the American Institute of Medical and Biological Engineering; the 2008 Institute Lecturer Award of the American Institute of Chemical Engineers; the 2008 Jay Bailey Award of the Biological Engineering Society; the 2000 General Electric Senior Research Award of ASEE recognizing the best engineering researcher of the U.S.; the 1999 Research Achievement Award in Pharmaceutical Technology of the American Association of Pharmaceutical Scientists (the highest scientific recognition in pharmaceutical technology); the 1995 International Pharmaceutical Technology Medal of the International Pharmaceutical Association (APV); the 1994 Pharmaceutical and Bioengineering Award of the American Institute of Chemical Engineers, and many others.

27. I have supervised the theses of 109 Ph.D. students, including 54 current professors in other Universities, and many other students, postdoctoral fellows and visiting scientists. My former students include many industrial leaders in chemical, pharmaceutical or medical companies. Several of them are in senior administrative positions.

28. A copy of my curriculum vitae, including a list of publications I authored is attached as Exhibit A.

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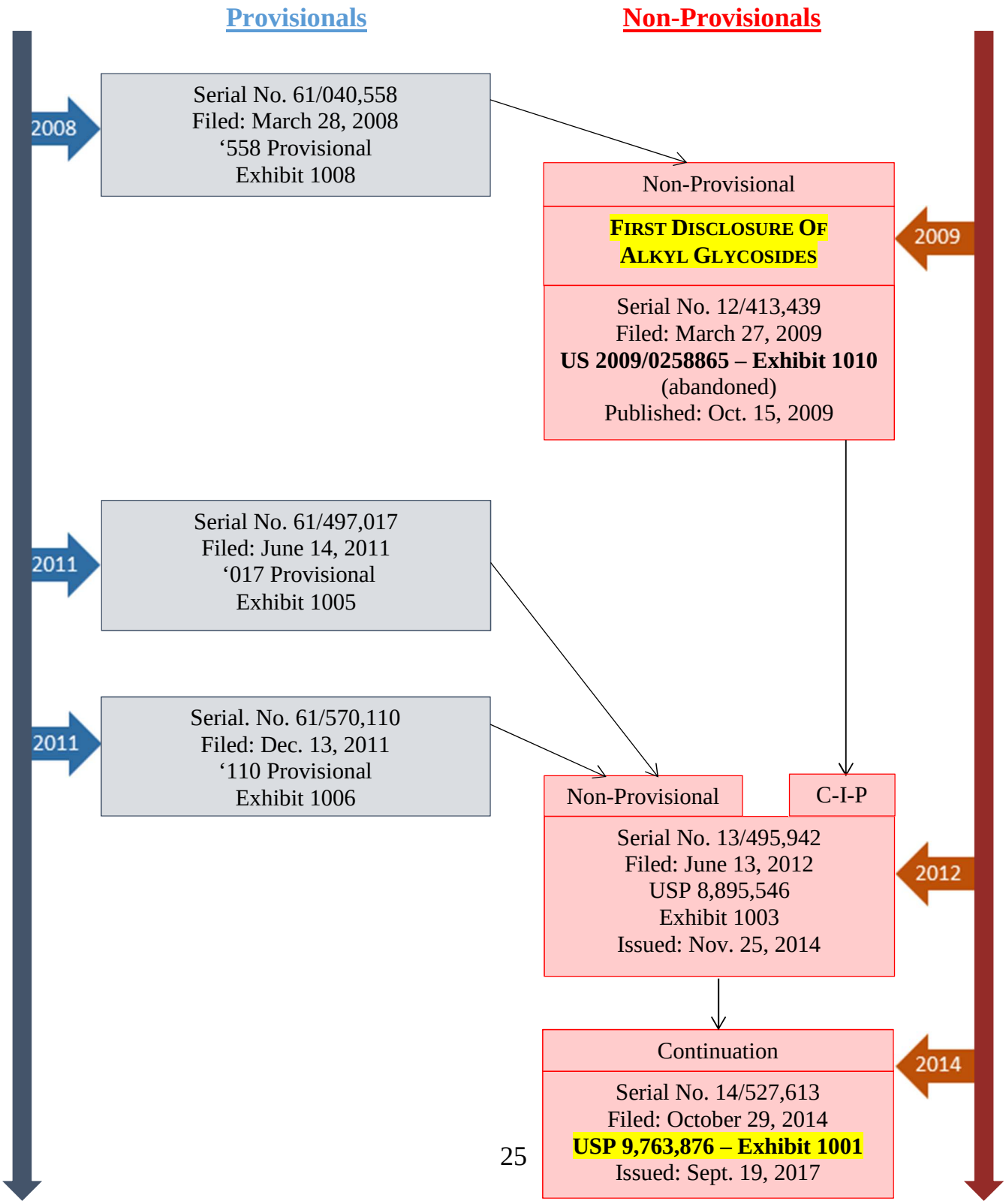
IV. THE '876 PATENT'S FILING/PROSECUTION HISTORY

A. Filing History and Priority Claims

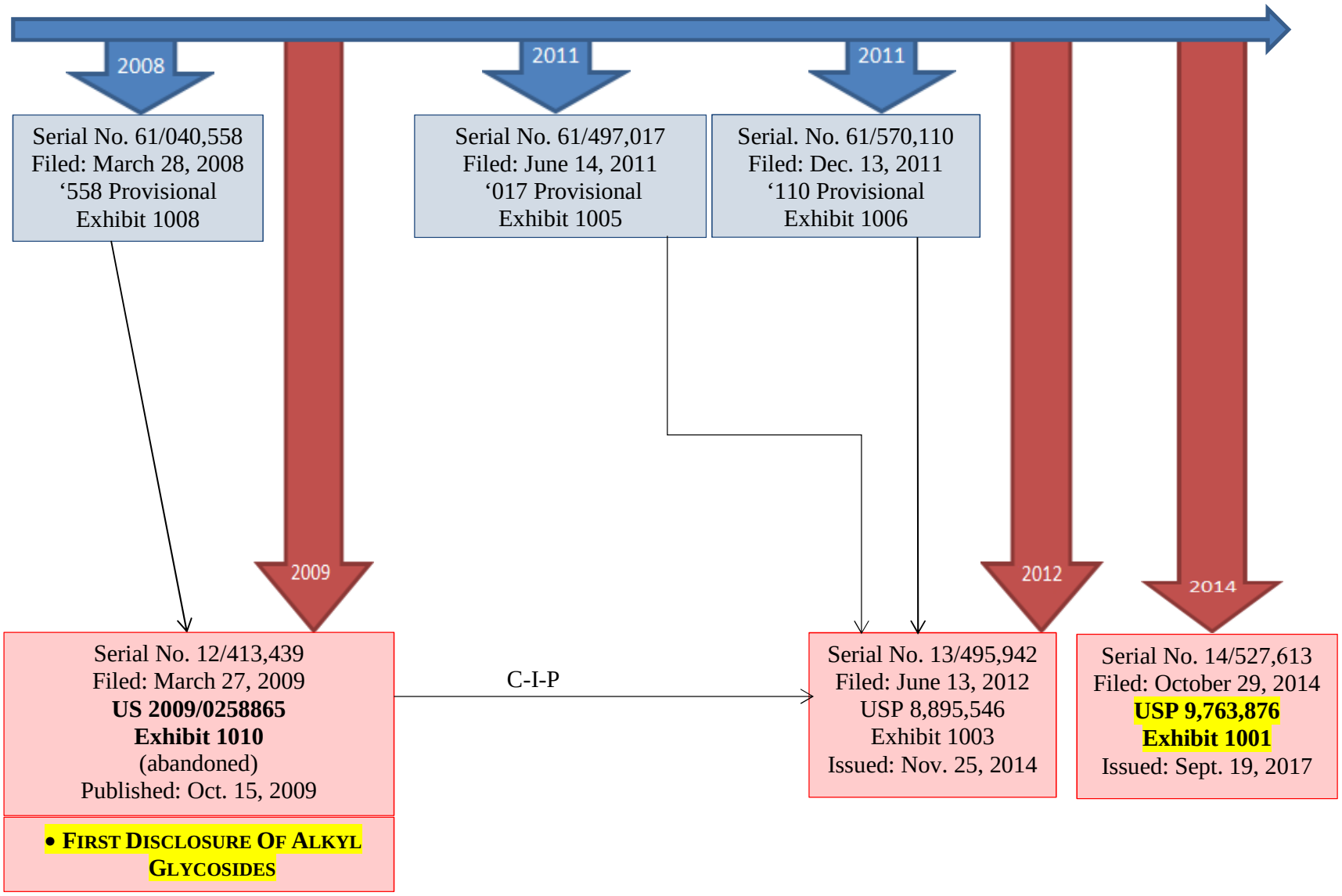
29. The '876 Patent states that it is a continuation of application No. 13/495,942, filed on June 13, 2012, now U.S. Patent No. 8,895,546 (henceforth designated "the '546 patent"), which in turn is a continuation-in-part of application No. 12/413,439 ("the '439 application"), filed on March 27, 2009, published as US 2009/0258865 ("Cartt'865")[1] on October 15, 2009, which in turn claims priority to U.S. provisional application No. 61/040,558 ("the '558 Provisional"), filed March 28, 2008. The '876 Patent also states that the '546 Patent also claims priority to U.S. provisional application No. 61/497,017 ("the '017 Provisional"), filed on June 14, 2011, and also to U.S. provisional application No. 61/570,110 ("the '110 Provisional"), filed December 13, 2011. I have been advised that the timelines on the following pages depict the chain of applications:

[1] For the remainder of my Declaration, I will generally refer to both the '439 application and its published version, i.e., Cartt'865, as Cartt'865 for simplicity (unless otherwise indicated).

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B. Prosecution History

1. Office Actions and PO's Responses/ Arguments

30. I have reviewed the file histories for the '876 Patent (Exhibit 1002), the '546 Patent (1004), and the '439 application (Exhibit 1007); I have also reviewed the '558 Provisional filing (Exhibit 1008), the '017 Provisional filing (Exhibit 1005) and the '110 Provisional filing (Exhibit 1006).

31. Sonne, Gwozdz, Meezan'962, and Cartt'865 were of record during prosecution of '876 Patent. However, only Sonne and Meezan'962 were cited by the Examiner in rejecting claims.

32. During prosecution of the '876 Patent, the Examiner issued provisional double patenting rejections over '439 application (which eventually published as Cartt'865). *See* '876 FH, Exhibit 1002, pp. 0170 and 0439. I have been informed that a "double patenting rejection" in this context means that the USPTO Examiner rejected the claims because (s)he believed that the rejected claims were very similar, i.e., patentably indistinct, as compared to the claims that were then pending in '439 application. Applicants did not dispute the rejections and filed a terminal disclaimer (Exhibit 1002, pp. 0469-0471), thus admitting that the claims of '876 Patent "are not patentably distinct from each other [i.e., from the '439 application claims] because it is

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obvious to administer a composition 'for nasal administration' to the nasal mucosal membranes. see MPEP 804.01(E)." '876 FH, Exhibit 1002, p. 0169.

33. Meezan'962 was relied on by the Examiner for obviousness rejections once in the parent application Serial No. 13/495,942 ("the '942 application", now U.S. Patent No. 8,895,546, "the '546 Patent") and (when cited as a secondary or tertiary reference with Sonne as discussed below) several times in the grandparent application Serial No. 12/413,439 (i.e., the '439 application, which published as Cartt'865).[2] *See* '546 FH, Exhibit 1004, pp. 2125-2127 and '439 FH, Exhibit 1007, pp. 0480-0481, 0515-0516, 2806-2810, 2938-2939, 3069-3072, 3095-3099, 3313-3318, and 3472-3477.[3]

34. Sonne was relied on by the Examiner as a primary reference (in view of Meezan'962, as noted above) during prosecution of the parent '942

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[2] Meezan'962 was also relied upon by the Examiner as a secondary reference in a double patenting rejection. *See* '439 FH, Exhibit 1007, p 0481.

[3] Patent Owner ultimately abandoned the application because the prior art combination, including Sonne and Meezan'962, could not be overcome. *See* '439 FH, Exhibit 1007, 3487-3488.

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application. *See* '546 FH, Exhibit 1004, pp. 2125-2127. Applicant amended independent Claim 1 to recite the presence of "ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w)". *See* '546 FH, Exhibit 1004, p. 2139. Applicant also made the following arguments:

> "All of the currently pending claims are directed to a pharmaceutical solution for nasal administration consisting of: (a) a benzodiazepine drug; (b) one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w); (c) ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and (d) an alkyl glycoside, or more specific embodiments thereof. Applicants submit that neither Sonne nor Meezan, whether taken alone or together, suggests such a formulation.
>
> The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. MPEP § 2111.03 (2012). Thus, the pending claims exclude such additional ingredients as water, poloxamer and benzalkonium chloride, which Sonne teaches. *See, e.g.*, Examples 1-3, 5. Meezan does not provide any additional teaching or suggestion to modify Sonne's teaching of emulsions containing water, poloxamer

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and/or benzalkonium chloride. Accordingly, the claimed solutions are not rendered obvious by the combination of Sonne and Meezan.

The pending claims also require both ethanol and benzyl alcohol in a combined amount of from 10% to 70% (w/w). Neither Sonne nor Meezan teaches or suggests using both ethanol and benzyl alcohol in such amounts. Thus, the combination of references fails to teach or suggest the claimed invention.

Furthermore, while Sonne mentions using ethanol as a viscosity-reducing agent, this teaching appears in the context of introducing the purported benefits of the therein-described colloidal formulations. Sonne does not provide any ranges of concentrations of ethanol, but does teach some ethanol-containing formulations. In Examples 3 and 5, for example, Sonne teaches use of 5% ethanol (5 g ethanol per 100 g of final emulsion formulation, further containing poloxamer and benzalkonium chloride.) In Example 12, Sonne teaches use of 4.5% ethanol. In Example 14, Sonne teaches 7.5% ethanol in a miconazole solution. Nowhere does Sonne or Meezan teach solutions consisting of benzodiazepine, 30-90% tocopherol or tocotrienol, an alkyl glycoside and both ethanol and

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> benzyl alcohol in a combined concentration of 10-70% (w/w).
>
> Moreover, given Sonne's admonition that solutions containing ethanol can be irritating, one of ordinary skill in the art would not have interpreted Sonne as teaching higher concentrations of ethanol than those exemplified in Sonne."

'546 FH, Exhibit 1004, pp. 2148-2149 (footnotes omitted; emphasis in original).

35. It must be noted that the Examiner had cited Sonne's Example 11 in the rejection ('546 FH, Exhibit 1004, p. 2125, 18th line). Yet, Applicants did not address Example 11 in their arguments (as quoted above).

36. Additionally, during prosecution of the '439 application (which was ultimately abandoned because Applicants could not overcome the prior art), the Examiner rejected pending claims based on Sonne as a primary reference ('439 FH, Exhibit 1007, pp. 0477-0481, 0514-0516) and as a secondary reference ('439 FH, Exhibit 1007, pp. 2806-2810, 2938-2939, 3069-3072, 3095-3099, 3313-3318, 3472-3477).

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37. In response to the first rejection in the file history ('439 FH, Exhibit 1007, pp. 0468-0481), Applicants tried amending the independent claim to recite a solution, the term "consisting of", and the optional presence of one or more alkyl glycosides ('439 FH, Exhibit 1007, p. 0492).

2. PO's Inaccurate and Misleading Statements Regarding Sonne Generally and Sonne Example 11

38. Significantly, Applicants included the following comments in their September 19, 2011 Response:

> "Sonne teaches specific benzodiazepine formulations in Examples 1-3, 7-11, 17-19 and 22-23. Of these, **Examples** 1-3, 7-**11**, 17, 19 and 22-23 **each describe an oil-in-water emulsion of the benzodiazepine**. Such emulsions are specifically excluded from the instant claims, which recite solutions (not emulsions) and exclude any ingredient (such as water and oil) not included within the group of benzodiazepine drugs, tocopherols or tocotrienols, alcohols or glycols, and optionally alkyglycosides [sic]. Of the remaining examples, Example 18 is a solution of alprazolam in α-tocopherol in sesame oil for oral administration. **Thus, each of the benzodiazepine**

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> **compositions taught by Sonne contains oil in some form or another**."

'439 FH, Exhibit 1007, p. 0501 (emphasis in original; **emphasis** added); *see also* p. 2833.

39. Applicants' statement is patently false; it is also demonstrably false. In particular, the **emphasized** portion of the quote above is: "**Examples** …**11**… **each describe an oil-in-water emulsion of the benzodiazepine… Thus, each of the benzodiazepine compositions taught by Sonne contains oil in some form or another**." Applicants are clearly stating that Example 11 of Sonne describes an oil-in-water emulsion of a benzodiazepine. Applicants are also clearly stating that all of Sonne's benzodiazepine compositions are emulsions and that none are solutions. Applicants' clear statements are false. Provided below is Sonne's Example 11 (Sonne, 11:1-13, Exhibit 1013, p. 0009:

Example 11

A solution of diazepam, eg. as nosedrop, (25 g):

Diazepam	1.250 g
α-Tocopherol	10.000 g
Triacetin	13.750 g

A less concentrated formulation of diazepam is needed for the rectal administration, but still it can be very difficult to find an acceptable vehicle with low irritation.

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40. As is clear, and contrary to Applicants' statement, Sonne's Example 11 is not "**an oil-in-water emulsion of the benzodiazepine**". Rather, Sonne's Example 11 is a solution of diazepam (a benzodiazepine). Therefore, Applicants' statements regarding Sonne, and particularly Sonne's Example 11 (which appears to be one of, if not the most, relevant portion of Sonne) are factually incorrect and may have mislead the Examiner away from considering the relevance of Example 11.

41. Applicants also argued that "In teaching that a high concentration of oil phase is required for nasal administration, Sonne is teaching away from nasal administration of compositions that contain no oil whatsoever." '439 FH, Exhibit 1007, p. 0501 (emphasis added). Again, Applicants' statement is demonstrably false because Sonne's Example 11 most definitely teaches toward a nasal administration of a composition that contains no oil whatsoever. Again, such factually incorrect statements appear to have mislead the Examiner away from considering the relevance of Example 11.

42. In the very same document, Applicants then argued that Sonne's "Example 11 is an oral solution of diazepam, α-tocopherol and triacetin (or 'glycerine triacetate' a tri-esterified from of glycerine)." '439 FH, Exhibit 1007,

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p. 0502 (emphasis added). As is clear from Sonne's Example 11 as reproduced above, Example 11 is a "nosedrop" which is not "an oral solution" as argued by Applicants. Putting aside the fact that both of the Applicants' statements are factually wrong, Applicants also do not appear to provide a reason why on one page of their response they argue that Example 11 is an oil-in-water emulsion and then *on the very next page* argue that Example 11 is an *oral* solution. This is yet another reason why the Examiner may have been misled away from considering the relevance of Example 11.

43. Applicants' factually incorrect arguments appear to have worked because in the November 21, 2011 Office Action, the Examiner ceased to discuss any of Sonne's Examples (although the Examiner did maintain the rejection). '439 FH, Exhibit 1007, p. 0514.

44. The Examiner of the '439 application eventually switched to relying on Sonne only as a secondary reference. *See* '439 FH, Exhibit 1007, pp. 2806-2810, 2938-2939, 3069-3072, 3095-3099, 3313-3318, and 3472-3477.

45. Only after the Examiner had successfully been misled away from primarily relying on Sonne (and Sonne's Examples) did Applicants make the

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statement that "Examples 11 and 16 are nose drop solutions." '439 FH, Exhibit 1007, p. 3085.

46. The Examiner never considered Sonne's Example 11 as a whole, which could easily be modified by a POSITA, because the Examiner was misled away from such consideration.

47. Unrelatedly, but still of note, Applicants argued that "Thus, Sonne teaches away from combining tocopherols and alkyl glycosides, presumably because tocopherol already serves to increase bioavailability of a drug." '439 FH, Exhibit 1007, p. 3120. However, Sonne's Example 10, a diazepam nosedrop, combines tocopherol with cetearyl glucoside (i.e., an alkyl glycoside). *See* Sonne, 10:53-66, Exhibit 1013, p. 0008. Sonne's Example 21 also combines a tocopherol with cetearyl glucoside. *See* Sonne, 13:11-23, Exhibit 1013, p. 0010. Again, Applicants appeared to have mislead the Examiner away from a full and proper consideration of Sonne's Examples.

48. The arguments made in this Declaration regarding any art mentioned in the prosecution history of '876 Patent were not made during the prosecution of '876 Patent, and are therefore not substantially the same as any arguments made during prosecution of '876 Patent, and those references of record are

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being applied in a different manner. Moreover, the Examiner inadvertently failed to appreciate the earliest effective filing date of the claims in the '876 Patent. That is, the Examiner did not realize that the subject matter of the claims was not supported by the '558 provisional. Rather (and as discussed in more detail below), the claims of the '876 Patent have an effective filing date of no earlier than March 27, 2009, i.e., the filing date of the '439 application. Therefore, the Examiner inadvertently failed to recognize and apply at least Gwozdz (Exhibit 1014) in an appropriate manner. In particular, if the Examiner did not look closely at the earliest possible effective filing date of the claims, the Examiner may not have realized that Gwozdz constituted prior art to the claims (as I have been advised by counsel).

3. PO Never Demonstrated or Evidenced Criticality or Unexpected Results With Respect to Claim Elements

49. Nowhere in the specification of the '876 Patent is there any evidence as to criticality or unexpected results with respect to specific types or amounts of alcohols, tocopherols, benzodiazepines, or alkyl glycosides.

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50. Similarly, nowhere in the prosecution history of the ‘876 Patent or its family members is there any evidence as to criticality or unexpected results with respect to specific types or amounts of alcohols, tocopherols, benzodiazepines, or alkyl glycosides.

51. I believe this is because *there simply is no criticality to (or unexpected results stemming from) the* specific types or amounts of alcohols, tocopherols, benzodiazepines, or alkyl glycosides recited in the ‘876 Patent’s claims. To be clear, by “criticality” I mean that the claimed ingredient and/or claimed amount of ingredient is critical to the operation of the claimed invention; if various similar ingredients and/or various amounts of an ingredient would still cause the invention to be operable, then I would consider that claimed ingredient and/or amount of ingredient to **not** be critical to the invention. Moreover, it would be expected that differences between a piece of prior art and a claim would translate into different, albeit predictable, properties. I would therefore consider an “unexpected result” to be present when the differences between the prior art and the claim translate into **unpredictably** different properties.

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a. No Criticality With Respect to Alcohols

52. Of note, during the prosecution of the related European application, the EPO appears to have taken a position consistent with my opinion:

> "No unexpected effect whatsoever has been demonstrated in the application for the selection of the claimed individual amounts of ethanol and benzyl alcohol."

EP FH, Exhibit 1040, p. 0297.

> "The solution proposed in claim 7[4] cannot be considered to be inventive because, in the absence of any unexpected effect associated therewith, the person skilled in the art would consider adjusting the amounts of ethanol and benzyl alcohol by mere routine experimentation and, by doing so, would inevitably arrive at the claimed amounts, without exercising inventive skill…The same argument applies *mutatis mutandis* to the subject-matter of claim 8,

[4] The "Claim 7" referred to by the European Examiner at the time of the rejection included 1-25% ethanol and 1-25% benzyl alcohol. EP FH, Exhibit 1040, pp. 0291 and 0297. This exact claim limitation is recited in Claim 8 of the '876 Patent.

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> which refers to the amounts 10-22.5 % (w/v) and 7.5-12.5 % (w/v) of ethanol and benzyl alcohol[5] respectively…"

EP FH, Exhibit 1040, p. 0298.

> "In the absence of any evidence of an unexpected effect associated therewith, the person skilled in the art would consider adjusting the amounts of ethanol and benzyl alcohol by mere routine experimentation and, by doing so, would inevitably arrive at the amounts of claim 7[6], without exercising any inventive skill. No inventive step can, therefore, be acknowledged for this claim…For exactly the same reason, no inventive step can be acknowledged for claim 8[7]…"

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[5] As stated by the European Examiner, "Claim 8" in the European application at the time of the rejection recited 10-22.5% ethanol and 7.5-12.5% benzyl alcohol. EP FH Exhibit 1040, pp. 0291 and 0298. This exact claim limitation is recited in Claim 15 of the '876 Patent.

[6] 1-25% ethanol, 1-25% benzyl alcohol; same as '876 Patent's Claim 8.

[7] 10-22.5% ethanol, 7.5-12.5% benzyl alcohol; same as '876 Patent's Claim 15.

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EP FH, Exhibit 1040, p. 0328.

53. PO did eventually obtain a European patent with an independent Claim 1 that recited "1-25% (w/v) ethanol and 1-25% (w/v) benzyl alcohol, in a combined amount from 10% to 50% (w/w)." EP FH, Exhibit 1040, p. 0648 (EPO's Intention to grant a European Patent, based on Main Request).

54. However, PO did not obtain this European patent by demonstrating any criticality or unexpected effects associated with the types or amounts of alcohols. Rather, PO compared a co-solvent system including tocopherol, ethanol, and benzyl alcohol to a suspension system. In particular, PO argued:

> "Accordingly, if it can be convincingly demonstrated that a solution on the basis of ethanol + benzyl alcohol provides an improvement over a suspension containing glycol + water as in D6 [prior art reference], it is not relevant whether the improvement is caused by the feature 'suspension' or 'ethanol + benzyl alcohol', since both features represent distinguishing over D6."

EP FH, Exhibit 1040, p. 0376 (emphasis in original).

55. The EPO apparently believed that PO "convincingly demonstrated" that its solution provided an improvement over a suspension.

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56. However, PO never demonstrated or proved that there was any criticality to the types and amounts of alcohols. In order to demonstrate such criticality, PO would need to have compared several combinations that included different amounts of ethanol and benzyl alcohol, as well as comparing combinations of each of ethanol and benzyl alcohol with different alcohols (e.g., ethanol/glycerol, benzyl alcohol/glycerol). Failing such a demonstration, there is no evidence that the amount and type of alcohols as recited in the claims of the '876 Patent display any unexpected results as compared to other alcoholic combinations.

57. Therefore, again, PO never demonstrated that there was any criticality to the types and amounts of alcohols.

b. No Criticality With Respect to Alkyl Glycosides

58. I have also not seen any evidence that would demonstrate the criticality of the amount of alkyl glycoside in general or dodecyl maltoside in particular. In fact, Meezan'962 provided evidence that doubling the amount of alkyl glycoside from 0.125% to 0.25% roughly doubled the bioavailability of its

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tested formulation from 43% to 90%, with an 8% variance being applicable to both. *See* Meezan'962, [0150]-[0151], Exhibit 1011, pp. 0017-0018.

59. Meezan'962 also taught that there is "a dose-dependent effect" based on the amount of the alkyl glycoside. *See* Meezan'962, [0159], Exhibit 1011, p. 0019.

60. That is, Meezan'962 provided evidence that the effects of the alkyl glycoside were linear; there were no unexpected results or criticality demonstrated. I have not seen any evidence that would rebut Meezan'962's evidence. Significantly, Edward T. Maggio is listed as an inventor on both Meezan'962 and the '876 Patent; therefore, it seems that inventor Maggio would agree with my assessment that there is no demonstrated criticality or unexpected results associated with the amounts of alkyl glycoside.

c. No Criticality With Respect to Tocopherols

61. PO has never demonstrated any criticality or unexpected results with respect to the specific type of tocopherol (or tocotrienol) or the amount/range of amounts of tocopherol (or tocotrienol).

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d. No Criticality With Respect to Benzodiazepines/ Diazepam

62. PO has never demonstrated any criticality or unexpected results with respect to the specific type of benzodiazepine (e.g., diazepam) or the amount/range of amounts of the benzodiazepine.

63. Moreover, benzodiazepines such as diazepam have been known for decades, and their effects on the human body are generally predictable.

V. EARLIEST APPEARANCE OF CERTAIN CLAIM ELEMENTS

64. I have been informed that to be entitled to an earlier priority date, each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. This means that claim limitation priority dates will be established based on the '876 Patent, the '439 application, the '546 patent, the '558 Provisional, the '017 Provisional, and/or the '110 Provisional disclosures. I have also been informed that to benefit from a claim of priority to an originally filed disclosure, the originally filed disclosure must contain a written description of the invention as claimed in the later application (i.e., in the '876 Patent), and of the manner and process

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of making and using it, in such full, clear, concise, and exact terms as to enable any person of ordinary skill in the art to make and use the invention as claimed.

65. I have been further informed that the test to determine if the claims in the later application, that is, the ‘876 Patent, are to receive the benefit of an earlier filed application or patent is whether a person of ordinary skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application or patent. The disclosure as originally filed in the earlier application or patent must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. That is, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations.

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A. Claim 1 (and All Claims Dependent Therefrom)

66. Each claim of the ‘876 Patent requires the presence of an alkyl glycoside (or particular species thereof, e.g., dodecyl maltoside) because Claim 1, which is the only independent claim, recites the presence of an alkyl glycoside.

67. I was asked to review all the patents and applications discussed in ¶¶ 29-30 above to determine which, if any, provide written support (i.e., written description and enablement) for the claim limitation (element) of the ‘876 Patent which requires the presence of an alkyl glycoside (or particular species thereof, e.g., dodecyl maltoside).

68. In my opinion, the first mention, disclosure, and written support of alkyl glycosides (or any particular species thereof, e.g., dodecyl maltoside) is in the ‘439 application, filed on March 27, 2009. In my further opinion, the ‘558 Provisional does not mention, disclose, or provide written support for alkyl glycosides (or any particular species thereof, e.g., dodecyl maltoside).

69. Therefore, it is my opinion that the ‘876 Patent, insofar as any disclosure of alkyl glycosides (or species thereof) is concerned, is entitled to a priority date no earlier than the March 27, 2009 filing date of the ‘439 application.

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See, e.g., '439 FH, Exhibit 1007, p. 0079 (filing receipt showing filing date of March 27, 2009).

70. It is also possible that some of the claims of the '876 Patent may be entitled to an even later effective filing date, if support for their claim elements is first found in the '546 Patent, the '876 Patent, the '017 Provisional and/or the '110 Provisional. In this regard, at least Claims 8-10, 15, and 30-36 are only entitled to effective filing dates that are *after* the '439 application's March 27, 2009 effective filing date. The reasons are discussed in much more detail in another of my Declarations, and these reasons are incorporated herein in their entirety.

VI. THE PERSON OF ORDINARY SKILL IN THE ART

71. I have been asked to provide my opinion regarding whether one of ordinary skill in the art at the relevant time would have understood that certain prior art references, alone or in combination, disclose or teach each of the elements and limitations recited in the claims of the '876 Patent. I have also been asked to provide my opinion regarding whether a person of ordinary skill in the art (a "POSITA") would have been motivated or had a rationale

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or reason to modify or combine those certain prior art references to arrive at the elements recited in the claims of the ‘876 Patent. In my opinion, the references discussed below disclose or teach each of the elements and limitations recited in the claims of the ‘876 Patent, and a POSITA would have had a strong rationale to combine the references discussed below.

72. I have been informed that “a person of ordinary skill in the art”, a POSITA, is not a specific, real individual, but rather a hypothetical individual or team of individuals working closely together, who is presumed to have known the relevant art at the time of the invention. In defining the POSITA, I have considered factors such as the educational level and years of experience not only of the person or persons who have developed the invention that is the subject of the case, but also others working in the pertinent art at the time of the invention; the types of problems encountered in the art; the teachings of the prior art; patents and publications of other persons or companies; and the sophistication of the technology.

73. I have assessed the level of ordinary skill in the art based upon my review of the ‘876 Patent, the prior art, and my own long-standing career of working in

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the field of delivery of pharmaceutical dosage forms, including intranasal dosage forms.

74. It is my opinion that as of the earliest priority date that the '876 Patent as a whole is entitled to (i.e., no earlier than March 27, 2009, as discussed in ¶¶ 68-70, above), a POSITA would have been a medicinal chemist, pharmaceutical chemist, chemist, or biologist involved in the research and development of pharmaceutical formulations for the treatment of epilepsy and related diseases/disorders. Such an individual would have at least a B.S. degree in chemical, biological, or pharmaceutical sciences or a medical degree and several years of experience in the field of transmucosal (including intranasal, rectal, vaginal, ocular, lacrimal, nasolacrimal, buccal, sublingual, urethral, inhalation, and auricular) pharmaceutical formulation development, the amount of post-graduate experience depending upon the level of formal education. The individual would also have some experience in design and testing of formulations for mucosal delivery (and particularly in intranasal formulations) of systemic-acting drugs.

75. I have been advised that a POSITA is considered to be aware of all relevant prior art.

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76. In my opinion, a POSITA would easily have understood the prior art references I discuss below. Moreover, the POSITA would have had the capability to draw inferences from the references, including combining the references and then drawing additional inferences from the combined teachings.

VII. OTHER RELEVANT CONSIDERATIONS

77. I provide my opinions in this declaration as informed below.

78. I have been informed that a claimed invention is unpatentable if the differences between the invention and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having ordinary skill in the art to which the subject matter pertains. I have also been informed that an obviousness analysis considers factual inquiries including the level of a person of ordinary skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed subject matter.

79. I have been informed that there are several accepted rationales for combining references or modifying a reference to show obviousness of the

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claimed subject matter. Some of these rationales include: (i) combining prior art elements according to known methods to yield predictable results; (ii) simply substituting one known element for another to obtain predictable results; (iii) employing a predictable use of prior art elements according to their established functions; (iv) applying a known technique to a known device to yield predictable results; (v) choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (vi) a teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

VIII. CLAIM CONSTRUCTION

80. I have been informed that claim terms are interpreted according to their ordinary and customary meaning as understood by a POSITA, in light of the specification of the patent in which they appear and also in light of the prosecution history pertaining to the patent. However, I have also been advised that certain terms may be construed in a manner other than their ordinary and customary meaning if defined in a particular way by the Patent

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Owner. Therefore, I have been requested to review and analyze the claim terms discussed in the following paragraphs. I have adopted the below constructions of certain claim terms; all other claim terms I have construed according to their ordinary and customary meaning as would be understood by a POSITA in the context of the entire disclosure.

81. In my opinion and based on my experience, as further modified by my reading of the documents listed in ¶¶ 29-30 above as well as the file histories for those documents, the following definitions reflect how a POSITA would have construed the identified terms. In particular, the terms and applied definitions are:

A. "Vitamin E" in Claims 1, 2, and 27-33

82. The '876 Patent discusses Vitamin E at Col. 33, lines 8-23, as follows:

> "Vitamin E is a class of fat soluble methylated phenols. There are at least eight naturally-occurring compounds that comprise this class: α-tocopherol, β-tocopherol, γ-tocopherol, δ-tocopherol, α-tocotrienol, β-tocotrienol, γ-tocotrienol, and δ-tocotrienol, all of which may be used in the compositions and methods of the present invention. There are multiple isomers of each of these compounds,

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> all of which may be used in the compositions and methods of the present invention. There are also multiple esters of each of these compounds, including tocophersolan, all of which may be used in the compositions and methods of the present invention. As used herein, Vitamin E refers to any of the natural or synthetic tocopherols, tocotrienols, any isomers thereof, any esters thereof, any analogs or derivatives thereof, or any combinations thereof."

83. Significantly, the above quote includes a specific definition for vitamin E: "As used herein, Vitamin E refers to any of the natural or synthetic tocopherols, tocotrienols, any isomers thereof, any esters thereof, any analogs or derivatives thereof, or any combinations thereof."

84. This definition is in accordance with my understanding of vitamin E. Moreover, I have not reviewed any evidence or documents that stand in contrast to the definition provided by Patent Owner.

85. Therefore, in my opinion, "vitamin E" is best defined as meaning: "any of the natural or synthetic tocopherols, tocotrienols, any isomers thereof, any esters thereof, any analogs or derivatives thereof, or any combinations thereof."

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B. "Bioavailability" in Claims 34, 35, and 36

86. '876 Patent discusses "bioavailability" at Col. 4, line 57 to Col. 5, line 4 as follows:

> "it is intended that bioavailability be determined by a suitable pharmacodynamics method, such as comparison of area under the blood plasma concentration curve (AUC) for the nasally and intravenously administered drug. It is further understood that the percent bioavailability of the nasally administered benzodiazepine may be determined by comparing the area under the blood plasma concentration curve obtained with one dose of the benzodiazepine (e.g. 10 mg of nasal diazepam) with another dose of the same benzodiazepine administered intravenously (e.g. 5 mg of i.v. diazepam), taking into consideration the difference in dose. Thus, for the sake of illustration, a 10 mg nasal diazepam dose that achieves an AUC that is precisely half of the AUC obtained with 5 mg of i.v. diazepam would have a bioavailability of 100%."

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87. In my opinion, this discussion simply expresses in words the well-known formula for assessing the absolute bioavailability of the same drug administered through a non-intravenous route versus the intravenous route, taking into account any differences in dosage. According to Ritschel, one of the most well-respected publications in the field of pharmacokinetics and pharmacodynamics and considered to be a bible in the field, the well-known formula for bioavailability may be written as:

$$f = \frac{AUC_{extravascular}^{0\rightarrow\infty}\left[(mg/ml)\cdot h\right]\cdot D_{I.V.}[mg]}{AUC_{I.V.}^{0\rightarrow\infty}\left[(mg/ml)\cdot h\right]\cdot D_{extravascular}[mg]}$$

where "f" is absolute bioavailability; "$AUC_{0\rightarrow\infty}$" is the total "area under the curve" for the intravenous route ("I.V.") and for the non-intravenous route (i.e., "extravascular"), as measured in mg/ml*h; and "D" is the dosage of the drug administered intravenously and extravascularly, as measured in mg. Ritschel, Equation 36.1, p. 506.

88. Therefore, I have interpreted the claim element "bioavailability" in accordance with the absolute bioavailability formula shown above, i.e., Equation 36.1 from Ritschel, p. 506, i.e., as meaning "bioavailability,

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determined by the ratio of ([$AUC_{\infty(IN)}$ x $Dose_{(IV)}$] divided by [$AUC_{\infty(IV)}$ x $Dose_{(IN)}$]) x 100%."

89. This interpretation of "bioavailability" is consistent with the various discussions of "bioavailability" that I have reviewed for this opinion.

90. If a comparison was being made between two different non-intravenous routes, then the correct terminology would be "relative bioavailability", with the denominator of the Ritschel 36.1 Equation being the AUC of whichever route is considered the reference route.

91. As discussed below with respect to bioavailability, the FDA provides a general guidance as to the range of bioavailability normally required.

92. For example, when comparing an experimental product (such as an intranasal product) to a reference product (an intravenous product of the same drug, when calculating absolute bioavailability), the FDA considers that if, as an example, the AUC and the C_{max} for the experimental product are each 80-125% with a 90% confidence interval as compared to the reference product, then the experimental product is generally considered bioequivalent to the reference product.

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93. That is, according to at least the FDA, both the AUCs and the C_{max} of an experimental product should generally fall within 80-125%, with a 90% confidence interval, of the reference product.

C. "% (W/W)" IN CLAIMS 1, 11-14, 24-26, AND "% (W/V)" IN CLAIMS 5, 6, 8, 15, 28, AND 30-33

94. I note that the two units, i.e., "% (w/w)" and "% (w/v)" appear to be used interchangeably in '876 Patent. For example, Claim 1 recites the presence of "ethanol and benzyl alcohol in a combined amount from about 10% to about 70**% (w/w)**." (**emphasis** added). However, Claim 8, e.g., which depends from Claim 1, recites that "the solution contains ethanol from 1 to 25**% (w/v)** and benzyl alcohol from 1 to 25**% (w/v)**." (**emphasis** added). That is, the measurement units for the alcoholic component changes between Claims 1 and 8 from being measured by weight to being measured by volume.

95. Based on my review of the various file histories, there does not appear to be any rhyme or reason for this change. I do note that all the formulation Examples provided in '876 Patent are expressed per volume, not weight. In particular, Examples 1, 2, 3, and 4 and Tables 1-1, 2-1, 3-1, and 4-1 recite

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units of "mg/mL" (which is a measurement of (w/v) before calculating percentage); Example 11 and Table 11-1 directly provides the unit of "% (w/v)." Therefore, there appears to be a typographical error somewhere, with the most likely candidate being that "% (w/w)" is incorrect because these are all solutions, meaning we would expect measurements to be expressed by volume. Moreover, more than half of the claims (that include %) use the "% (w/v)" unit. However, based on the specific gravities of the three ingredients[8], the differences between measurements of "% (w/v)" and "% (w/w)" (and even % (v/v)) should be small enough as to be insignificant to my discussion here as well as to the arguments laid out in the Petition. Therefore, I have interpreted "% (w/w)" and "% (w/v)" as being interchangeable in the context of '876 Patent.

[8] Specific gravities: (i) ethanol at 20°C – 0.8119-0.8139, and dehydrated ethanol at 20°C – 0.7904-0.7935 (*see* Rowe, Exhibit 1031, p. 0004; *see also* Table II on p. 0003 and Table III on p. 0005); (ii) *d*-alpha tocopherol – 0.95 (*Id*. at p. 0007; *see also* Table I on p. 0006); and (iii) benzyl alcohol at 20°C – 1.0454 (*Id.* at p. 0010; *see also* Table I on p. 0009). *See* Rowe, Exhibit 1031, pp. 0004, 0007.

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D. "About 56.47% (w/v) vitamin E"

96. The '876 Patent describes the term "about" as follows:

> "As used herein, the modifier "about" is intended to have its regularly recognized meaning of approximately. In some embodiments, the term may be more precisely interpreted as meaning within a particular percentage of the modified value, e.g. "about" may in some embodiments mean±20%, ±10%, ±5%, ±2%, or ±1% or less."

'876 Patent, 17:60-65, Exhibit 1001, p. 0018.

97. Therefore, it appears that the '876 Patent leaves us to decide when to apply ±20%, ±10%, ±5%, ±2%, or ±1% or less, when "about" is recited.

98. I note that "±5%" is the middle listed value. Moreover, based on my past work in the field, a definition of ±5% appears to be correct with respect to the vitamin E amount recited in Claim 28. Additionally, I have not reviewed any documents that would cause me to change my opinion.

99. Therefore, in my opinion, "about 56.47% (w/v) of vitamin E" would be interpreted by a POSITA as meaning ±5% of 56.47%. Mathematically, 5% less is 53.65%; 5% more is 59.29%. Therefore, a POSITA would interpret

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"about 56.47% (w/v) of vitamin E" as meaning "53.65% to 59.29% of vitamin E".

IX. GENERAL STATE OF THE PRIOR ART – A VERY BRIEF HISTORY

100. In the 1970s, nasal delivery systems were designed and developed for delivery of drugs throughout mucosal areas including the nasal mucosal membranes. Main research interests at that time included treatment of the flu (i.e., influenza), as with the Japanese company's Teijin's Rhinocort® system. In addition, there was significant interest in insulin delivery, with several systems being proposed by Teijin, as well as by U.S. companies. All the systems were based on macro- and micro-particulates consisting of polymers, gels, and various swollen polymers.

101. While effective in delivering some of these drugs, these systems had several problems:

a. The particles were disturbing or preventing the mucocilliary beat which is necessary for physiological function of the nasal cavity.

b. Often, the particles were adhering to the cilia, and they were difficult to dislocate.

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c. Only a portion of the drug could be delivered through the nasal mucous.

d. For larger drugs, it was necessary to use enhancers in order to attain high bioavailability.

102. In the late 1980s, nasal formulations started including suspensions and liquid formulations. In the 1990s, it was discovered that nanoparticulate nasal systems could not address all needs in the field.

103. By about 2000, formulators were initially seeking emulsion-based systems (i.e., specialized suspension-based systems), followed by liquid systems, that could attain the contour of the nasal cavity without obstructing the cilliary beat. Formulators therefore began to modify suspension and emulsion-based systems in the following ways:

a. Improvement of the drug solubility by finding better liquids as solvents or carriers for the drug.

b. This lead to the use of "solvents" such as ethanol, benzyl alcohol, propylene glycol, etc., that could improve the solubility with one

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caveat: to avoid irritation of the nasal cavity caused by some of these solvents.[9]

c. An alternative "solvent" that became very important was vitamin E/tocopherols. Benzodiazepines are much more soluble in vitamin E than in water. *See also, e.g.*, Sonne.

d. Improvement of the stability of the formulation. This was achieved by additional vitamin E.

e. Elimination of the suspension/emulsion characteristics in favor of solution characteristics in order to have more intimate contact with the nasal cavity. In this goal/task, surfactants or emulsifiers were preferred.

f. Improvement in the enhancement of drug transport across the nasal mucosal membrane. Again, here we were helped by the Kee and

[9] Significantly, these three alcoholic solvents (i.e., ethanol, benzyl alcohol, and propylene glycol) were – and are – used in intravenous and rectal compositions for administration of diazepam. *See, e.g.*, PDR, Exhibit 1042, pp. 0002 (Diastat® diazepam rectal gel) and 0010 (Valium® diazepam injection).

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Shaw 1994 Alcon patent (USP 5,369,095) that identified glycosides (including alkyl glycosides, and especially dodecyl maltoside) as preferred enhancers for nasal (and ocular) delivery.

g. From both my earlier work as well as others' work, we generally know that ocular and nasal delivery have similar characteristics because drugs placed in the ocular area are often found to also be active in the nasal cavity. *See generally* Maitani, Exhibit 1045.

104. At the same time, i.e., around 2000, an interest developed in fast-acting delivery systems through the nasal cavity. The effort was to have a fast onset of delivery, especially in cases of pain relief problems for cancer patients (e.g., fentanyl) and also some larger molecular weight molecules, e.g., insulin for treatment of diabetes. The natural consequence of these needs was the development of nasal delivery systems without the delayed action provided by a polymer carrier and with ease in transport provided by liquid systems or sometimes ointments (liquid systems that could deliver a portion of the active as fast as possible to ameliorate the pain and improve immediate action).

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X. THE '876 PATENT (EXHIBIT 1001)

105. The '876 Patent relates to "pharmaceutical compositions comprising one or more benzodiazepine drugs for nasal administration, methods for producing and for using such compositions." '876 Patent, Abstract. The patent describes compositions (e.g., solutions and suspensions) containing benzodiazepines (e.g., diazepam) that are intended for intranasal administration; the patent also describes methods of using and administering such compositions.

106. The '876 Patent contains only one independent claim, i.e., Claim 1. Claim 1 recites in full:

> A method of treating a patient with a disorder which is treatable with a benzodiazepine drug, comprising: administering to one or more nasal mucosal membranes of a patient a pharmaceutical solution for nasal administration consisting of a benzodiazepine drug, one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w); ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and an alkyl glycoside.

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107. Claim 1 requires the treatment of a patient, wherein the patient has a disorder which is treatable with a benzodiazepine. The treatment comprises one step, i.e., administering a pharmaceutical solution to "one or more nasal mucosal membranes of a patient." The pharmaceutical solution consists of the following:

a. a benzodiazepine drug;
b. at least one tocopherol and/or tocotrienol, in a combined amount of from about 30% to about 95% (w/w);
c. both ethanol and benzyl alcohol, in a combined weight of from about 10% to about 70% (w/w); and
d. an alkyl glycoside.

XI. INTRANASAL ADMINISTRATION OF PHARMACEUTICALS

A. Brief History of Intranasal Administration

108. Intranasal administration of pharmaceuticals has been known for a very long time. For example, as early as 1992, those working in the art recognized that "[n]asal administration of drugs is not new and has been used since ancient times to give drugs locally or systemically." Edman I, Exhibit 1034, p. 0002. Others agree: "The nose has been used for the systemic administration of drugs since ancient times." Davis, Exhibit 1035, p. 0001.

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"Knowledge of the nasal mucosa's high permeability and use of the nasal route for drug administration can be traced to ancient times." Behl, Exhibit 1039, p. 0002.

B. BENEFITS OF INTRANASAL ADMINISTRATION

109. While probably not recognized by the ancients, "[t]he most important advantage with the nasal route is how the blood circulation in the nose is linked to the systemic circulation, thus avoiding first-pass hepatic metabolism."[10] Edman I, Exhibit 1034, p. 0002. In particular, it is generally very desirable to avoid first-pass hepatic metabolism so that lower amounts of drug may be used in a formulation. As recognized by Edman I, one

[10] "First-pass hepatic metabolism" means that a drug is metabolized in the liver prior to absorption into the blood stream, thereby reducing the amount of drug available to be introduced into the blood stream (i.e., the bioavailability). Avoiding first-pass hepatic metabolism generally avoids loss of some of the drug to the metabolic processes in the liver, thereby increasing bioavailability.

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preferred method of avoiding first-pass hepatic metabolism is by nasal administration.

110. Another reason for, and benefit of, nasal administration is that it allows for the "rapid absorption and quick pharmacodynamics effect of the drug". Edman II, Exhibit 1032, p. 0001. One of the benefits of the rapid absorption is that "the nose can be used in so called 'crisis treatments' for the rapid administration of compounds, such as in the treatment of pain, migraine, convulsions, seizures, sedation and nausea." Davis, Exhibit 1035, pp. 0001-0002. There are other administration routes that may have the same benefit with respect to absorption and pharmacodynamics; however, there are serious drawbacks to these routes.

111. For example, while rectal administration is generally a very effective method for administering drugs, drawbacks include lack of training, lack of qualified personnel, and difficulty in provision of privacy (necessary for the rectal administration of a drug, especially in public settings such as, e.g., schools). *See generally* O'Dell, Exhibit 1029. Moreover, rectal "therapy, however, is not that convenient in adults". Gizurarson, Exhibit 1030, p. 0001.

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112. Similarly, the intravenous route of administration is generally also very effective, but it has its drawbacks as well. For example, "i.v. administration of [diazepam or clonazepam] to a patient in seizure requires skilled personnel and an acute care facility, since the treatment may be associated with hypotension, cardiac dysrhythmias or central nervous system depression." Gizurarson, Exhibit 1030, p. 0001. Others have recognized the same difficulties: "However, i.v. administration [of benzodiazepines] requires skilled personnel and transport to a medical facility which can delay initiation of therapy." Ivaturi, Exhibit 1028, p. 0001. Of course, it may not be possible to timely transport a seizing patient to an acute care facility in the middle of a seizure; similarly, properly skilled and trained personnel may not be readily available.

113. Thus, it has been recognized by many that intranasal administration is a very promising route for drug delivery (especially for certain types of drugs, such as benzodiazepines or any drug intended to arrest or treat epileptic seizures):

    a. "Intranasal administration of diazepam may be a practical alternative to the conventional acute medication of seizures, such as status epilepticus." Gizurarson, Exhibit 1030, Abstract, p. 0001.

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b. "In the near future we should expect to see a range of novel nasal products reaching the market." Illum, Exhibit 1027, p. 0010.

c. "Intranasal administration of drugs is likely to gain further importance in time." Colombo, Exhibit 1037, p. 0015.

d. "Recently, focus has been on the nasal mucosa as an alternative route to achieve faster and higher drug absorption." Behl, Exhibit 1039, p. 0002.

e. "The availability of a fast-acting intranasal (i.n.) treatment that can be easily administered by the patient or a caregiver would greatly improve the management of seizure disorders." Ivaturi, Exhibit 1028, pp. 0001-0002.

114. Therefore, during the time period leading up to 2009, the POSITA working in the field was well aware of the importance of intranasal delivery.

C. Problems Associated With Intranasal Delivery

115. While there are many benefits associated with intranasal delivery, it isn't without its own set of problems. For example, some drugs are known to cause irritation to the delicate nasal mucosa. Additionally, some drugs are

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actively degraded by enzymes located in the nasal mucosa area. Behl, Exhibit 1039, pp. 0008-0009.

116. However, one of the problems associated with intranasal delivery is that for some drugs, not enough of the actual drug itself crosses the nasal mucosa and enters the bloodstream. Therefore, an intranasal dosage form may not achieve the same effect as the, e.g., intravenous dosage form that it is trying to replace.[11]

[11] Indeed, the FDA provides guidance for acceptable replacements for intravenous dosages that offer modes of administration that should provide bioavailability within 85-125% (with a 90% confidence interval) of that provided by the intravenous dosage. *See, e.g.,* USP NF 2003, "Statistical Analysis" section, Exhibit 1044, p. 0007 ("[t]he currently accepted criteria in the United States for equivalence for most dosage forms require that the mean pharmacokinetic parameters of the test dosage form should be within 80% to 125% of the reference dosage form using the 90% confidence interval…, and the upper and lower bounds must be within the 90% confidence interval.").

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117. There are several reasons for this problem. One reason is that the drug is simply not very water-soluble, and so the drug formulation that is being administered does not contain a sufficient dose of the drug. *See* Behl, Exhibit 1039, p. 0019 ("drug solubility in water remains a major limitation for nasal drug delivery.").

118. Relatedly, the volume of the drug formulation that may be administered is limited, based on the available amount of nasal mucosa that can be exposed to the drug formulation. *See* Behl, Exhibit 1039, pp. 0008-0009. According to Behl:

> "If the dose is increased by increasing formulation volume, there may be a limit as to what extent nasal absorption can be increased. The nostrils can retain only a limited volume, beyond which a formulation will drain out of the nasal cavity. The ideal dose volume range is 0.05-0.15 ml with an upper limit of 0.20 ml." Behl, Exhibit 1039, p. 0017.[12]

[12] *See also*: "Normally, 150 µl is the maximum volume that can be applied at any one time into one nostril." Davis, Exhibit 1035, p. 0005. "The subjects received 100 µl into one nostril." Gizurarson, Exhibit 1030, p. 0001.

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119. 0.05-0.15 ml is equivalent to 50-150 µl; the 0.20 ml upper limit is equivalent to 200 µl. In other drugs, chemistry is a factor. For example, the pH of the nasal mucosa relative to the pH of the formulation can affect drug absorption. Behl, Exhibit 1039, pp. 0011-0013. Moreover, polar molecules are known to have difficulty crossing the nasal mucosa. *See* Illum, Exhibit 1027, p. 0003; Davis, Exhibit 1035, p. 0003.

120. Before the earliest filing date of the '876 Patent, various researchers routinely experimented with several different well-known methods to solve the permeation problem, at least because it was known that "by selecting an optimal formulation, a mediocre drug can be converted into a more effective and successful product." Behl, Exhibit 1039, p. 0014. I discuss two of these methods below.

D. Solution #1 for Solving Permeation Problem – Increasing the Drug Solubility to Allow More Drug to Dissolve Per Unit Solvent/Formulation

121. As one of the main problems associated with drugs permeating the nasal mucosa was that many drugs were not very soluble in water, one of the most

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obvious solutions was to increase the amount of drug that was able to be dissolved in the drug formulation's carrier system.

122. Clearly, merely adding more drug into the solvent would not work because the drug simply wouldn't dissolve. Similarly, just increasing the amount of solvent used also wouldn't work because there is a finite limit to the amount of the formulation that can be administered to a nostril. Therefore, researchers experimented (successfully[13], in many cases) with many different solvents (including combinations of different solvents) in an effort to increase the amount of drug that could be dissolved.

123. Several solvents for pharmaceutical use were already well-known well in advance of the '876 Patent's earliest filing date. The widely-referenced Handbook of Pharmaceutical Excipients (i.e., Rowe, Exhibit 1031) discusses ethanol's pharmaceutical uses:

[13] For example, at least as early as 1999, "[a] non-toxic intranasal delivery system for water-insoluble substance, such as benzodiazepines, has been developed." Gizurarson, Exhibit 1030, p. 0001.

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a. "Ethanol and aqueous ethanol solutions of various concentrations…are widely used in pharmaceutical formulations and cosmetics". Rowe, Exhibit 1031, p. 0003.

b. "ethanol is primarily used as a solvent." Rowe, Exhibit 1031, p. 0003.[14]

c. "Topical ethanol solutions are also used as penetration enhancers." Rowe, Exhibit 1031, p. 0003.

d. "Included in the FDA Inactive Ingredients Guide (dental preparations; inhalations; IM and IV injections; nasal and ophthalmic preparations; oral capsules, solutions, suspensions, syrups, and tablets; rectal, topical, and transdermal preparations). Included in nonparenteral and parenteral medicines licensed in the UK." Rowe, Exhibit 1031, p. 0004.

124. Regarding benzyl alcohol, Rowe noted the following:

a. "Benzyl alcohol is an antimicrobial preservative used in cosmetics, foods, and a wide range of pharmaceutical formulations, including

[14] Interestingly, Rowe also notes that "[t]opical ethanol solutions are also used as penetration enhancers". Rowe, Exhibit 1031, p. 0003.

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oral and parenteral preparations, at concentrations up to 2.0% v/v. In cosmetics, concentrations up to 3.0% v/v may be used as a preservative. *Concentrations of 5% v/v or more are employed as a solubilizer*…" Rowe, Exhibit 1031, p. 0009 (*emphasis* added).

b. "Benzyl alcohol 10% v/v solutions also have some local anesthetic properties, which are exploited in some parenterals, cough products, ophthalmic solutions, ointments, and dermatological aerosol sprays." Rowe, Exhibit 1031, p. 0009 (*emphasis* added). (Ophthalmic and intranasal dosage forms are generally formulated similarly because both are for mucosal surfaces and formulations applied to the eye can easily travel into the nose via the nasolacrimal duct (i.e., the tear duct). Thus, a POSITA would understand that teachings related to ophthalmic formulations are generally applicable to intranasal formulations, and vice-versa.)

c. Benzyl alcohol is noted as being "[m]iscible in all proportions" with ethanol. Rowe, Exhibit 1031, p. 0010.

d. "Included in the FDA Inactive Ingredients Guide (injections, oral capsules, solutions and tablets, topical, and vaginal preparations).

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Included in parenteral and nonparenteral medicines licensed in the UK." Rowe, Exhibit 1031, p. 0011.

125. Regarding alpha tocopherol (generally considered synonymous with vitamin E), Rowe noted the following:

a. Under the "nonproprietary names" section, noted that the USP uses the term "Vitamin E". Rowe, Exhibit 1031, p. 0006.

b. "Alpha-tocopherol is a highly lipophilic compound, and is an excellent solvent for many poorly soluble drugs." Rowe, Exhibit 1031, p. 0006.[15]

[15] The next sentence in Rowe seems to indicate that tocopherol is used in a range of from 0.001 – 0.05% v/v. However, a comparison of the monograph with the monograph from the 3rd edition from three years previous (i.e., Kibbe, Exhibit 1026, p. 0007) reveals that the above-quoted sentence is new and that the 0.001-0.05% v/v range is with respect to tocopherol's use as an antioxidant. Moreover, it is my opinion that a POSITA would readily understand that a much higher amount, i.e., much higher than 0.001-0.05% v/v, would be required to act as a solvent.

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126. These three solvents were not simply relegated to scientific discussions in dusty reference tomes. Rather, these solvents were actively being used in intranasal drug formulation development at the time. For example (and as discussed in more detail below), Sonne (Exhibit 1013) tested the solubility of many drugs – including several benzodiazepines – in tocopherol and found that "[a]ll the investigated biologically active agents show a surprisingly high solubility in α-tocopherol." Sonne, 9:43-60, Exhibit 1013, p. 0008.

127. Sonne also recognized that ethanol and benzyl alcohols could be used as co-solvents. Sonne, 3:65-67, Exhibit 1013, p. 0005[16] (ethanol) and 6:49-53, p. 0006 (ethanol and benzyl alcohol).

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[16] Sonne states that the use of ethanol may be "less desired, since solutions of this kind tend to be irritating to mucosal tissue." *Id*. The owner of the '876 Patent has argued in the '439 application that a POSITA would be lead away from using ethanol based on the above-quoted passage. *See* '439 FH, Exhibit 1007, pp. 3084-3085. It is my opinion that, contrary to the patent owner's reasoning, a POSITA would not be dissuaded from using ethanol based on this passage; rather, the POSITA would simply understand that the

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128. Cartt‘784 also recognized that both ethanol and benzyl alcohol are suitable solvents. Cartt’784, [0182], Exhibit 1015, p. 0033.

129. Similarly, Jamieson recognized ethanol’s utility in dissolving clonazepam, a benzodiazepine known to be poorly soluble in water. Jamieson, [0162], Exhibit 1012, pp. 0018-0019.[17]

130. Further, Meezan‘962 also recognized that benzyl alcohol was useful in drug compositions. Meezan‘962, [0074], Exhibit 1011, pp. 0010-0011.

131. Therefore, well in advance of the ‘876 Patent’s earliest filing dates, the POSITA understood that the solubility of poorly soluble drugs could be increased through the use of different solvents, such as tocopherols and alcohols (e.g., ethanol and benzyl alcohol). Therefore, in an effort to

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amount of ethanol used would need to be optimized to avoid irritation while enhancing its co-solvency properties. Such optimization would be routine and well within the skill of the POSITA. Moreover, Sonne uses ethanol in its own Examples 3, 5, 12, and 14, with Example 3 being intended for administration to (rectal) mucosa.

[17] Jamieson’s Tables 12A and 12B also disclose several clonazepam (a benzodiazepine) formulations that contain ethanol.

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increase the amount of the insoluble drug that could pass through the mucous membrane, the POSITA was actively engaged in preparing and routinely experimenting with combinations of drugs and solvents, such as tocopherols and alcohols (e.g., ethanol and benzyl alcohol).

132. The combination of ethanol and benzyl alcohol as a combination solvent for pharmaceuticals is very well-known and goes back to at least the mid-1970s, including in various amounts and proportions.

133. For example, the combination of ethanol and benzyl alcohol is used (along with other ingredients) in publically available diazepam formulations. In particular, the rectal gel Diastat® and the injectable solution Valium® both use ethanol and benzyl alcohol. *See* PDR, Exhibit 1042, pp. 0002 (Diastat® diazepam rectal gel) and 0010 (Valium® injectable).

134. Additionally, Tenta, U.S. Patent No. 3,949,072 (filed in the U.S. in May 1974, and issued in April 1976) (Exhibit 1018) notes that it "prefer[s] to use a solvent system containing about 61.5% weight benzyl alcohol and 38.5% ethanol." Tenta, 3:52-54, Exhibit 1018, p. 0003; *see also* Examples 1-3 (4:7-23 on p. 0003).

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135. Moreover, Ueda et al., U.S. Patent No. 4,657,901 (filed in the U.S. in September 1984, and issued in April 1987) (Exhibit 1019) notes that "ethanol and benzyl alcohol are frequently used, and these alcohols, making up for low solubility of the Compound [I], function to increase absorption and penetration of the composition of the present invention." Ueda, 3:65–4:1, Exhibit 1019, p. 0003. Ueda also notes that its most preferred pharmaceutical composition includes a combination of ethanol and benzyl alcohol. Ueda, 5:5-7, Exhibit 1019, p. 0004; *see also* Formulation Examples 1-8 (5:64–6:51 on p. 0004; containing combinations of ethanol and benzyl alcohol in various ratios).

136. Both Tanta and Ueda are directed to topical preparations as opposed to transmucosal preparations. This would not pose a problem to the POSITA. In particular, the two fields (i.e, topical formulation development and transmucosal preparation development) are related, and a POSITA having expertise in one field would have at least a working understanding and knowledge of the other field.

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E. Solution #2 for Solving Permeation Problem – Using Penetration Enhancers to Increase the Permeability of the Nasal Mucosa With Respect to the Drug

137. Aside from increasing the solubility of the drug in order to solve the problem associated with drugs permeating the nasal mucosa, i.e., that many drugs were not very soluble in water, another very obvious solution was to increase the amount of the insoluble drug that was able to be absorbed into and pass through, i.e., permeate, the nasal mucosa.

138. Fortunately, and well in advance of the earliest filing dates of the '876 Patent, drug formulators were very much aware that it was possible to use certain ingredients to increase the amount of a drug that could permeate through various surfaces (such as mucosa in general and nasal mucosa in particular, as well as normal skin surfaces).

139. Researchers working in the field of nasal administration also discussed the benefits of penetration enhancers. For example, Colombo noted that "absorption enhancers" were used to overcome absorption problems associated with intranasal delivery. Colombo, Exhibit 1037, p. 0011.

140. For example, as early as 1997, researchers were publishing lists of various excipients that could be used as penetration enhancers. In particular,

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Osborne (Exhibit 1024) lists seven classes of penetration enhancers, containing more than ten types of penetration enhancers, totaling well over 100 compounds.[18] Significantly, Osborne lists "Octyl-β-D(thio)glucopyranoside" as a known enhancer under the heading "Miscellaneous compounds and groups." *See* Osborne, Exhibit 1024, p. 0004. Octyl-β-D(thio)glucopyranoside appears to be an alkyl glycoside as defined by the '876 Patent.[19]

141. While working with peptides, Edman et al. noted that "[a]n enhancer is therefore usually needed to reach an acceptable absorption of larger peptides." Edman II, Exhibit 1032, p. 0002. Edman also noted that

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[18] For each of Osborne's listed compounds, Osborne includes a citation to at least one reference where more information may be found.

[19] '876 Patent incorporates by reference Meezan'130 (Exhibit 1020). *See* '876 Patent, 11:43-45, 16: 56-59, 34: 6-9, Exhibit 1001, pp. 0015, 0017, 0026. Meezan'130 lists "alkyl thioglucosides, such as heptyl- or octyl 1-thio α- or β-D-glucopyranoside" as some of the "[e]xamples form which useful alkyl glycosides can be chosen for the therapeutic composition". Meezan'130, 6:10-24, Exhibit 1020, p. 0004.

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"[s]everal enhancers have been tested, such as surfactants, bile salts, gels and fusidic acid derivatives." Edman II, Exhibit 1032, p. 0002.

142. As early as 1992, it was known that "[t]o improve nasal peptide bioavailability, absorption-promoting systems/enhancers have to be used." Edman I, Exhibit 1034, p. 0005. Edman made clear that even as of 1992, the use of penetration enhancers was not new: "Much biopharmaceutical research in this area during the past decade has been devoted to finding and testing different absorption-promoting systems." Edman I, Exhibit 1034, pp. 0005-0006. These penetration enhancers apparently had some associated problems, so Edman dedicated the next several pages of its article to "describ[ing] in more detail the most recently introduced enhancer systems, namely microspheres, STDHF[20] and glycyrrhetinic acid derivatives." Edman I, Exhibit 1034, p. 0007.

143. Luckily, later researchers – i.e., after 1992 but still well before the '876 Patent's earliest priority date – continued to experiment with penetration enhancers. For example, in 1998, Behl et al. noted:

[20] Sodium tauro-24,25-dihydrofusidate. Edman I, Exhibit 1034, p. 0002.

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> "Seldom, one obtains the desired or close to ideal drug absorption profile. Either a drug does not absorb at all or has poor absorption or has delayed absorption or the C_{max} or T_{max} are not adequate. Invariably, a formulator will be faced with a situation where the drug absorption will need to be optimized. The use of absorption promoters or enhancers is an interesting area of research and often provokes controversy." Behl, Exhibit 1039, p. 0020.

144. Researchers in 1999 still recognized that "the absorption of polar drugs from the nose is not normally good." Davis, Exhibit 1035, p. 0003. However, those 1999 researchers "appreciated that it is possible to improve the transport of drugs across the nasal mucosa (and other mucous membranes) by using enhancer systems". Davis, Exhibit 1035, p. 0003. Also in 1999, it was generally accepted that "[t]he poor nasal bioavailability of many substances (in particular, peptide and protein drugs) can be substantially improved by the use of absorption enhancers." Colombo, Exhibit 1037, p. 0007. However, Colombo cautioned that "[t]he acceptability of these enhancers is not only dependent on their promoting effect but also on their safety profile for systemic and local adverse effects." Colombo, Exhibit 1037, p. 0007. Therefore, because Colombo recognized that "[n]asal

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absorption enhancers differ substantially in efficacy and safety", Colombo mentioned that at the time, "research has been focusing on new classes of promoters of nasal drug absorption." Colombo, Exhibit 1037, p. 0012.

145. Similarly, in 2003, Illum stated that "[t]he nasal absorption of such polar drugs can be greatly improved if administered in combination with absorption promoting agents." Illum, Exhibit 1027, p. 0003. Illum also cautions the POSITA that "it is of great importance that one considers carefully the choice of an absorption enhancer for a nasally delivered drug that is not readily absorbed especially in terms of potential nasal and systemic toxicity." Illum, Exhibit 1027, p. 0003.

146. Therefore, well in advance of the '876 Patent's earliest filing date, the POSITA understood that penetration enhancers could be combined with poorly soluble drugs to increase the amount of the drug that could pass through the mucous membrane, the POSITA was actively engaged in, and routinely experimenting with, combinations of drugs and penetration enhancers.

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147. A POSITA would not be limited to just one solution for solving the problem of low drug solubility. Rather, the POSITA could easily combine at least the two above-discussed methods.[21]

1. Alkyl Glycosides In General

148. Aside from penetration enhancers being known in general before the earliest priority dates of the '876 Patent, alkyl glycosides' utility as penetration enhancers was also known in particular – this fact was even admitted by patent owner.

149. In particular, the '876 Patent includes the following statement: "In some embodiments, the compositions comprise at least one alkyl glycoside. In some embodiments, the at least one alkyl glycoside is one described in U.S. Pat. No. 5,661,130, which is incorporated by reference herein." '876 Patent, 11:42-43, Exhibit 1001, p. 0015.

150. The "U.S. Pat. No. 5,661,130" that is referenced is Meezan'130, i.e., Exhibit 1020.

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[21] *See* Behl, Exhibit 1039, p. 0019: "If a certain drug has an extremely low water solubility, it may be worth exploring more than one approach."

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151. According to Meezan‘130 (filed in June 1993, titled “Absorption Enhancers for Drug Administration”):

> “a ‘suitable’ alkyl glycoside means one that fulfills the limiting characteristics of the invention, i.e., that the alkyl glycoside be nontoxic and nonionic, and that it increases the absorption of a compound when it is administered with the compound via the ocular, nasal, nasolacrimal or inhalation route. Suitable compounds can be determined using the methods set forth in the examples.” Meezan‘130, 4:64-5:3, Exhibit 1020, pp. 0003-0004.

152. Similarly, albeit several years later in May of 2006, Meezan et al. filed a patent application titled “Absorption Enhancers for Drug Administration.” Meezan‘962, Exhibit 1011. According to Meezan‘962:

> “[a]ny ‘suitable’ alkyl glycoside means one that fulfills the limiting characteristics of the invention, i.e., that the alkyl glycoside be nontoxic and nonionic, and that it increases the absorption of a compound when it is administered with the compound via the ocular, nasal, nasolacrimal, inhalation or pulmonary, oral cavity (sublingual or Buccal cell), or CSF delivery route.” Meezan‘962, [0054], Exhibit 1011, p. 0008.

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153. At about the same time that Meezan‘130 was filed, Kee et al. filed a patent application that would eventually issue as Kee, Exhibit 1016. Kee was directed to “[t]he use of substituted glycosides to enhance the penetration of drugs across mucus covered epithelial tissues of humans and animals”. Kee, Abstract, Exhibit 1016, p. 0001. According to Kee, such mucus covered tissues included nasal tissues. Kee, 1:21-23, Exhibit 1016, p. 0004. Kee’s terminology of “substituted glycosides” appears to reference the same subject matter as the ‘876 Patent’s “alkyl glycosides” (which are glycosides substituted with an alkyl group).

154. Sonne also included an alkyl glycoside in its invention. In particular, Sonne taught that its emulsion invention could include a surfactant such as “cetearyl glucoside.” Sonne, 6:54-59, Exhibit 1013, p. 0006; *see also* Sonne, Examples 10 and 21 (10:52-67 and 13:11-23, respectively), Exhibit 1013, pp. 0008 and 0010, respectively. Cetearyl glucoside is a mix of C16-C18 alkyl glycosides.

155. Therefore, well in advance of the ‘876 Patent’s earliest filing date, the POSITA understood that alkyl glycosides were safe, non-toxic, and effective

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at increasing the penetration of various drugs across mucosal membranes, such as the nasal mucosal membranes.

156. Moreover, the POSITA would easily be able to pick-and-choose which drugs to combine with the various alkyl glycosides. I believe the owner of the '876 Patent agrees with me, or at least one of the inventors agrees with me.

157. In this regard, Meezan'962 states: "[s]uitable compounds [i.e., active ingredient] can be determined using the methods set forth herein." Meezan'962, [0054], Exhibit 1011, p. 0008. Bearing in mind that Meezan'962 was filed on May 11, 2005, this means that well in advance of the '876 Patent's earliest filing date, the inventors of Meezan'962 provided a methodology for selecting an appropriate drug/alkyl glycoside combination. Significantly, Meezan'962 and the '876 Patent share a common named co-inventor, Edward T. Maggio. Therefore, at least one of the inventors of the '876 Patent, i.e., Maggio, believed that the selection of an appropriate drug/alkyl glycoside combination was not at all difficult because he had already provided a roadmap for doing so. Thus, Inventor Maggio had previously provided a way for the POSITA to conduct some routine

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experimentation, and the POSITA would then be able to select an appropriate drug/alkyl glycoside combination. I agree with Inventor Maggio's belief that such a selection for a specific application would be well within a POSITA's skill and would not require undue experimentation.

2. Dodecyl Maltoside In Particular

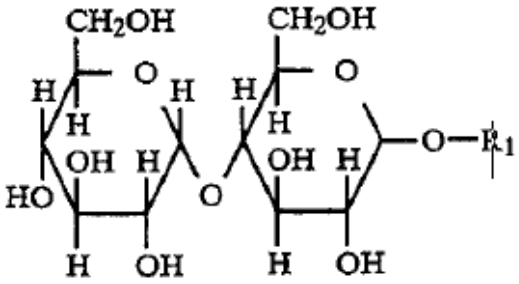
158. Based on my review of the '876 Patent, I believe that the '876 Patent considers dodecyl maltoside to be its most preferred alkyl glycoside. In particular, dodecyl maltoside is named in Example 11 / Table 11-1 of the '876 Patent, which provides the basis for the bioavailability testing. *See* '876 Patent, 60:1-20, 62:24-49, Table 11-3, Exhibit 1001, pp. 0039-0040. Also, dodecyl maltoside is the only specific alkyl glycoside recited in any of the claims. *See* '876 Patent, Claims 26-28 and 30-33, Exhibit 1001, pp. 0041-0042.

159. However, well in advance of the '876 Patent's earliest priority date, dodecyl maltoside was a compound that was well-known for its enhancing abilities/properties.

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160. In particular, while disclosing several different alkyl glycosides,[22] Kee made the following significant statement:

The most preferred penetration enhancer is:



Dodecyl Maltoside

See Kee, 4:42-50, Exhibit 1016, p. 0005.

161. Kee also stated that its "preferred method for enhancing the penetration of a drug or therapeutic agent comprises the use of dodecyl maltoside at a concentration of about 0.01% to 1.0%", combined with a viscosity-modifying agent such as HPMC. Kee, 6:15-20, Exhibit 1016, p. 0006. Kee also included nine Examples which compared formulations containing dodecyl maltoside with other formulations that did not include dodecyl maltoside. In every single Example, Kee's conclusion was that the presence

[22] Or "substituted glycosides", according to Kee's terminology.

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of dodecyl maltoside increased the penetration of the drug. *See* Kee, Examples 1-9, 6: 27-11:12, Exhibit 1016, pp. 0006-0009.[23]

162. Moreover, in its 1993 filing, Meezan‘130 recognized previous reports that "the use of high concentrations of dodecyl maltoside to increase the absorption of insulin across the rectal mucosa in rats. High concentrations were found to be necessary for rectal absorption (3.2%-12.8% dodecyl maltoside)." Meezan‘130, 2:4-7, Exhibit 1020, p. 0002. Such high amounts, however, were viewed as being "too irritating and toxic to the much more sensitive ocular and nasal mucosa and that unsuitable for ocular and nasal absorption enhancers." Meezan‘130, 2:12-15, Exhibit 1020, p.

[23] Example 10 of Kee tested ten other enhancers, at least the first seven of which fit the definition of "alkyl glycoside." Every single enhancer tested increased the penetration of the drug as compared to the control. *See* Kee, Example 10, 11:13-35, Exhibit 1016, p. 0009. Examples 11 and 12 of Kee included dodecyl maltoside and were found to be effective in treating allergic conjunctivitis and inflammation, respectively; however, neither Example 11 nor Example 12 mention a control. *See* Kee, 11:37-67, Exhibit 1016, p. 0009.

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0002. Therefore, Meezan‘130 tested lower amounts of dodecyl maltoside (i.e., 0.50% and lower) and “noted that no damaging effects to the ocular surface were observed with any of the alkylmatoside or alkylsucrose agents employed in these studies.” Meezan‘130, Table 1, 10:9-23 and 10:54-56, Exhibit 1020, p. 0006.

163. Several years later, as of its May 11, 2005 filing date, Meezan‘962 also recognized that dodecyl maltoside was effective for increasing, e.g., the ocular absorption of insulin, as measured by blood glucose levels. *See , e.g.*, Meezan‘962, [0158] and [0162], Exhibit 1011, pp. 0018-0019.

164. I have been informed that just a few months after Meezan‘962 was filed, Aegis Therapeutics, LLC (“Aegis”) filed U.S. Trademark Application No. 78/694,451 for the mark “INTRAVAIL” on August 17, 2005. I have also been informed that Aegis included a statement that the mark “INTRAVAIL” was being used at least as early as May 31, 2005 for “Drug delivery agents consisting of absorption enhancement agents that facilitate delivery of a wide range of pharmaceuticals.” I have been further informed that as proof, Aegis submitted a photo specimen that included a bottle labeled “INTRAVAIL A3”. Therefore, it is my understanding that Aegis was

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certifying that it publically sold "[d]rug delivery agents absorption enhancement agents that facilitate delivery of a wide range of pharmaceuticals", at least as early as May 31, 2005.

165. The '876 Patent states that "Intravail A3" is dodecyl maltoside. '876 Patent, Table 11-1, 60:10-20, Exhibit 1001, p. 0039. Moreover, one of the named co-inventors of the '876 Patent is Edward T. Maggio. *Id*. at p. 0001.

166. According to its website as of August 22, 2018 (apparently as specified by the "20180822" portion of the following website URL), Aegis had named Edward T. Maggio as its CEO, director, and co-founder. *See* https://web.archive.org/web/20180822144759/http://aegisthera.com/corporate/management-and-board-of-directors/#maggio.

167. Therefore, the patent owner, through the work of one of the co-inventors, admitted long ago that dodecyl maltoside is an effective absorption enhancer.

168. Therefore, well in advance of the '876 Patent's earliest filing date, the POSITA understood that dodecyl maltoside in particular was safe and effective at increasing the penetration of various drugs across mucosal membranes, such as the nasal mucosal membranes.

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XII. SUMMARY OF THE PRIOR ART REFERENCES

169. The following paragraphs and pages are a discussion of various art prior art references. The references each recognize several of the same problems, including low solubility of some drugs, low bioavailability of some drugs, problems associated with intranasal administration of drugs, etc. The references also each attempt to solve one or more of these problems (or other problems) through various solutions, such as using solvents such as alcohols (including ethanol and benzyl alcohol) and tocopherols; other potential solutions include the use of penetration enhancers, variously including non-ionic surfactants generally and alkyl glycosides in particular. The goals for the various references range across increasing drug solubility, increase absorption of a drug (including across mucosa such as nasal mucosa), and increasing the overall bioavailability of a drug.

170. A POSITA would easily be able to understand the references discussed below, would easily be able to draw inferences from these references, and would also be able to easily modify these references (including conducting routine experiments based on their singular and/or combined teachings).

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A. Sonne (Exhibit 1013)

171. Sonne disclosed all the elements of the claims of the ‘876 Patent, with the exception of including alkyl glycosides in solution. However, Sonne does include Examples 10 and 21, which include an alkyl glycoside (cetearyl glucoside) in emulsions. In fact, Example 10 is for intranasal diazepam. *See,* Sonne, 10:53-66 (Example 10) and 13:1-23 (Example 21).

1. Problem to be Solved and Solution

172. Sonne recognized that “many biologically active compounds are substantially insoluble or only sparingly soluble in water and in such cases, organic solvents are required to dissolve these agents. The problem here is that mucosal tissues are generally very sensitive and such solvents are frequently too irritant to be of clinical use.” Sonne, 1:50-55, Exhibit 1013, p. 0004.

173. Sonne also recognized that “[a] further constraint concerning nasal administration is that a small administration volume is required; it is not generally possible to administer more than about 0.1 ml per dose per nostril. Therefore, a great need exists for solvents, in which, on the one hand the

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solubility of the active drug is high, and which, on the other hand, are non-irritating to the mucosa." Sonne, 2:30-36, Exhibit 1013, p. 0004.

174. Sonne specifically states that its aim "is to provide a solution to the above mentioned problems." Sonne, 2:37-38, Exhibit 1013, p. 0004.

2. Sonne's General Teachings

175. Sonne teaches me that it is possible to use its invention "directly as solutions of the bioactive agent in the tocopherol solution." Sonne, 3:60-61, Exhibit 1013, p. 0005.[24] The tocopherol may be present in amounts of "from 1 to 99.99% (w/w), preferably 20 to 99.99%, most preferably 40 to 99.99% (w/w)." Sonne, 5:55-58, Exhibit 1013, p. 0006. However, such a solution may be too viscous "for certain applications, for example to achieve a

[24] The bioactive agent may be diazepam, as well as many other benzodiazepines. Sonne, 5:34-38, 7:33-8:42 (Examples 1-3), 9:35-60 (Example 7), 10:20-11:12 (Examples 8-11), 12:23-66 (Examples 17-19), Exhibit 1013, pp. 0006-0009; *see also* Sonne Claims 5, 7, 8, 13, 18, 19, 24, 27, and 28, on pp. 0011-0012.

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sprayable formulation for nasal application." Sonne, 3:62-64, Exhibit 1013, p. 0005.

176. Therefore, Sonne provides a way to solve this viscosity problem – add ethanol. In particular, Sonne directs me to reduce viscosity "by addition of co-solvents such as ethanol". Sonne, 3:65-66, Exhibit 1013, p. 0005. Sonne also provides an alternative, i.e., converting the solutions into emulsions (rather than adding, e.g., ethanol). Therefore, it appears that Sonne encompasses both solutions and emulsions, with each having their own benefits; Sonne does not appear to favor one more than the other. In fact, Sonne provides examples of both solutions and emulsions. *Solutions*: Examples 11-14, 11:1-55, p. 0009; Example 16, 12:9-20, p. 0009; Example 18, 12:37-51, p. 0009; Example 20, 13:1-10, p. 0010. *Emulsions*: Examples 8-10, 10:20-66, p. 0008; Example 15, 11:58-12:7, p. 0009; Example 17, 12:22-35, p. 0009; Example 19, 12:53-67, p. 0009; Example 21, 13:11-23, p. 0010.

177. Although Sonne cautions that using ethanol may "be irritating to certain mucosal tissues" (Col. 3, lines 66-67), I am not concerned about potential irritation to mucosal tissues, such as nasal tissues. In particular, the

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combination of the high levels of vitamin E with the ethanol would counteract the potential for irritation because vitamin E is well-known for its soothing qualities. In fact, Sonne even commented that tocopherols have "a very low irritative potential for mucosal tissues." Sonne, 2:55-58, Exhibit 1013, p. 0004. Even the inventors of '876 Patent admit as much: "Furthermore, use of Vitamin E can have the added benefit of either avoiding irritation of sensitive mucosal membranes and/or soothing irritated mucosal membranes." '876 Patent, 33:47-49, Exhibit 1001, p. 0026. Lastly, Sonne indicated that triacetin was irritating to the nose. *See* Sonne, 1:58-63, Exhibit 1013, p. 0004. However, Sonne still found the use of triacetin in the nose acceptable, including with diazepam, as evidenced by Example 1 (7:32-42, p. 0007); Example 2 (8:11-21, p. 0007); Example 10 (10:53-66, p. 0008); and Example 11 (11:1-10, p. 0009). A POSITA would not be dissuaded from replacing one nose irritant (i.e., triacetin) with another potential nose irritant (i.e., ethanol/alcohol).

178. In addition to mentioning the use of ethanol to reduce viscosity, Sonne helpfully provides additional ways that its invention can be "optimized with respect to bioadhesion, sprayability and viscosity, as desired." Sonne, 6:47-

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49, Exhibit 1013, p. 0006. In order to optimize its invention, Sonne then lists three categories of co-solvents: vegetable oils, alcohols, and triacetin. Ethanol is among the five alcohols listed, along with propylene glycol, glycerol, polyethylene glycol, and benzyl alcohol. Sonne, 6:50-53, Exhibit 1013, p. 0006

179. Moreover, Sonne itself suggests that its invention can include "one or more pharmaceutically acceptable carriers or excipients" while in a form such as a solution or a spray, among others. Sonne, 6:28-35, Exhibit 1013, p. 0006. Therefore, a POSITA would be motivated to experiment with combinations of ethanol and any of these four other alcohols. However, propylene glycol, glycerol, and polyethylene glycol (as well as vegetable oils and triacetin) all have relatively high levels of viscosity as compared to ethanol. Benzyl alcohol's viscosity of 6 cP at 20°C compares favorably to ethanol's viscosity of 1.22 cP at 20°C. *See* Rowe, pp. 54 and 14, respectively. In fact, of all the listed co-solvents, benzyl alcohol and ethanol have the two lowest viscosities, with triacetin being next, followed by the other listed co-solvents. Therefore, if I am looking to decrease viscosity of a formulation (e.g., in order to make it more sprayable), I would gravitate towards using

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ethanol and/or benzyl alcohol as co-solvent and away from using the other co-solvents such as triacetin; if I am looking to increase viscosity of a formulation to prepare non-sprayable formulations, I would naturally gravitate towards one of the vegetable oils, triacetin, or one of the other alcohols. In fact, Sonne's Example 11 is a nosedrop diazepam solution that uses triacetin.

180. Therefore, because Sonne would motivate the POSITA to try "one or more pharmaceutically acceptable carriers or excipients" (Col. 6, lines 28-35) while in a form such as a solution or a spray, and because only benzyl alcohol would work together with ethanol to decrease viscosity, the POSITA would naturally experiment with a combination of ethanol and benzyl alcohol when trying to make a sprayable formulation according to Sonne. Such experimentation is routinely and easily conducted by a POSITA.

181. Therefore, Sonne teaches me that I can create a solution for intranasal administration that includes diazepam, vitamin E, ethanol, and benzyl alcohol. Sonne also is not adverse to using alkyl glycosides. In fact, and as noted above, Sonne does mention using cetearyl glucoside (an alkyl glycoside). Sonne, 4:53, 6:56, Exhibit 1013, p. 0005, 0006.

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3. Sonne's Example 11 as Applied to '876 Patent's Claims

182. Sonne's Example 11 (Col. 11, lines 1-13) is instructive.[25] It teaches a diazepam solution for nasal administration as nose drops, with a formulation of: 1.250 g diazepam, 10.000 g α-tocopherol, and 13.750 g triacetin, for a total mass of 25 g. Mathematically, diazepam is therefore present in Example 11 in an amount of 5.0% (w/w). Mathematically, α-tocopherol is therefore present in Example 11 in an amount of 40.0% (w/w). Mathematically, Example 11 also has 55% (w/w) of a co-solvent. In Example 11's case, the co-solvent is triacetin.

183. As discussed above, Sonne teaches me that its preferred way of making a viscous solution (such as nose drops) into a sprayable formulation is through use of ethanol. Thus, converting Sonne's Example 11 into a sprayable formulation would pose no difficulty to the POSITA and would simply require routine experimentation by the POSITA. Therefore, a POSITA seeking to convert Example 11's nosedrop formulation into an intranasal sprayable formulation would naturally replace Example 11's triacetin with

[25] Sonne's Example 11 may be alternatively referred to herein as "DS11", for Diazepam Solution from Example 11." *See* Exhibit 1050.

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ethanol, as directed by Sonne's Col. 3, lines 65-67, because Sonne considers ethanol to be interchangeable with triacetin as a co-solvent but prefers ethanol over triacetin for reducing viscosity. In fact, because Example 11 is a nosedrop formulation that uses triacetin, triacetin is clearly not sufficient to formulate a sprayable formulation. Therefore, the POSITA would use ethanol to thin out Example 11's nosedrops, thereby creating what I refer to as "DS11-A." *See* Exhibit 1050.[26]

184. Moreover, as discussed above, Sonne motivates the POSITA to try "one or more pharmaceutically acceptable carriers or excipients" (Col. 6, lines 28-35) while in a form such as a solution or a spray. Therefore, after thinning out the Example 11 nosedrop with ethanol, the POSITA seeking to try an additional "pharmaceutically acceptable carriers or excipients" would turn to the only other Sonne co-solvent with a viscosity that would not compromise

[26] Exhibit 1050 is a listing of the various "DS11" diazepam solutions discussed throughout my Declaration. As should be apparent, because each of the DS11 solutions contain diazepam, a POSITA would clearly understand that the DS11 solutions could all be used to treat patients requiring benzodiazepine treatment, especially diazepam treatment.

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the sprayability – benzyl alcohol. That is, all the other co-solvents listed in Sonne as being useful to optimize bioadhesion, sprayability, and viscosity are too viscous and would be expected to convert DS11-A into a nosedrop, i.e., they would not maintain or optimize the sprayable formulation. *See, e.g., also* Rowe, Exhibit 1031, listing viscosities for these co-solvents, all of which except for ethanol and benzyl alcohol are higher than triacetin. Moreover, olive oil and fractionated coconut oil (not listed in Rowe) are generally known to be thicker than ethanol and benzyl alcohol and are not usually suitable for spraying.

185. Therefore, by following Sonne's Example 11 and modifying it by Sonne's other teachings, the POSITA would simply substitute ethanol in for triacetin, and then add benzyl alcohol, for a total alcohol amount of 55%. After that, finding a workable balance between the amount of ethanol and the amount of benzyl alcohol would be a routine day for a POSITA. The POSITA would therefore create a sprayable dosage form I refer to as "DS11-B." *See* Exhibit 1050. Moreover, it appears that the EPO agrees with me with respect to finding a workable balance between the amounts of alcohols:

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> "No unexpected effect whatsoever has been demonstrated in the application for the selection of the claimed individual amounts of ethanol and benzyl alcohol."

EP FH, Exhibit 1040, p. 0297.

> "The solution proposed in claim 7 cannot be considered to be inventive because, in the absence of any unexpected effect associated therewith, the person skilled in the art would consider adjusting the amounts of ethanol and benzyl alcohol by mere routine experimentation and, by doing so, would inevitably arrive at the claimed amounts, without exercising inventive skill".

EP FH, Exhibit 1040, p. 0298; *see also* p. 0365.

> "In the absence of any evidence of an unexpected effect associated therewith, the person skilled in the art would consider adjusting the amounts of ethanol and benzyl alcohol by mere routine experimentation and, by doing so, would inevitably arrive at the amounts of claim 7, without exercising any inventive skill."

EP FH, Exhibit 1040, p. 0328.

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> "An inventive step could be acknowledged for claim 7 if it would be demonstrated that an unexpected technical effect is associated with the use of the claimed amounts of ethanol and benzyl alcohol. This effect should be demonstrated by comparison with another nasal solution including exactly the same components but different amounts of the same solvents".

EP FH, Exhibit 1040, p. 0328.

186. Therefore, after some routine experimentation with Sonne's Example 11, a POSITA could easily arrive at a formulation containing (similar to Example 11): 1.250 g diazepam, 10.000 g α-tocopherol, and 13.750 g ethanol + benzyl alcohol, for a total mass of 25 g. This is equivalent to 5% diazepam, 40% α-tocopherol, and 55% ethanol+benzyl alcohol (i.e., DS11-B). These values fall within the ranges recited in the '876 Patent's Claims 1-7, 9, 10, 13, 16-23, 27, 29, and 34-36. Moreover, they are not far off from the values recited in the '876 Patent's Claims 8 and 11.[27]

[27] In fact, lacking criticality in the amount of tocopherol, a POSITA could easily experiment with various amounts of tocopherols, including various amounts that would fall within the ranges recited in e.g., Claims 11-12, with an expectation of success.

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187. Additionally, if a POSITA wanted to experiment with the viscosity of the formulation a bit more, the POSITA could easily experiment with increasing the tocopherol and simultaneously decreasing one or both of the alcohols – while at the same time ensuring that the solution does not become too viscous to spray. The POSITA would readily understand that if the solution did become too thick to spray, the remedy would simply be to again reduce the amount of tocopherol and increase the amount of the alcohol(s). Therefore, the POSITA could easily increase the amount of tocopherol in DS11-B from 40% to, e.g., about 65% while simultaneously decreasing the total amount of alcohol from 55% down to, e.g., about 30%. That is, tocopherol would be increased by about 25% while the alcohols would be decreased by about 15%.

188. The POSITA would easily be able to experiment with different combinations of ethanol and benzyl alcohol, with a combined total of 30%. In particular, because there is no criticality associated with the alcohols, a POSITA could easily generate many, many different ethanol/benzyl alcohol combinations, several of which would fall within the ranges recited in, e.g.,

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Claims 13 and 14. It would be well within the skill of the POSITA to easily generate, e.g., the following ethanol/benzyl alcohol combinations:

- 30% ethanol/0% benzyl alcohol;
- 0% ethanol/30% benzyl alcohol;
- 10% ethanol/20% benzyl alcohol;
- 20% ethanol/10% benzyl alcohol;
- 15% ethanol/15% benzyl alcohol; and
- 19% ethanol/11% benzyl alcohol.

189. Using the last combination, i.e., 19% ethanol/11% benzyl alcohol, would result in what I refer to as "DS11-C", which has about:

- 5% diazepam;
- 65% α-tocopherol;
- 19% ethanol; and
- 11% benzyl alcohol.

See Exhibit 1050.

190. Even further, a POSITA would be motivated by Sonne to experiment with different amounts of drug in the Example 11 formulation. In particular, Sonne provides solubility data for several benzodiazepines (and other drugs)

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in α-tocopherol (and in sesame oil as a reference point). Below, I have reproduced the benzodiazepine solubility data:

TABLE 1

Active agent	g drug in 100 g of α-tocopherol
Diazepam	12
Alprazolam	4 <x< 6
Midazolam	>13

191. Therefore, the POSITA would understand that a 12% solution of diazepam could be achieved in pure α-tocopherol. Obviously, such a solution would be expected to be too viscous for a nasal spray and so would need to be thinned out with ethanol and benzyl alcohol. Doing so would result in a decrease in the % of diazepam below 12%. Routine experimentation of the various amounts of the limited number of ingredients would easily allow the POSITA to reach amounts, e.g., of about 10% diazepam, of down to 5% as in DS11, and even lower (simply be reducing the amount of diazepam being dissolved).

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B. Gwozdz (Exhibit 1014)

192. Gwozdz discloses all elements of the claims of the ‘876 Patent, with the exception of alkyl glycosides and some dosing regiments. In particular, Gwozdz makes the following general and specific statements:

- “the present invention relates to a pharmaceutical solution comprising a therapeutic agent dissolved in one or more natural or synthetic tocopherols or tocotrienols, or any combination thereof and one or more alcohols or glycos, or any combinations thereof.” Gwozdz, 4:13-17;
- “combining tocopherol and ethanol has been found to provide solubility of the Diazepam approaching the 10% level.” Gwozdz, 7:14-16.

1. Problem to be Solved and Solution

193. Gwozdz recognized that “[a] vast number of potential therapeutic agents are discovered each year, many of which are water insoluble or poorly water soluble. For such hydrophobic compounds, direct injection may be impossible or highly dangerous, and can result in hemolysis, phlebitis,

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hypersensitivity, organ failure and/or death." Gwozdz, 1:10-15, Exhibit 1014, p. 0001. Gwozdz specifically recognized that diazepam is an example of such a therapeutic agent. Gwozdz, 1:18-20, Exhibit 1014, p. 0001.

194. Therefore, Gwozdz attempted to solve this problem by developing its invention which is "solutions of one or more tocopherols and/or tocotrienols and one or more alcohols and/or glycols [that] are used in the solubilization of hydrophobic or lipophilic therapeutic agents thereby providing increased bioavailability of the therapeutic agent." Gwozdz, 7:3-8, Exhibit 1014, p. 0007. Significantly, Gwozdz solved the problem with respect to diazepam ("combining tocopherol and ethanol has been found to provide solubility of the Diazepam approaching the 10% level." Gwozdz, 7:14-16, Exhibit 1014, p. 0007.

2. Gwozdz's General Teachings

195. Gwozdz teaches me that I can produce a pharmaceutical solution "by dissolving any difficult to solubilize therapeutic agent (i.e., hydrophobic or lipophilic therapeutic agents) in one or more tocopherols and/or tocotrienols

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and one or more alcohols and/or glycols as pharmaceutically acceptable solvents." Gwozdz, 7:29-34, Exhibit 1014, p. 0007.

196. Gwozdz also teaches me that "[e]xemplary hydrophobic or lipophilic therapeutic agents which can be solubilized in accordance with the present invention include, but are not limited to,…benzodiazepenes [sic] such as iazepam, alpraxolam, bromazepam, chlordiazepoxidem, clonazepam, estazolam, flunitrazepam, flurazepam, lorazepam, lormetazepam, mexazolam, nitrazepam, oxazepam, temazepam, and triazolam;" Gwozdz, 8:6-13, Exhibit 1014, p. 0008.

197. Additionally, "[e]xamples of alcohol(s) for use in the present invention include, but are not limited to ethanol, propyl alcohol, butyl alcohol, pentanol, benzyl alcohol, and any isomers thereof, and any combinations thereof." Gwozdz, 6:16-19, Exhibit 1014, p. 0006.

198. Significantly, Gwozdz tells me that a solution of a tocopherol and alcohols will "provid[e] increased bioavailability of the therapeutic agent" (which can be a benzodiazepine). Gwozdz, 7:3-8, Exhibit 1014, p. 0007.

199. Therefore, overall, Gwozdz teaches me that I can increase the bioavailability of a benzodiazepine (e.g., diazepam) by preparing a pharmaceutical solution

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by dissolving the benzodiazepine (e.g., diazepam) in a tocopherol and a combination of ethanol and benzyl alcohol.

200. When making such a solution, Gwozdz instructs me to use about 30-99% (w/w) of the tocopherol and about 1-70% (w/w) of the alcohols.

201. Additionally, Gwozdz teaches me that I can dissolve almost 10% diazepam in such a solution. Gwozdz, 7:12-19, Exhibit 1014, p. 0007.

202. Therefore, a solution prepared according to Gwozdz would result in a product that increases bioavailability of the dissolved drug and which encompasses the '876 Patent's Claim 1 recitations (excluding the alkyl glycoside):

a. about 30-99% (w/w) tocopherol;

b. about 1-70% (w/w) of ethanol and benzyl alcohol; and

c. almost 10% diazepam.

3. Gwozdz as Applied to '876 Patent's Claims

a. Gwozdz Applied to Claim 1

203. Similar to '876 Patent's Claim 1, Gwozdz teaches that pharmaceutical solutions containing 30-99% tocopherols, 1-70% alcohols (including

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combinations of ethanol and benzyl alcohol), and benzodiazepines (such as diazepam) can be created. Gwozdz, 4:13-21. Gwozdz also teaches its "invention relates to methods of treatment of a patient with these pharmaceutical solutions." Gwozdz, 4:24-26. Also similar to Claim 1, Gwozdz discloses that "[p]harmaceutical solutions of the instant invention are particularly useful in formulations to be administered to mucosal membranes, i.e. the nasal mucos or lungs of a subject by any suitable means." Gwozdz, 9:19-22.

b. Gwozdz Applied to Claim 2

204. Similar to '876 Patent's Claim 2, Gwozdz teaches me that the tocopherol can be vitamin E. Gwozdz, 5:33-6:2, Exhibit 1014, p. 0005-0006.

c. Gwozdz Applied to Claim 3

205. Similar to '876 Patent's Claim 3, Gwozdz teaches me that the benzodiazepine can be various benzodiazepines (many of which are recited in '876 Patent's Claim 3. Gwozdz, 8:9-13, Exhibit 1014, p. 0008.

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d. 'Gwozdz Applied to Claim 4

206. Similar to '876 Patent's Claim 4, Gwozdz teaches me that the benzodiazepine can be diazepam. Gwozdz, 7:12-19, 8:10, Exhibit 1014, p. 0007, 0008.

e. Gwozdz Applied to Claims 5 and 6

207. Similar to '876 Patent's Claims 5 and 6, Gwozdz teaches me that diazepam can be present in an amount "approaching the 10% level" because "[d]iazepam is soluble to greater than or equal to 8%" in some tocopherol/alcohol combinations and that "[d]iazepam is soluble at greater than or equal to 9%" in other tocopherol/alcohol combinations. Gwozdz, 7:12-19, Exhibit 1014, p. 0007.

f. Gwozdz Applied to Claim 7

208. Similar to '876 Patent's Claim 7, Gwozdz teaches me that the tocopherol can be alpha-, beta-, gamma-, and delta-tocopherols and/or -tocotrienols, and derivatives or analogs thereof. Gwozdz, 6:2-11, Exhibit 1014, p. 0006.

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g. Gwozdz Applied to Claims 8 and 15

209. Similar to '876 Patent's Claim 8, Gowzdz teaches me that alcohol can generally be present in amounts of 1-70%, with ethanol specifically being called out in amounts of 10-30%. Gwozdz, 4:19-21, 7:10-11 and 20-24, Exhibit 1014, pp. 0004, 0007. Moreover, because there is no criticality or unexpected effects associated with the amount or type of alcohol(s), a POSITA would easily be able to experiment with different amounts, especially in view of Gwozdz's teachings that the tocopherol:ethanol ratio may be approximately 95:5, 90:10, 85:15, 80:20, 75:25, 70:30, 65:35, or 60:40. Gwozdz, 7:25-28, Exhibit 1014, p. 0007.

h. Gwozdz Applied to Claims 9 and 10

210. Claim 9 recites a benzodiazepine "concentration of from about 10 mg/mL to about 250 mg/mL", and Claim 10 recites that the concentration is "from about 20 mg/mL to about 50 mg/mL." This is equivalent to ranges of about 1-25% and about 2-5%, respectively.

211. Similar to these claims, Gwozdz teaches me that diazepam may be present in tocopherol/alcohol solutions in amounts of "greater than or equal to 8%",

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"greater than or equal to 9%", and "approaching the 10% level." Gwozdz, 7:14-19, Exhibit 1014, p. 0007.

212. A POSITA would easily be able to reduce these percentages to the 2-5% range simply by adding less of the active ingredient.

i. Gwozdz Applied to Claims 11 and 12

213. Similar to '876 Patent's Claims 11 and 12, Gwozdz teaches me that the tocopherol can be present in an amount of , e.g., 70-90%. Gwozdz, 7:22-25, Exhibit 1014, p. 0007.

j. Gwozdz Applied to Claims 13 and 14

214. Similar to '876 Patent's Claims 13 and 14, Gwozdz teaches me that the combined amount of ethanol and benzyl alcohol can be present in an amount of 10-30%. Gwozdz, 7:22-25, Exhibit 1014, p. 0007. In particular, ethanol is taught as being present in an amount of 10-30%, with benzyl not being mentioned in that particular portion of Gwozdz; thus, the combined amount of ethanol and benzyl alcohol is 10-30%.

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k. Gwozdz Applied to Claim 16

215. Similar to '876 Patent's Claim 16, Gwozdz teaches me that its formulation can be in the form of "a mist sprayer." Gwozdz, 10:2, Exhibit 1014, p. 0010.

l. Gwozdz Applied to Claims 24-26

216. Gwozdz does not disclose alkyl glycosides generally or specifically, nor amounts of alkyl glycosides. However, Gwozdz does teach that it is possible to add penetration enhancers to its invention. *See* Gwozdz, 10:14, Exhibit 1014, p. 0010. Therefore, because Gwozdz does not list any penetration enhancers, a POSITA would be lead to seek out similar references that do include specific penetration enhancers (and amounts), e.g., Meezan'962 (Exhibit 1011).

m. Gwozdz Applied to Claims 27-33

217. Claims 27-33 each recite the presence of diazepam, vitamin E, ethanol, benzyl alcohol, and alkyl glycoside (or dodecyl maltoside in particular), differing from each other only in the amounts of each ingredient recited.

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218. Similar to these claims, Gwozdz teaches me that it is possible to make solutions of tocopherols (i.e., vitamin E), alcohol(s) (including ethanol and benzyl alcohol combinations), and diazepam. *See generally* Gwozdz, 7:3-34, Exhibit 1014, p. 0007; *see also* 6:16-19 on p. 0006 (ethanol, benzyl alcohol, and combinations thereof). Various amounts/ranges of amounts of each of these ingredients is also disclosed. *See*, *e.g.*, Gwozdz, 4:17-21, 7:8-28, Exhibit 1014, pp. 0004, 0007. As discussed with respect to Claims 24-26, above, Gwozdz also teaches the use of a penetration enhancer. Gwozdz, Exhibit 1014, 10:14, p. 0010. According to PO's own admission, alkyl glycosides are penetration enhancers. *See* '876 Patent, 16:55-56, Exhibit 1001, p. 0017.

n. Gwozdz Applied to Claims 34-36

219. While not disclosing specific bioavailability ranges, Gwozdz does teach that "solutions of one or more tocopherols…and one or more alcohols…are used in the solubilization of hydrophobic or lipophilic therapeutic agents thereby providing increased bioavailability of the therapeutic agent." Gwozdz, 7:3-8, Exhibit 1014, p. 0007.

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220. Determining bioequivalence of a drug dosage form is not difficult, and a POSITA would readily know how to conduct such experiments and analyze the collected data. *See, e.g.*, Ritschel, Equation 36.1 on p. 506, Exhibit 1023, p. 0016.

221. Moreover, a POSITA would have readily known to target a bioavailability approaching 100%, based on FDA requirements and general knowledge in the art. *See, e.g.*, USP/NF 2003, Exhibit 1044, p. 0007 (left column).

C. Meezan'962 (Exhibit 1011)

222. Meezan'962 discloses intranasal solutions (which could include sprays) for the administration of various drugs, including small organic molecules and a couple of anti-seizure agents. Although not specifically named, a POSITA would readily expect that Meezan'962 would be applicable to benzodiazepines because benzodiazepines are small organic molecules and are known to be anti-seizure agents. Meezan'962, [0004], [0052], Exhibit 1011, pp. 0005, 0008. Moreover, the POSITA would understand that Meezan'962 expected its teachings to be applicable to drugs such as benzodiazepines

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223. Meezan‘962 further discloses that alkyl glycosides (such as dodecyl maltoside) could be added to greatly increase bioavailability. *See, e.g.*, Meezan’962, [0150], Exhibit 1011, p. 0018 (“intranasal delivery of MIACALCIN® with 0.125% and 0.250% alkyl glycoside (TDM) resulted in about 43% to about 90% bioavailability, respectively. The bioavailability of intranasal administration of MIACALCIN® without alkyl glycoside is only about 3% in humans…”).

224. Moreover, Meezan’962 teaches that different amounts of alkyl glycoside could be used to fine-tune the increase in absorption/penetration. *See, e.g.*, Meezan‘962, [0158], Exhibit 1011, pp. 0018-0019 (“The effects of the alkylmaltosides as absorption enhancers are dose-dependent, as can be seen by examining the effects of different concentrations ranging from 0.125-0.5% in producing a hypoglycemic effect when combined with insulin.”). The POSITA would understand that an increase in absorption/penetration would result in an increase in bioavailability.

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1. Problem to be Solved and Solution

225. Meezan‘962 recognized that although the combination of therapeutic agents and surfactants was well know, such combinations could be problematic. In particular, “surfactants are frequently irritating to the skin and other tissues, including mucosal membranes such as those found in the nose, mouth, eye, vagina, rectum, esophagus, intestinal tract, and the like.” Meezan‘962, [0003], Exhibit 1011, p. 0005.

226. Therefore, Meezan‘962 attempted to solve this problem by developing “a therapeutic composition containing a drug enhancing agent useful for increasing the absorption and bioavailability of the drug, while at the same time avoiding various adverse toxic effects of the drug.” Meezan‘962, [0004], Exhibit 1011, p. 0005. That is, Meezan’962 did not seek to increase the amount of a low-solubility drug that could be dissolved; rather, Meezan’962 took however much drug was already dissolved and sought to make it as available to the body as possible (i.e., bioavailable).

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2. Meezan‘962’s (Exhibit 1011) General Teachings

227. Meezan‘962 is directed towards “non-irritating, non-toxic compositions providing enhanced bioavailability and more specifically to alkyl glycoside or saccharide alkyl ester compositions for delivery of therapeutic agents to a subject.” Meezan‘962, [0002], Exhibit 1011, p. 0005.

228. The therapeutic agent can be a small molecule. In particular, Meezan‘962’s “invention also anticipate the use of small molecules, for example, an organic compound that has a molecular weight of less than 3 kD, or less than 1.5 kD.” Meezan‘962, [0130], Exhibit 1011, p. 0015; *see also* [0004], [0050] on pp. 0005, 0007. Anti-seizure agents are listed as a type of therapeutic agent that can be used. Meezan‘962, [0052], Exhibit 1011, p. 0008. A POSITA would readily recognize that benzodiazepines, e.g., diazepam, are small organic molecules – with diazepam having a molecular weight of 284.4 Daltons (i.e., fitting the description of “less than 3 kD, or less than 1.5 kD”) – that are considered to be anti-seizure agents. *See also* PDR, Exhibit 1042, p. 0002 (DIASTAT®) and pp. 0010-0011 (VALIUM®).

229. Meezan‘962’s alkyl glycosides include “octyl-, nonyl-, decyl-, undecyl-, dodecyl-, tridecyl-, tetradecyl-, pentadecyl-,hexadecyl-, heptadecyl-, and

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octadecyl-α- or β-D-maltoside, -glucoside or -sucroside." Meezan'962, [0056], Exhibit 1011, p. 0008; *see also* [0058] and [0061] on p. 0009.

230. Dodecyl maltoside is specifically mentioned. Meezan'962, [0092], [0156], [0158], and Table I, Exhibit 1011, pp. 0012, 0018-0019.

231. Meezan'962 also teaches that the alkyl glycoside may be present in formulations in amounts of "about 0.01% to 20% by weight. More preferred levels of incorporation are from about 0.01% to 5% by weight, from about 0.01% to 2% by weight, from about 0.01% to 1%, most preferably from about 0.01% to 0.125% by weight." Meezan'962, [0070], Exhibit 1011, p. 0010.

232. In particular, Meezan'962 tested the effects of dodecyl maltoside in amounts of 0.125%, 0.25%, 0.375%, and 0.50%. Meezan'962, Table I, Exhibit 1011, p. 0019. While the 0.125% amount was considered ineffective, amounts of 0.375% and 0.5% dodecyl maltoside were considered to be equally effective in increasing bioavailability (0.25% was considered to be effective but less so than the 0.375% and 0.5% amounts). Meezan'962, [0158], Exhibit 1011, pp. 0018-0019.

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233. Therefore, Meezan‘962 concluded that “alkyl glycosides enhance the absorption of the drug.” Meezan‘962, [0162], Exhibit 1011, p. 0019.

234. Meezan‘962 also provided Example 2, which discussed alkyl glycosides’ use for improving bioavailability of a drug composition:

“EXAMPLE 2

Alkyl Glycoside and/or Ester Compositions
Stabilize Drugs by Increasing Drug Bioavailability
and Reducing Drug Bioavailability Variance

> Stability of the alkyl glycoside depends, in part, on the number of carbon atoms, or branching of the alkyl chain, with tetradecylmaltoside (TDM) having the greatest effect; but other highly branched alkyl chains including DDM [dodecylmaltoside] also have stabilizing effects. In contrast to Hovgaard-1, which described the preference for a high alkyl glycoside to drug ratio, the instant invention shows that this ratio is much lower. For example, alkyl glycosides in the range of about 0.01% to about 6% by weight result in good stabilization of the drug; whereas Hovgaard-1 shows stabilization is only achieved at much higher ratios of alkyl glycosides to drug (10:1 and 16: 1). **Even more interesting, alkyl glycosides of the invention in the range of about 0.01% to about 6% have increased bioavailability (see**

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FIG. 1). This is in sharp contrast to Hovgaard-2, which showed relatively low bioavailability (0.5-1%) at the high alkyl glycoside ratios (10:1 and 16:1).

FIG. 1 is a graph comparing the bioavailability of the drug MIACALCIN® (salmon calcitonin from Novartis) with and without alkyl glycoside (TDM). MIACALCIN® is a nasal spray and administered directly onto the nasal epithelium or nasal mucosa. FIG. 1 shows that MIACALCIN® minus alkyl glycoside has very low bioavailability levels in humans (MIACALCIN® product specification insert), as compared to the MIACALCIN® with alkyl glycoside as administered to rats. **More specifically, intranasal delivery of MIACALCIN® with 0.125% and 0.250% alkyl glycoside (TDM) resulted in about 43% to about 90% bioavailability, respectively.** The bioavailability of intranasal administration of MIACALCIN® without alkyl glycoside is only about 3% in humans, and was undetectable in rats, suggesting that the rat is a stringent model for estimating intranasal drug absorption in humans. **Thus, the alkyl glycoside of the invention enhances absorption and increases bioavailability of the drug**.

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> Furthermore, besides increasing the bioavailability of the drug, the alkyl glycoside compositions of the invention effectively decrease the bioavailability variance of the drug. FIG. 1 shows that administration of MIACALCIN® with alkyl glycoside (0.125% or 0.25%) intranasally has a bioavailability variance of ±8%, whereas the bioavailability variance without alkyl glycoside is 0.3% to 30%, or a two orders of magnitude change. **The increase in bioavailability and the decrease in the bioavailability variance ensures patient-to-patient variability is also reduced. The results as shown in FIG. 1 are administered intranasally, however, similar results are expected for oral, buccal, vaginal, rectal, etc. delivery and at different alkyl glycoside concentrations.**" Meezan'962, Example 2, [0149]-[0151], Exhibit 1011, pp. 0017-0018 (**emphasis** added).

235. Based on the above, a POSITA would understand that Meezan'962 was able, through use of an alkyl glycoside, to increase the bioavailability of a tested intranasal drug product from 3% (without alkyl glycoside) up to about 90%. Moreover, the POSITA would understand that Meezan'962 was able to narrow the bioavailability variance to ±8%, meaning that of the dosage form

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that achieved 90% bioavailability, some subjects experienced bioavailability of 82%, and some subjects experienced bioavailability of 98%. A 98% bioavailability clearly falls within the ranges recited in Claims 34-36.

236. Although the tested product was not a benzodiazepine, as discussed above, Meezan‘962 taught that alkyl glycosides could be used with therapeutic agents such as “small molecule organic drug molecules.” *See* Meezan‘962, [0004], Exhibit 1011, p. 0005; *see also* [0008] at p. 0005. The POSITA would know that benzodiazepines are small molecule organic drug molecules and would therefore understand that Meezan‘962 expected that its teachings would be applicable to drugs such as benzodiazepines. In fact, Meezan‘962 specifically lists “anti-seizure agents” as types of drugs with which alkyl glycosides may be used. *See* Meezan‘962, [0052], Exhibit 1011, p. 0008.[28]

237. Although the above teachings of Meezan were directed to ocular formulations, Meezan‘962 teaches that alkyl glycosides can be used for

[28] While Meezan‘962 lists two non-benzodiazepine anti-seizure agents, the POSITA would readily understand that benzodiazepines are anti-seizure agents.

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intranasal formulations. Meezan‘962, [0044]-[0046], Exhibit 1011, p. 0007; *see also* Figs. 1-3 on pp. 0002-0004.

238. Moreover, a POSITA would readily understand that ocular and nasal delivery routes (and, therefore, formulations) have similar characteristics because drugs placed in the ocular area are often found to also be active in the nasal cavity.

239. In particular, the eye and the nose are connected by the nasolacrimal duct (colloquially referred to as the tear duct). This is part of the reason why it is possible to sometimes taste eye drops (as is well known, smell is a big part of tasting).

240. The formulation can be in the form of a spray. Meezan‘962, [0063], [0070], [0073], [0144], Exhibit 1011, pp. 0009, 0010, 0017.

D. Cartt’784 (Exhibit 1015)

1. Problem to be Solved and Solution

241. Cartt’784 noted that “[n]asal formulations of benzodiazepines have been suggested for the acute treatment of seizure…However, the utility of the existing nasal benzodiazepine formulations has been limited to a degree by

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the poor solubility of such benzodiazepines as diazepam….As smaller dose volumes are preferred for nasal administration, poor water solubility of benzodiazepines limits the effective dose that may be administered to a patient at any given time. This in turn limits the clinical effectiveness of nasally-administered benzodiazepines for the acute treatment of seizure." Cartt'784, [0007], Exhibit 1015, p. 0001.

242. Therefore, Cartt'784 recognized the "need for benzodiazepine formulations that are capable of providing to the nasal mucosa sufficient quantity of benzodiazepine in a small enough volume to provide therapeutically effective blood plasma concentration of benzodiazepine within a short period after administration of the formulation to the nasal mucosa." Cartt'784, [0008], Exhibit 1015, p. 0001.

2. Cartt'784's General Teachings

243. Cartt'784 teaches me that "[n]asal formulations of benzodiazepines have been suggested for the acute treatment of seizures" because they can result in "fast achievement of pharmaceutically effective plasma levels." Cartt'784, [0007], Exhibit 1015, p. 0001. However, "the utility of the

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existing nasal benzodiazepine formulations has been limited to a degree by the poor solubility of such benzodiazepines as diazepam." Cartt'784, [0007], Exhibit 1015, p. 0001.

244. Cartt'784 then enumerates problems that it is attempting to solve in the very next paragraph (i.e., [0008] on p. 0001):

a. "There is a need for benzodiazepine formulations that are capable of providing to the nasal mucosa sufficient quantity of benzodiazepine in a small enough volume to provide therapeutically effective blood plasma concentration of benzodiazepine within a short period after administration of the formulation to the nasal mucosa."

b. "There is also a need for methods of treating a variety of disorders, including anxiety and seizure, by administering a therapeutically effective amount of a benzodiazepine drug to the nasal mucosa."

c. "In particular, there is a need for an intranasal formulation of diazepam that is capable of producing anticonvulsant effective blood plasma levels within a short period after having been administered to a patient.

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d. "There is also a need for a method of providing acute relief from seizure to a patient within a short period after administering a benzodiazepine, such as diazepam, to the patient."

245. Therefore, in order to solve at least some of these problems, Cartt'784 "provides methods of administering a benzodiazepine to a patient, comprising nasally administering an effective amount of the benzodiazepine to the patient, wherein the effective amount of the composition is effective to treat seizure, protect against seizure, reduce or ameliorate the intensity of seizure, reduce or ameliorate the frequency of seizure, and/or prevent occurrence or re-occurrence of seizure." Cartt'784, [0028], Exhibit 1015, p. 0003.

246. Additionally, I am taught by Cartt'784 that its invention "provides for improved bioavailability of benzodiazepine drugs, delivery of higher concentrations of benzodiazepine drugs via the nasal route, faster attainment of therapeutic levels of benzodiazepine in the blood plasma, avoidance of the liver portal vein and concomitant avoidance of first pass effects and/or faster presentation of benzodiazepine drug to the brain." Cartt'784, [0053], Exhibit 1015, p. 0016.

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247. Cartt'784 appears to prefer that its benzodiazepines be in particulate form. *See, e.g.*, Cartt'784, Abstract. However, the dosage form itself may be "a nasal spray or nasal drop, although presently preferred embodiments are nasal sprays…[which] may be liquid or solid nasal sprays." Cartt'784, [0138], Exhibit 1015, p. 0029. Moreover, Cartt'784 acknowledges that "[i]t is also possible for the drug to be fully soluble in the liquid." Cartt'784, [0139], Exhibit 1015, p. 0029. In particular, the dosage form may be in the form of liquid droplets which "may be formed from solutions…" Cartt'784, [0139], Exhibit 1015, p. 0029. Additionally, Cartt'784 notes that its formulation "may be contained within the reservoir [of a delivery device], optionally in a liquid solution…" Cartt'784, [0141], Exhibit 1015, p. 0029.

248. The solution itself may be a combination of the drug in a "non-aqueous medium." Cartt'784, [0139], Exhibit 1015, p. 0029. Although not explicitly mentioned in Cartt'784, a tocopherol would be such a non-aqueous medium.

249. Moreover, Cartt'784 classifies both ethanol and benzyl alcohol as useful solvents. Cartt'784, [0182], Exhibit 1015, p. 0033.

250. Because, as noted above, Cartt'784 recognized that it was difficult to provide a "sufficient quantity of benzodiazepine in a small enough volume"

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to the nasal mucosa (¶ [0008), Cartt'784 decided to utilize absorption enhancers, which was defined as "any material which acts to increase absorption across the mucosa and/or increases bioavailability." Cartt'784, [0124], Exhibit 1015, p. 0026. One such absorption enhancer is a "surface active agent", which includes "surface stabilizers." Cartt'784, [0126]-[0127], Exhibit 1015, p. 0026.

251. Significantly, Cartt'784 lists the following as "surface stabilizers": "n-decyl-β-D-glucopyranoside; n-decyl β-D-maltopyranoside; n-dodecyl β-D-glucopyranoside; n-dodecyl β-D-maltoside; n-heptyl- β-D-glucopyranoside; n-hexyl β-D-glucopyranoside; n-noyl β-D-glucopyranoside; and n-octyl-β-D-glucopyranoside. Cartt'784, [0047], [0048], [0128], [0129], Exhibit 1015, pp. 0014-0015, 0026-0027.[29]

[29] I note for the record that ¶¶ [0047], [0048], and [0129] all seem to include the same typographical errors wherein the Greek letter "β" is being transcribed as an open parenthesis, i.e., "(". ¶ [0128] appears to correctly recite that Greek letter "β."

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252. Therefore, Cartt'784 teaches me that one of the above listed chemicals – which are all alkyl glycosides – can be used to enhance the absorption of a benzodiazepine (such as diazepam) across the nasal mucosa.

3. Cartt'784 as Applied to '876 Patent's Claims 17-23

a. '876 Patent's Claim 17

253. Similar to the '876 Patent's Claim 17, Cartt'784 teaches me that the dosage amount of the benzodiazepine, diazepam in particular, can be in range of about 1 to about 20 mg. Cartt'784, [0063], Exhibit 1015, p. 0018. Cartt'784 also teaches other ranges of other benzodiazepines that overlap with the amounts recited in '876 Patent's Claim 17. Cartt'784, [0055], [0071], Exhibit 1015, pp. 0017, 0019.

b. '876 Patent's Claim 18

254. Similar to the '876 Patent's Claim 18, Cartt'784 teaches me that the volume of the formulation for benzodiazepines should be "less than 250 µl, preferably less than 150 µl, and ideally from 25 to 100 µl". Cartt'784, [0007], Exhibit 1015, p. 0001. Significantly, Cartt'784 also discloses that

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the formulation should be in amounts of 25-250 µl, 50-150 µl, and about 100 µl for alprazolam, diazepam, and flurazepam. Cartt'784, [0056], [0064], [0072], Exhibit 1015, pp. 0017, 0018, 0019.

c. '876 Patent's Claims 19-22

255. Similar to the '876 Patent's Claims 19-22, Cartt'784 teaches me that the spray formulation should be sprayed into at least one nostril or both nostrils, either once or twice each. Cartt'784, [0031], Exhibit 1015, p. 0004.

d. '876 Patent's Claim 23

256. Similar to the '876 Patent's Claim 23, Cartt'784 teaches me that its formulation can be used to, e.g., prevent occurrence or re-occurrence of a seizure, i.e., before the symptoms of a seizure disorder occur. Cartt'784, [0031], Exhibit 1015, p. 0004, Exhibit 1015, p. 0004.[30]

[30] However, as noted earlier, in my opinion a POSITA would not construe claim 23 as being limiting.

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XIII. MOTIVATION TO COMBINE

257. A person of ordinary skill in the art would have understood that all the aforementioned teachings are naturally combinable because all references above are related to the same field of endeavor and are directed towards solving the same problems.

258. In particular, and as discussed above as a preface to each reference, each of the following mentioned references (i.e., Sonne, Gwozdz, Meezan‘962, and Cartt’784) all recognized that there are benefits to administering active agents intranasally. However, inherent difficulties were also recognized; these inherent difficulties meant that certain drugs could not be intranasally administered unless and until the difficulties were overcome. Therefore, each of the above mentioned references sought to provide solutions to these difficult problems, and each reference experimented with different potential solutions.

259. For example, some references sought to increase the solubility of the drug so that more drug was present in the small volume that could be intranasally administered. Other references considered ways to increase the amount of the drug that could penetrate across the nasal mucosa, so that although the

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same amount of drug may be present in the small volume, more of the drug would make its way across the nasal mucosa (and, therefore, into the bloodstream). In fact, some of references tried both methods.

260. A POSITA seeking to solve these same difficulties would naturally seek out and review other references that attempted to solve the difficulties. Moreover, mentally combining the references would be the next logical step, with experiments to combine the teachings coming next.

261. Regarding Ueda – it issued more than 20 years before the earliest filing date of the ‘876 Patent claims. It therefore forms part of the general knowledge and prior art of which a POSITA would be aware. Moreover, Ueda is in the field of pharmaceutical formulations, including using combinations of alcohols as solvents and carriers.

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XIV. THE '876 PATENT CLAIM CHARTS

262. I have reviewed the '876 Patent Claim Charts attached hereto as Peppas Appendix A[31] in light of the prior art discussed above and as further discussed below. It is my opinion that a POSITA would have been motivated to combine the various disclosures found in the discussed prior art to arrive at the subject matter of the claims of the '876 Patent. My opinions are discussed in more detail in the Grounds set forth below.

263. It is my understanding that the Grounds[32] are:

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[31] I have been informed by counsel that the attached claim charts (Peppas Appendix A) prepared by counsel, are the same claim charts found in the Petitions.

[32] I have been informed by counsel that my Declaration may be used in at least two different Petitions for *Inter Partes* Review. Therefore, the "Ground numbers" in this Declaration may differ slightly from the organization in the Petition(s). It should not be difficult for the reader to determine which of my numbered Grounds corresponds to the Grounds in the Petition(s).

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Ground	Reference(s)	Basis	Claims Challenged
1	Sonne (Exhibit 1013) Meezan'962 (Exhibit 1011)	35 U.S.C. § 103(a)	1-36
2	Gwozdz (Exhibit 1014) Meezan'962 (Exhibit 1011)	35 U.S.C. § 103(a)	1-16, 24-36
3	Gwozdz (Exhibit 1014) Meezan'962 (Exhibit 1011) Cartt'784 (Exhibit 1015)	35 U.S.C. § 103(a)	17-23

XV. GROUND 1 – CLAIMS 1-36 AS OBVIOUS OVER SONNE (EXHIBIT 1013) IN VIEW OF MEEZAN'962 (EXHIBIT 1011)

A. Claim 1

264. As discussed above, DS11-C (Exhibit 1050) includes about:

- 5% diazepam;
- 65% α-tocopherol;
- 19% ethanol; and
- 11% benzyl alcohol.

265. Therefore, DS11-C includes all the elements of the solution recited in Claim 1, with the exception of "alkyl glycoside." A POSITA seeking to optimize

the bioavailability of DS11-C would look to Meezan'962, for the reasons discussed above under the "Motivation to Combine" section. Based on Meezan'962's teachings, the POSITA would add an alkyl glycoside to DS11-C with an expectation of successfully increasing the bioavailability of DS11-C.

266. Meezan'962 specifically teaches, e.g., an alkyl glycoside amount of about 0.25%. *See, e.g.*, Meezan'962, [015-]-[0151], Exhibit 1011, pp. 0018; *see also* Fig. 1 on p. 0002, [0158]-[0159] on p. 0019, Table I on p. 0019, Example 6 on p. 0020.

267. Meezan'962 also specifically lists alkyl glycosides, including dodecyl maltoside. *See* Meezan'962, [0056], [0058], [0061], Exhibit 1013, p. 0008, 0009.

268. Therefore, based on Meezan's teaching of 0.25% alkyl glycoside, dodecyl maltoside, and the fact that the amount and identity of the alkyl glycoside is not critical (and is, in fact, predictable), a POSITA would easily select about 0.25% dodecyl maltoside to add to DS11-C, thereby creating DS11-D.

269. Of all the ingredients present, ethanol is most likely to be considered added q.s. and not with a specific amount being targeted. Therefore, on adding

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about 0.25% dodecyl maltoside, the POSITA would naturally reduce the amount of ethanol by about 0.25%. DS11-D therefore includes about:

- 5% diazepam;
- 65% α-tocopherol;
- 18.75% ethanol;
- 11% benzyl alcohol; and
- 0.25% dodecyl maltoside.

See Exhibit 1050.

270. Therefore, intranasal DS11-D falls within the ranges specified in the pharmaceutical solution recited in Claim 1.

271. Moreover, Sonne specifically states that its "invention can be seen to provide a method of treatment of a human or non-human animal subject…" Sonne, 6:41-43, Exhibit 1013, p. 0006.

272. Therefore, all the elements recited in Claim 1 can be found in DS11-D, which is a combination of Sonne and Meezan'962.

273. Therefore, in my opinion, Claim 1 of the '876 Patent is obvious in view of the combination of Sonne and Meezan'962.

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B. Claim 2

274. Claim 2 requires the presence of vitamin E.

275. DS11-D includes α-tocopherol. As discussed in my Claim Construction section above, α-tocopherol is considered to be a form of vitamin E.

276. Therefore, in my opinion, Claim 2 of the '876 Patent is obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

C. Claims 3-4

277. Claim 3 requires that the benzodiazepine is selected from a long list that includes diazepam; Claim 4 requires that the benzodiazepine be diazepam.

278. DS11-D includes diazepam.

279. Therefore, in my opinion, Claims 3-4 of the '876 Patent are obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

D. Claims 5-6

280. Claim 5 requires the presence of about 1-20% benzodiazepine; Claim 6 requires that the benzodiazepine be diazepam.

281. DS11-D includes about 5% diazepam.

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282. Therefore, in my opinion, Claims 5-6 of the ‘876 Patent are obvious in view of the combination of Sonne and Meezan’962, as evidenced by DS11-D.

E. Claim 7

283. Claim 7 requires that the tocopherol be selected from a long list that includes α-tocopherol.

284. DS11-D includes α-tocopherol.

285. Therefore, in my opinion, Claim 7 of the ‘876 Patent is obvious in view of the combination of Sonne and Meezan’962, as evidenced by DS11-D.

F. Claims 8 and 15

286. Claim 8 requires the presence of 1-25% ethanol and 1-25% benzyl alcohol; Claim 15 requires the presence of 10-22.5% ethanol and 7.5-12.5% benzyl alcohol.

287. DS11-D includes 19% ethanol and 11% benzyl alcohol.

288. Therefore, in my opinion, Claims 8 and 15 of the ‘876 Patent are obvious in view of the combination of Sonne and Meezan’962, as evidenced by DS11-D.

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G. Claims 9-10

289. Claim 9 requires the presence of about 10-250 mg/mL of benzodiazepine; Claim 10 requires the presence of about 20-50 mg/mL of benzodiazepine.

290. These ranges are equivalent to about 1-25% and about 2-5%, respectively.

291. DS11-D includes about 5% diazepam (a benzodiazepine).

292. Therefore, in my opinion, Claims 9 and 10 of the '876 Patent are obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

H. Claims 11-12

293. Claim 11 requires that the tocopherol be present in an amount of about 45-85%; Claim 12 requires that the tocopherol be present in an amount of about 60-75%.

294. DS11-D includes about 65% α-tocopherol.

295. Therefore, in my opinion, Claims 11 and 12 of the '876 Patent are obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

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I. Claims 13-14

296. Claim 13 requires that the combined total of ethanol and benzyl alcohol be about 15-55%; Claim 14 requires that the total be about 25-50%.

297. DS11-D includes a combined total of ethanol and benzyl alcohol of 30% (19% ethanol and 11% benzyl alcohol).

298. Therefore, in my opinion, Claims 13 and 14 of the ‘876 Patent are obvious in view of the combination of Sonne and Meezan’962, as evidenced by DS11-D.

J. Claim 16

299. Claim 16 requires that the solution be a spray formulation.

300. DS11-D is formulated as a spray, as discussed above.

301. Therefore, in my opinion, Claim 16 of the ‘876 Patent is obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

K. Claims 17-18

302. Claim 17 requires the presence of about 1-20 mg benzodiazepine; Claim 18 requires that the dosage spray volume be about 10-200 µL.

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303. Sonne teaches that dosage volumes should be no larger than about 100 µL. *See* Sonne, 2:30-33, 7:25-28, 10:12-14, Exhibit 1013, pp. 0004, 0007, 0008.

304. 100 µL of DS11-D (which includes about 5% diazepam) includes about 5 mg of diazepam (a benzodiazepine).

305. Therefore, in my opinion, Claims 17-18 of the ‘876 Patent are obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

306. Moreover, Sonne also discusses intranasally administering 10 mg diazepam, 2.5 mg diazepam, 2 mg diazepam, and 1.25 mg midazolam. *See* Sonne, 7:15-18, 7:50-53 (Example 1), 14:49-50, 14:60-15:8 (Example 23), Exhibit 1013, pp. 0007, 0010-0011; *see also* 13:2-14:2 on p. 0010.

L. Claims 19-20

307. Claims 19 and 20 require that the solution be administered to at least one nostril and into each nostril, respectively.

308. Similar to Claim 19, a POSITA would readily recognize that a spray intended for nasal administration must be administered to at least one nostril. Moreover, and similar to Claim 20, a POSITA would readily recognize that

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humans generally have two nostrils and, therefore, would further readily recognize that a nasal spray could easily be administered to both nostrils in order to double the amount of drug being administered due to the doubling in available surface area of the nasal mucosa.

309. A POSITA would also recognize that it is possible to administer to the same nostril twice (or more), rather than (or in addition to) both nostrils. A POSITA would also recognize that such administrations could be done either once, twice, or several times to one or both nostrils.

310. Further, the POSITA would understand that when administering drug to both nostrils, it is generally preferable (for reasons of ease of use, comfort, and convenience) to administer the drug to the nostrils consecutively rather than concurrently. That is, it is preferable to administer the drug to one nostril, and then only after a period of time has passed (even if only a very minimal period of time), administer the drug to the second nostril.

311. Similarly, if administering to the same nostril twice, there would inherently be at least a small period of time between when the drug is administered to the first nostril and then when it is again administered to the first nostril. A POSITA would readily comprehend this inherent requirement.

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312. Therefore, based on the simple fact that DS11-D is a nasal spray, the POSITA would clearly realize that it could be applied to either or both nostrils, either once, twice, or several times.

313. Further, Sonne discusses the administration of diazepam formulations in Example 23 "in each nostril" of human test subjects. Sonne, 14:65-67, Exhibit 1013, p. 0010. Sonne also recognizes that it is possible to administer doses to each nostril ("it is not generally possible to administer more than about 0.1 ml per dose per nostril."). Sonne, 2:31-33, Exhibit 1013, p. 0004

314. Therefore, in my opinion, Claims 19-20 of the '876 Patent are obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

M. Claims 21-22

315. Claims 21 and 22 require only that the solution be administered into both nostrils. After that, Claim 21 allows for the possibility (i.e., "optionally") that the solution will again be administered to the first nostril. However, this is *optional* and is not a requirement of Claim 21. Similarly, Claim 22 allows for the possibility (i.e., "optionally") that the solution will again be

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administered to the first nostril and then again be administered to the second nostril. However, this is *optional* and is not a requirement of Claim 22.

316. That is, Claims 21 and 22 do not limit Claim 20 (i.e., the claim from which they depend). I have been advised by counsel that optional claim elements are not actual limitations and need not be found in the prior art in order to be invalidated.

317. Therefore, because Claims 21 and 22 recite only *optional* elements and do not include any additional requirements over Claim 20, it is my opinion that Claims 21 and 22 of the '876 Patent are obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

318. Further, a POSITA would understand and consider that a drug could be administered multiple times into each nostril, requiring only that a period of time pass (even if a very short period of time) between each administration within the same nostril and – generally for convenience purposes – between the administration to both nostrils. The amount of time that must pass can depend on several factors, including how quickly the formulation dries in the nostril, the total volume being applied, the type of drug being administered,

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the other excipients in the formulation, etc. Determining the length of time that must be waited is well within the skill of the POSITA.

N. Claim 23

319. Claim 23 requires that the solution be administered either before symptoms begin or after symptoms begin.

320. In my opinion, this is not a limiting claim element because there is no other time when symptoms may occur. When the solution is administered, either symptoms have already occurred and the solution is being administered in response to the symptoms, or symptoms have not yet occurred and the solution is being administered prophylactically. There is no other option.

321. Regardless, Sonne teaches me that alprazolam, e.g., can be used to treat anxiety. Sonne, 12:18-20, Exhibit 1013, p. 0009. If anxiety has already occurred, then the alprazolam is administered in response to anxiety. If a patient is trying to ward off anxiety and so is administered alprazolam, then the alprazolam administration is before symptoms have occurred.

322. Similarly, Sonne teaches that midazolam, e.g., is a tranquilizer that is useful for sedating subjects, for treating anxiety and tension, and significantly, it

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can be used as a "premedication." Sonne, 12:47-49, Exhibit 1013, p. 0009. That is, Sonne teaches that midazolam, e.g., is a "premedication", i.e., it is used prophylactically *before* symptoms begin.

323. Therefore, in my opinion, Claim 23 of the '876 Patent is obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

O. Claims 24-26

324. Claim 24 requires the presence of at least about 0.01% of the alkyl glycoside; Claim 25 provides an upper limit of 1%; and Claim 26 specifies that the alkyl glycoside is dodecyl maltoside in particular.

325. DS11-D includes about 0.25% dodecyl maltoside (an alkyl glycoside).

326. Therefore, in my opinion, Claims 24-26 of the '876 Patent are obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

P. Claims 27, 29, 30, and 31

327. Claims 27, 29, 30, and 31 require the presence of diazepam, vitamin E, ethanol, benzyl alcohol and either alkyl glycosides generally or dodecyl

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maltoside in particular. Several of the claims also recites ranges for these elements. For convenience, I am providing below Table Peppas-1 that lists these elements, range amounts (if recited), and the composition of DS11-D.

TABLE PEPPAS-1

Claim #	Diazepam	Vitamin E	Ethanol	Benzyl Alcohol	Alkyl glycoside (AG) / Dodecyl Maltoside (DM)
27	(not listed)	(not listed)	(not listed)	(not listed)	(not listed) (DM)
29	(not listed)	(not listed)	(not listed)	(not listed)	(not listed) (AG)
30	5-15%	45-65%	10-25%	5-15%	about 0.01-1% (DM)
31	5-15%	45-65%	10-25%	5-15%	0.01-1% (DM)
DS11-D	about 5%	about 65%	about 18.75%	about 11%	about 0.25% (DM)

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328. As can be seen in Table Peppas-1, every element of Claims 27, 29, 30, and 31 are met by DS11-D.

329. Therefore, in my opinion, Claims 27, 29, 30, and 31 of the '876 Patent are obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-D.

Q. Claim 28

330. Claim 28 is similar to Claims 27 and 29-31 in that it recites the same five elements, albeit with specific amounts of each (albeit modified by the term "about").

331. In particular, Claim 28 recites about: 56.47% vitamin E, 10.5% benzyl alcohol, 10% diazepam, 0.25% dodecyl maltoside, q.s. dehydrated ethanol. Mathematically, "q.s. dehydrated ethanol" means there is about 22.78% ethanol.

332. As discussed above in my Claim Construction section, I have construed the term "about 56.47% vitamin E" as meaning 53.65% to 59.29% vitamin E. That is, Claim 28 encompasses 59.29% vitamin E, which is about 60% vitamin E.

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333. In the embodiments where Claim 28 includes about 60% vitamin E, the amount of ethanol (which is q.s.) would drop to about 19.25%. For convenience, I am providing below Table Peppas-2 that lists these elements in comparison to DS11-D:

TABLE PEPPAS-2

Claim #	Diazepam	Vitamin E	Ethanol	Benzyl Alcohol	Dodecyl Maltoside
28	about 10%	about 60%	about 19.25%	about 10.5%	about 0.25%
DS11-D	about 5%	about 65%	about 18.75%	about 11%	about 0.25% (DM)

334. Clearly, "about 19.25% ethanol" and "about 18.75% ethanol" are very similar (i.e., a POSITA would consider "about 19%" as encompassing both "about 19.25%" and "about 18.75%").

335. Moreover, "about 10.5% benzyl alcohol" and "about 11% benzyl alcohol" are very similar (i.e., a POSITA would consider "about 10.75%" as encompassing both "about 10.5% benzyl alcohol" and "about 11% benzyl alcohol").

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336. Further, the total amount of alcohol in Claim 28 is "about 29.75%"; the total amount of alcohol in DS11-D is "about 29.75%". Therefore, both Claim 28 and DS11-D contain about the exact same amount of alcohols.

337. As discussed above, and because there was never any criticality demonstrated with respect to the alcohol component(s), a POSITA would easily be able to modify the exact amounts/ratios of ethanol and/to benzyl alcohol.

338. Therefore, the only difference between Claim 28 and DS11-D is that DS11-D includes 5% more vitamin E and 5% less diazepam (as compared to Claim 28).

339. In fact, Sonne teaches me that diazepam can be dissolved in pure α-tocopherol in concentrations of up to 12%. *See* Sonne, Table 1, 9:45-47, Exhibit 1013, p. 0008. Therefore, a POSITA would be motivated to modify DS11-D in order to attempt to increase the amount of diazepam to various concentrations between the 5% in DS11-D and the 12% possible in pure α-tocopherol. One of the concentrations a POSITA would clearly try would be about 10% diazepam.

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340. The increase in the amount of diazepam would need to be at the expense of one of the co-solvents. As no criticality has ever been shown regarding the amounts/ratios of the co-solvents (as discussed above), the POSITA could easily choose to lessen the amount of any of the three co-solvents with an expectation of success. Therefore, the POSITA would readily lower the amount of vitamin E to compensate for the increase in the diazepam concentration. Admittedly, the POSITA may also try lowering the ethanol or the benzyl alcohol or both the ethanol and benzyl alcohol or the vitamin E, ethanol, and benzyl alcohol. Regardless, there are only a handful of options that the POSITA would try, and reducing the amount of vitamin E is one of those options that the POSITA would try.

341. Therefore, the POSITA would be motivated to increase the diazepam in DS11-D by 5% while decreasing the amount of vitamin E by 5%, thereby resulting in what I refer to as "DS11-E", which includes about:

- 10% diazepam;
- 60% vitamin E;
- 19% ethanol;
- 10.75% benzyl alcohol; and

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- 0.25% dodecyl maltoside.

See Exhibit 1050.

342. Therefore, in my opinion, Claim 28 of the '876 Patent is obvious in view of the combination of Sonne and Meezan'962, as evidenced by DS11-E.

R. Claims 32-33

343. Claims 32 and 33 require the presence of diazepam, vitamin E, ethanol, benzyl alcohol and dodecyl maltoside in certain amounts/ranges of amounts. For convenience, I am providing below Table Peppas-3 that lists these elements, range amounts (if recited), and DS11-D and -E compositions.

TABLE PEPPAS-3

Claim #	Diazepam	Vitamin E	Ethanol	Benzyl Alcohol	Dodecyl Maltoside
32	9-11%	50-60%	15-22.5%	7.5-12.5%	0.1-0.5%
33	10%	50-60%	17-20%	10-12%	0.15-0.3%
DS11-E	about 10%	about 60%	about 19%	about 10.75%	about 0.25%
DS11-D	about 5%	about 65%	about 18.75%	about 11%	about 0.25% (DM)

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344. As can be seen in Table Peppas-3, every element of Claims 32 and 33 are met by DS11-E.

345. Therefore, in my opinion, Claims 32 and 33 of the ‘876 Patent are obvious in view of the combination of Sonne and Meezan’962, as evidenced by DS11-E.

346. Moreover, DS11-D is very similar to Claims 32 and 33, the only difference being DS11-D includes about 5% less diazepam and about 5% more vitamin E.

347. Similar to my discussion of Claim 28, above, a POSITA would easily be able to – and would be motivated by Sonne to – increase the amount of diazepam by about 5% at the expense of reducing the vitamin E amount by about 5%.

348. Therefore, in my opinion, Claims 32 and 33 of the ‘876 Patent are obvious in view of the combination of Sonne and Meezan’962, as evidenced by DS11-D.

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S. Claims 34-36

349. Claim 34 narrows Claim 1 by reciting that a bioavailability of about 80-125% is achieved by the recited intranasal administration method, when compared to an intravenous administration method of the same benzodiazepine. Claims 35 and 36 narrow the bioavailability range to about 90-110% and about 92.5-107.5%, respectively.

350. As discussed above, DS11-D and DS11-E disclose all the elements of Claim 1 (from which Claims 34-36 depend). Therefore, a POSITA would simply need to prepare DS11-D and/or DS11-E and then test it; such experiments and data analysis are well within the skill of a POSITA. Moreover, Sonne provides the POSITA with a specific motivation to test bioavailability because Sonne's two Figures (i.e., Figs. 2 and 2) are "graph[s] showing mean serum concentrations (ng/mL) against time (minutes) after" either intranasal (Fig. 1) or oral (Fig. 2) administration of diazepam. *See* Sonne, 7:15-22, Exhibit 1013, p. 0007; *see also* 14:29-40 on p. 0010. The data provided in the figures and in Column 14, lines 29-40 is the type of data commonly analyzed for bioavailability. In fact, PO has admitted that this type of data is used for this reason: "[I]t is intended that bioavailability be

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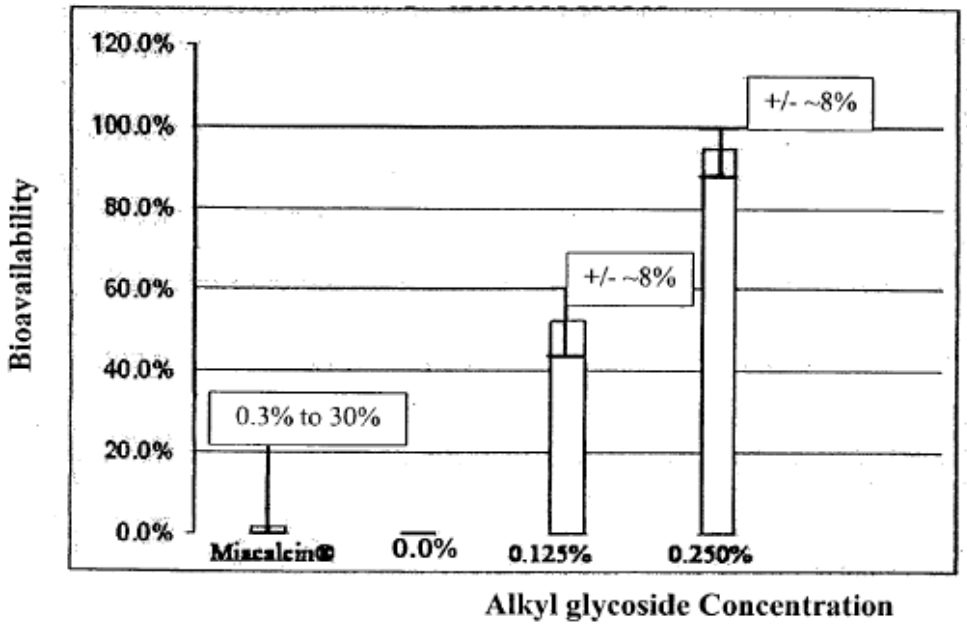
determined by a suitable pharmacodynamics method, such as comparison of area under the blood plasma concentration curve". '876 Patent, 4:57-60, Exhibit 1001, p. 0011.

351. If a bioavailability in the recited ranges is not achieved, a POSITA would simply need to tweak the DS11-D and/or DS11-E Solutions a bit. Such tweaking is routinely conducted by a POSITA seeking to optimize a formulation for a specific purpose.

352. In fact, Meezan'962 discloses that the presence of an alkyl glycoside "increases the bioavailability of the drug." Meezan'962, [0005], Exhibit 1011, p. 0005; *see also* [0007] on p. 0005. In fact, in some cases, Meezan'962 found that the presence of an alkyl glycoside increased the bioavailability of an intranasal formulation from 3% (without alkyl glycoside), to a bioavailability of about 43% (with 0.125% alkyl glycoside), and even further to a bioavailability of about 90% (with 0.250% alkyl glycoside). *See* Meezan'962, [0150], Exhibit 1011, pp. 0017-0018. Moreover, the presence of the alkyl glycoside reduced the variance in bioavailability to ±8%, down from a variance range of 0.3-30%. Meezan'962, [0151], Exhibit 1011, p. 0018. For convenience, below is the

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chart from Meezan'962 graphically showing these results (Meezan'962, Fig. 1, Exhibit 1011, p. 0002:



353. Meezan'962 therefore achieved bioavailabilities for its intranasal formulation (using an alkyl glycoside) that in some cases ranged as high as 98% as compared to the intravenous route. A bioavailability of 98% falls within the ranges recited in Claims 34-36.

354. The POSITA would therefore understand Meezan‘962 as teaching that it was easily achievable to target various bioavailability levels by experimenting with types and amounts of alkyl glycosides. In particular, based on Meezan‘962’s ¶¶ [0150] and [0151], the POSITA would be directed to also experiment with the amount of alkyl glycoside present in the DS11-D and/or DS11-E Solutions in an effort to increase the bioavailability to levels approaching 100% of the intravenous route, in order to easily meet FDA’s required 80-125% (with 90% confidence interval).

355. Even further, Meezan‘962 discusses comparing the bioavailability of a dosage form to its reference intravenous dosage form (i.e., basically the definition of “absolute bioavailability”). If the bioavailability is too low, then Meezan‘962 further discusses how to increase pharmacokinetics up to 100% (i.e., in Meezan‘962’s words: how “to achieve similar plasma concentrations.”). Meezan‘962, [0109], Exhibit 1011, p. 0014. The POSITA would clearly take this passage as a direction to experiment with the amount of drug present in an effort to meet the pharmacokinetic profile of the reference drug – including bioavailability – in in order to easily meet FDA’s required 80-125% (with 90% confidence interval).

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356. Therefore, based on the combination of Sonne and Meezan‘962, the POSITA would be taught to experiment with DS11-D and/or DS11-E solutions by modifying the amounts of the various ingredients in general, and the alkyl glycoside in particular, in an effort to increase the bioavailability of the intranasal dosage form. Moreover, the combination of Sonne and Meezan‘962 provides directions and examples of how to vary the amounts, thus making such experimentation even more routine than normal. Thus, the POSITA would have an expectation of successfully increasing the bioavailability of the intranasal formulation to a desired level. As a POSITA would have been aware of FDA requirements, the POSITA would target a desired level approaching 100%, i.e., within the ranges recited in Claims 34-36.

357. In this regard, and as mentioned above, the POSITA would understand that when preparing new drug products, the FDA has certain requirements that must be met before the FDA will approve the new drug product. In particular, a POSITA would readily understand that most drug products must have a pharmacokinetic profile, e.g., bioavailability, that is 80-125% (with a 90% confidence interval) of a reference drug product. If such a

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pharmacokinetic profile is achieved by an experimental product as compared to a reference product, then the experimental product is generally considered bioequivalent to the reference product. Otherwise, if an approvable pharmacokinetic profile were not obtained, the POSITA would realize that potentially vast amounts of time and sums of money had been wasted.

358. USP/NF 2003 basically codifies what the POSITA already knows:

> "The currently accepted criteria in the United States for equivalence for most dosage forms require that the mean pharmacokinetic parameters of the test dosage form should be within 80% to 125% of the reference dosage form using the 90% confidence interval…, and the upper and lower bounds must be within the 90% confidence interval."

USP/NF 2003, Exhibit 1044, p. 0007 (left column).

359. Therefore, based on the general knowledge that an experimental drug product would only be considered bioequivalent to a reference product if the experimental drug product's bioavailability fell between 80-125% (with a 90% confidence interval) of the reference drug product, the POSITA would aim for as close to the 100% bioavailability mark as possible. That is, because the POSITA would want his/her newly developed experimental

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drug product to pass FDA requirements and become marketable, the POSITA would aim for as close to the 100% bioavailability mark as possible so as to easily fall within the FDA's required 80-125% (with 90% confidence interval).

360. Meezan'962 teaches a POSITA a variety of ways of increasing the bioavailability of dosage forms intended for mucosal administration, e.g., intranasal administration. Therefore, the POSITA would turn to Meezan'962 in order to optimize the bioavailability of the DS11-D and/or DS11-E Solutions. Based on the ease with which Meezan'962 achieved 98% bioavailability (simply by including 0.25% alkyl glycoside), a POSITA would easily make the necessary modifications to the DS11-D and/or DS11-E Solutions with an expectation of successfully achieving: (i) bioavailabilities approaching 100%, and (ii) bioavailabilities falling within the ranges recited in Claims 34-36.

361. Even if the bioavailabilities in Meezan'962's Figure 1 are not accurate and/or incorrect, the POSITA would be lead to believe that such bioavailabilities could be achieved and would therefore still be motivated to achieve such bioavailabilities with an expectation of success.

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362. Therefore, in my opinion, Claims 34-36 of the ‘876 Patent are obvious in view of the combination of Sonne and Meezan’962, as evidenced by DS11-D and DS11-E.

XVI. GROUND 2 – CLAIMS 1-16 and 24-36 - AS OBVIOUS OVER GWOZDZ (EXHIBIT 1013) IN VIEW OF MEEZAN’962 (EXHIBIT 1011)

A. Claim 1

363. As discussed above, Gwozdz teaches all the elements of Claim 1. In particular, Gwozdz teaches the creation of pharmaceutical solutions containing 30-99% tocopherols, 1-70% alcohols (including combinations of ethanol and benzyl alcohol), and benzodiazepines (such as diazepam). Gwozdz, 4:13-21, 6:18, 8:9-13, Exhibit 1014, pp. 0004, 0006, 0008. As discussed above, PO never demonstrated any criticality for these claim elements. Therefore, a POSITA would easily have been able to experiment with different amounts and types of tocopherols and alcohols with an expectation of successfully arriving at the amounts recited in Claim 1.

364. Gwozdz therefore teaches all the elements of the solution in Claim 1, with the exception of “alkyl glycoside.” A POSITA seeking to optimize the

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bioavailability of Gwozdz's invention would look to Meezan'962, for the reasons discussed above under the "Motivation to Combine" section. Based on Meezan'962's teachings, the POSITA would add an alkyl glycoside to Gwozdz's teachings with an expectation of successfully increasing the bioavailability.

365. Meezan'962 specifically teaches, e.g., an alkyl glycoside amount of about 0.25%. *See, e.g.*, Meezan'962, [015-]-[0151], Exhibit 1011, pp. 0018; *see also* Fig. 1 on p. 0002, [0158]-[0159] on p. 0019, Table I on p. 0019, Example 6 on p. 0020.

366. Meezan'962 also specifically lists alkyl glycosides, including dodecyl maltoside. *See* Meezan'962, [0056], [0058], [0061], Exhibit 1013, p. 0008, 0009.

367. Therefore, based on Meezan's teaching of 0.25% alkyl glycoside, dodecyl maltoside, and the fact that the amount and identity of the alkyl glycoside is not critical (and is, in fact, predictable), a POSITA would easily select about 0.25% dodecyl maltoside to add to Gwozdz's invention.

368. Due to the lack of criticality to the ingredients in the solution, the POSITA would easily be able to experiment with different amounts and types of

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tocopherols, alcohols, benzodiazepines, and alkyl glycosides (e.g., dodecyl maltoside) with an expectation of success.

369. Gwozdz also teaches its "invention relates to methods of treatment of a patient with these pharmaceutical solutions." Gwozdz, 4:24-26. Further, Gwozdz discloses that "[p]harmaceutical solutions of the instant invention are particularly useful in formulations to be administered to mucosal membranes, i.e. the nasal mucos or lungs of a subject by any suitable means." Gwozdz, 9:19-22.

370. Therefore, in my opinion, Claim 1 of the '876 Patent is obvious in view of the combination of Gwozdz and Meezan'962.

B. Claim 2

371. Claim 2 requires the presence of vitamin E.

372. Gwozdz discloses that the tocopherol can be vitamin E. Gwozdz, 5:33-6:2, Exhibit 1014, pp. 0005-0006.

373. Therefore, in my opinion, Claim 2 of the '876 Patent is obvious in view of the combination of Gwozdz and Meezan'962.

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C. Claims 3-4

374. Claim 3 requires that the benzodiazepine is selected from a long list that includes diazepam; Claim 4 requires that the benzodiazepine be diazepam.

375. Gwozdz discloses diazepam among a listing of many benzodiazepines (many of which are recited in Claim 3). Gwozdz, 8:9-13, Exhibit 1014, p. 0008; *see also* 7:12-19 on p. 0007.

376. Therefore, in my opinion, Claims 3 and 4 of the '876 Patent are obvious in view of the combination of Gwozdz and Meezan'962.

D. Claims 5-6

377. Claim 5 requires the presence of about 1-20% benzodiazepine; Claim 6 requires that the benzodiazepine be diazepam.

378. Gwozdz discloses that diazepam can be present in an amount "approaching the 10% level" because "[d]iazepam is soluble to greater than or equal to 8%" in some tocopherol/alcohol combinations and that "[d]iazepam is soluble at greater than or equal to 9%" in other tocopherol/alcohol combinations. *See* Gwozdz, 7:12-19, Exhibit 1014, p. 0007.

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379. Therefore, in my opinion, Claims 5 and 6 of the ‘876 Patent are obvious in view of the combination of Gwozdz and Meezan’962.

E. Claim 7

380. Claim 7 requires that the tocopherol be selected from a long list that includes, e.g., α-tocopherol.

381. Gwozdz discloses that the tocopherol can be alpha-, beta-, gamma-, and delta-tocopherols and/or -tocotrienols, and derivatives or analogs thereof. *See* Gwozdz, 6:2-11, Exhibit 1014, p. 0006.

382. Therefore, in my opinion, Claim 7 of the ‘876 Patent is obvious in view of the combination of Gwozdz and Meezan’962.

F. Claims 8 And 15

383. Claim 8 requires the presence of 1-25% ethanol and 1-25% benzyl alcohol; Claim 15 requires the presence of 10-22.5% ethanol and 7.5-12.5% benzyl alcohol.

384. Gowzdz teaches that alcohol can generally be present in amounts of 1-70%, with ethanol specifically being called out in amounts of 10-30%. Gwozdz,

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4:19-21, 7:10-11 and 20-24, Exhibit 1014, pp. 0004, 0007. Moreover, and as discussed above, because there is no criticality or unexpected effects associated with the amount or type of alcohol(s), a POSITA would easily be able to experiment with different amounts, especially in view of Gwozdz's teachings that the tocopherol:ethanol ratio may be approximately 95:5, 90:10, 85:15, 80:20, 75:25, 70:30, 65:35, or 60:40. Gwozdz, 7:25-28, Exhibit 1014, p. 0007.

385. Therefore, the POSITA would easily arrive at combinations of ethanol and benzyl alcohol that fall within the ranges recited in Claims 8 and 15, while also falling within the total alcohol range of "about 10% to about 70%" required by Claim 1.

386. Therefore, in my opinion, Claims 8 and 15 of the '876 Patent are obvious in view of the combination of Gwozdz and Meezan'962.

G. Claims 9 And 10

387. Claim 9 requires the presence of about 10-250 mg/mL of benzodiazepine; Claim 10 requires the presence of about 20-50 mg/mL of benzodiazepine.

388. These ranges are equivalent to about 1-25% and about 2-5%, respectively.

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389. Gwozdz discloses the presence of diazepam in tocopherol/alcohol solutions in amounts of "greater than or equal to 8%", "greater than or equal to 9%", and "approaching the 10% level." Gwozdz, 7:14-19, Exhibit 1014, p. 0007.

390. Moreover, a POSITA desiring a less concentrated diazepam solution would readily know that the concentration could be reduced down to the 2-5% range, simply by dissolving less diazepam in the co-solvents.

391. In fact, as discussed repeatedly above, the problems in the art at the relevant time was period was how to dissolve more of an insoluble drug. Dissolving less of an insoluble drug was not considered a problem, and the solution to the problem was well-known to a POSITA, i.e., simply use less drug.

392. Therefore, in my opinion, Claims 9 and 10 of the '876 Patent are obvious in view of the combination of Gwozdz and Meezan'962.

H. Claims 11 and 12

393. Claim 11 requires that the tocopherol be present in an amount of about 45-85%; Claim 12 requires that the tocopherol be present in an amount of about 60-75%.

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394. Gwozdz discloses the tocopherol in an amount of, e.g., 70-90%. Gwozdz, 7:22-25, Exhibit 1014, p. 0007. A POSITA would easily be able to experiment with tocopherol amounts in this disclosed range, including at the lower end of the range which falls within both Claims 11 and 12.

395. Therefore, in my opinion, Claims 11 and 12 of the '876 Patent are obvious in view of the combination of Gwozdz and Meezan'962.

I. Claims 13 and 14

396. Claim 13 requires that the combined total of ethanol and benzyl alcohol be about 15-55%; Claim 14 requires that the total be about 25-50%.

397. Gwozdz discloses the presence of ethanol in an amount of 10-30%. Gwozdz, 7:22-25, Exhibit 1014, p. 0007. Benzyl alcohol is not mentioned in that particular portion of Gwozdz; thus, benzyl alcohol is present in an amount of 0%. Therefore, the combined total of ethanol (10-30%) and benzyl alcohol (0%) is 10-30%.

398. Therefore, in my opinion, Claims 13 and 14 of the '876 Patent are obvious in view of the combination of Gwozdz and Meezan'962.

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J. Claim 16

399. Claim 16 requires that the solution be a spray formulation.

400. Gwozdz discloses that its formulation can be in the form of "a mist sprayer." Gwozdz, 10:2, Exhibit 1014, p. 0010.

401. Therefore, in my opinion, Claim 16 of the '876 Patent is obvious in view of the combination of Gwozdz and Meezan'962.

K. Claims 17-23

402. *See* my discussion of Claims 17-23 under Ground 3.

L. Claims 24-26

403. Claim 24 requires the presence of at least about 0.01% of the alkyl glycoside; Claim 25 provides an upper limit of 1%; and Claim 26 specifies that the alkyl glycoside is dodecyl maltoside in particular.

404. Gwozdz discloses the use of penetration enhancers generally. *See* Gwozdz, 10:14, Exhibit 1014, p. 0010. Therefore, the POSITA would seek out penetration enhancers known to be useful in intranasal formulations and would therefore be motivated to modify Gwozdz's disclosure with

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Meezan'962's teaching of penetration enhancers, specifically alkyl glycosides. As discussed above, a POSITA would not be dissuaded from applying Meezan'962 to Gwozdz.

405. Meezan'962 discloses adding alkyl glycosides to formulations in amounts of "about 0.01-20%, preferably about 0.01-5%, more preferably about 0.01-2%, even more preferably 0.01-1%, and most preferably 0.01-0.125%. *See* Meezan'962, [0070], Exhibit 1011, p. 0010.

406. Meezan'962 specifically discloses dodecyl maltoside. Meezan'962, [0092], [0156], [0158], and Table I, Exhibit 1011, pp. 0012, 0018-0019.

407. Meezan'962's also lists many different alkyl glycosides including "octyl-, nonyl-, decyl-, undecyl-, dodecyl-, tridecyl-, tetradecyl-, pentadecyl-,hexadecyl-, heptadecyl-, and octadecyl-α- or β-D-maltoside, -glucoside or -sucroside." Meezan'962, [0056], Exhibit 1011, p. 0008; *see also* [0058] and [0061] on p. 0009.

408. Further, Meezan'962 tested the effects of dodecyl maltoside in amounts of 0.125%, 0.25%, 0.375%, and 0.50%. Meezan'962, Table I, Exhibit 1011, p. 0019.

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409. Therefore, the POSITA would be motivated to modify Gwozdz's disclosure with Meezan'962's teaching of, e.g., 0.01-1% or 0.01-0.125% of an alkyl glycoside, such as dodecyl maltoside.

410. Therefore, in my opinion, Claims 24-26 of the '876 Patent are obvious in view of the combination of Gwozdz and Meezan'962.

M. Claims 27-33

411. Claims 27-33 each recite the presence of diazepam, vitamin E, ethanol, benzyl alcohol, and alkyl glycoside (or dodecyl maltoside in particular), differing from each other only in the amounts of each ingredient recited.

412. For convenience, I am providing below Table Peppas-4 that lists these elements and range amounts (if recited).

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TABLE PEPPAS-4

Claim #	Diazepam (%)	Vitamin E (%)	Ethanol (%)	Benzyl Alcohol (%)	Alkyl glycoside (AG) / Dodecyl Maltoside (DM) (%)
27	(not listed)	(not listed)	(not listed)	(not listed)	(not listed) (DM)
28	about 10%	about 56.47%	q.s. (about 22.78%)	about 10.5%	about 0.25% (DM)
29	(not listed)	(not listed)	(not listed)	(not listed)	(not listed) (AG)
30	5-15%	45-65%	10-25%	5-15%	about 0.01-1% (DM)
31	5-15%	45-65%	10-25%	5-15%	0.01-1% (DM)
32	9-11%	50-60%	15-22.5%	7.5-12.5%	0.1-0.5% (DM)
33	10%	50-60%	17-20%	10-12%	0.15-0.3% (DM)

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413. Regarding diazepam – Gwozdz discloses that diazepam can be dissolved in tocopherol/alcohol combinations at concentrations "approaching the 10% level", "greater than or equal to 8%", and "greater than or equal to 9%". Gwozdz, 7:14-19, Exhibit 1014, p. 0007. These disclosures meet the diazepam elements of Claims 27-33.

414. Regarding vitamin E – Gwozdz discloses that tocopherols can be present in amounts of about 30-99%, 60-99%, and 70-90%. *See* Gwozdz, 4:18-19, 7:8-10, 7:20-24, Exhibit 1014, pp. 0004, 0007. As there is no criticality to the exact amounts of tocopherols (as discussed above), a POSITA would easily experiment with tocopherols at various amounts falling within the ranges recited in the claims. Moreover, there does not appear to be anything unique, surprising, critical, or unexpected about Claim 28's recitation of "about 56.47%" of vitamin E.

415. Regarding alcohol amounts – Gwozdz discloses that alcohols can be present in amounts of about 1-70%, 1-40%, 10-30%, 30%, 5%. *See* Gwozdz, 4:20-21, 7:10-25, Exhibit 1014, pp. 0004, 0007. Gwozdz also discloses that the alcohols can be selected from a short list that includes both ethanol and benzyl alcohol, and the alcohol can also be a combination thereof. *See*

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Gwozdz, 6:16-19, Exhibit 1014, p. 0007. As there is no criticality to the exact amount or identity of alcohols (as discussed above), a POSITA would easily experiment with alcohols, including ethanol, benzyl alcohol, and combinations thereof, in various amounts falling within the ranges recited in the claims.

416. Regarding alkyl glycosides – as discussed above with respect to Claims 24-26, Gwozdz discloses the use of penetration enhancers generally. *See* Gwozdz, 10:14, Exhibit 1014, p. 0010. Therefore, the POSITA would seek out penetration enhancers known to be useful in intranasal formulations and would therefore be motivated to modify Gwozdz's disclosure with Meezan'962's teaching of penetration enhancers, specifically alkyl glycosides. As discussed above, a POSITA would not be dissuaded from applying Meezan'962 to Gwozdz. Meezan'962 discloses adding alkyl glycosides to formulations in amounts of "about 0.01-20%, preferably about 0.01-5%, more preferably about 0.01-2%, even more preferably 0.01-1%, and most preferably 0.01-0.125%. *See* Meezan'962, [0070], Exhibit 1011, p. 0010.

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417. Meezan'962 specifically discloses dodecyl maltoside. Meezan'962, [0092], [0156], [0158], and Table I, Exhibit 1011, pp. 0012, 0018-0019.

418. Meezan'962's also lists many different alkyl glycosides including "octyl-, nonyl-, decyl-, undecyl-, dodecyl-, tridecyl-, tetradecyl-, pentadecyl-,hexadecyl-, heptadecyl-, and octadecyl-α- or β-D-maltoside, -glucoside or -sucroside." Meezan'962, [0056], Exhibit 1011, p. 0008; *see also* [0058] and [0061] on p. 0009.

419. Further, Meezan'962 tested the effects of dodecyl maltoside in amounts of 0.125%, 0.25%, 0.375%, and 0.50%. Meezan'962, Table I, Exhibit 1011, p. 0019.

420. Therefore, the POSITA would be motivated to modify Gwozdz's disclosure with Meezan'962's teaching of, e.g., 0.01-1% or 0.01-0.125% of an alkyl glycoside, such as dodecyl maltoside.

421. Therefore, as discussed above, the combination of Gwozdz and Meezan'962 teaches and strongly suggests all the limitations found in Claims 27-33.

422. Therefore, in my opinion, Claims 27-33 of the '876 Patent are obvious in view of the combination of Gwozdz and Meezan'962.

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N. Claims 34-36

423. Claim 34 narrows Claim 1 by reciting that a bioavailability of about 80-125% is achieved by the recited intranasal administration method, when compared to an intravenous administration method of the same benzodiazepine. Claims 35 and 36 narrow the bioavailability range to about 90-110% and about 92.5-107.5%, respectively.

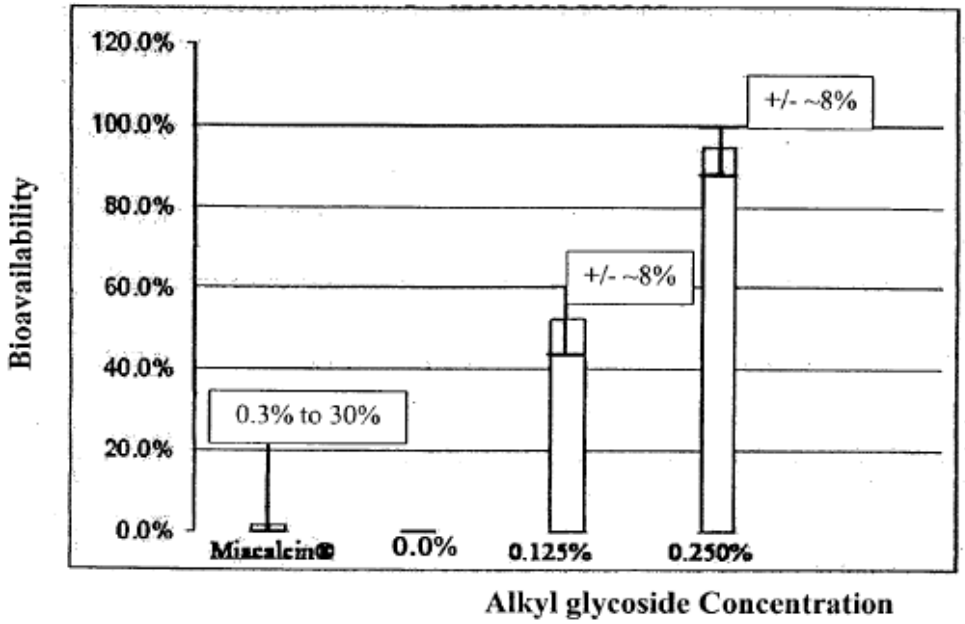
424. As discussed above, the combination of Gwozdz and Meezan'962 disclose all the elements of Claim 1 (from which Claims 34-36 depend). Therefore, a POSITA would simply need to prepare a solution according to the Gwozdz/Meezan'962 combination and then test it; such experiments and data analysis are well within the skill of a POSITA. Moreover, Gwozdz provides the POSITA with a specific motivation to test bioavailability because Gwozdz specifically states that "solutions of one or more tocopherols…and one or more alcohols…are used in the solubilization of hydrophobic or lipophilic therapeutic agents thereby providing increased bioavailability of the therapeutic agent." Gwozdz, 7:3-8, Exhibit 1014, p. 0007 (emphasis added). In order to determine by how much bioavailability is increased, the POSITA would run experiments to test bioavailabilities.

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425. If a bioavailability in the ranges recited in Claims 34-36 s is not achieved, a POSITA would simply need to tweak the combination Gwozdz/Meezan'962 solutions a bit. Such tweaking is routinely conducted by a POSITA seeking to optimize a formulation for a specific purpose.

426. In fact, Meezan'962 discloses that the presence of an alkyl glycoside "increases the bioavailability of the drug." Meezan'962, [0005], Exhibit 1011, p. 0005; *see also* [0007] on p. 0005. In fact, in some cases, Meezan'962 found that the presence of an alkyl glycoside increased the bioavailability of an intranasal formulation from 3% (without alkyl glycoside), to a bioavailability of about 43% (with 0.125% alkyl glycoside), and even further to a bioavailability of about 90% (with 0.250% alkyl glycoside). *See* Meezan'962, [0150], Exhibit 1011, pp. 0017-0018. Moreover, the presence of the alkyl glycoside reduced the variance in bioavailability to ±8%, down from a variance range of 0.3-30%. Meezan'962, [0151], Exhibit 1011, p. 0018. For convenience, below is the chart from Meezan'962 graphically showing these results (Meezan'962, Fig. 1, Exhibit 1011, p. 0002:

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427. Meezan‘962 therefore achieved bioavailabilities for its intranasal formulation (using an alkyl glycoside) that in some cases ranged as high as 98% as compared to the intravenous route. A bioavailability of 98% falls within the ranges recited in Claims 34-36.

428. The POSITA would therefore understand Meezan‘962 as teaching that it was easily achievable to target various bioavailability levels by experimenting with types and amounts of alkyl glycosides. In particular, based on Meezan‘962’s ¶¶ [0150] and [0151], the POSITA would be

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directed to also experiment with the amount of alkyl glycoside in an effort to increase the bioavailability to levels approaching 100% of the intravenous route, in order to easily meet FDA's required 80-125% (with 90% confidence interval).

429. Even further, Meezan'962 discusses comparing the bioavailability of a dosage form to its reference intravenous dosage form (i.e., basically the definition of "absolute bioavailability"). If the bioavailability is too low, then Meezan'962 further discusses how to increase pharmacokinetics up to 100% (i.e., in Meezan'962's words: how "to achieve similar plasma concentrations."). Meezan'962, [0109], Exhibit 1011, p. 0014. The POSITA would clearly take this passage as a direction to experiment with the amount of drug present in an effort to meet the pharmacokinetic profile of the reference drug – including bioavailability – in in order to easily meet FDA's required 80-125% (with 90% confidence interval).

430. Therefore, based on the combination of Gwozdz and Meezan'962, the POSITA would be taught to experiment with solutions prepared according to the Gwozdz/Meezan'962 combination by modifying the amounts of the various ingredients in general, and the alkyl glycoside in particular, in an

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effort to increase the bioavailability of the intranasal dosage form. Moreover, the combination of Gwozdz and Meezan‘962 provides directions and examples of how to vary the amounts, thus making such experimentation even more routine than normal. Thus, the POSITA would have an expectation of successfully increasing the bioavailability of the intranasal formulation to a desired level. As a POSITA would have been aware of FDA requirements, the POSITA would target a desired level approaching 100%, i.e., within the ranges recited in Claims 34-36.

431. In this regard, and as mentioned above, the POSITA would understand that when preparing new drug products, the FDA has certain requirements that must be met before the FDA will approve the new drug product. In particular, a POSITA would readily understand that most drug products must have a pharmacokinetic profile, e.g., bioavailability, that is 80-125% (with a 90% confidence interval) of a reference drug product. If such a pharmacokinetic profile is achieved by an experimental product as compared to a reference product, then the experimental product is generally considered bioequivalent to the reference product. Otherwise, if an approvable

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pharmacokinetic profile were not obtained, the POSITA would realize that potentially vast amounts of time and sums of money had been wasted.

432. USP/NF 2003 basically codifies what the POSITA already knows:

> "The currently accepted criteria in the United States for equivalence for most dosage forms require that the mean pharmacokinetic parameters of the test dosage form should be within 80% to 125% of the reference dosage form using the 90% confidence interval…, and the upper and lower bounds must be within the 90% confidence interval."

USP/NF 2003, Exhibit 1044, p. 0007 (left column).

433. Therefore, based on the general knowledge that an experimental drug product would only be considered bioequivalent to a reference product if the experimental drug product's bioavailability fell between 80-125% (with a 90% confidence interval) of the reference drug product, the POSITA would aim for as close to the 100% bioavailability mark as possible. That is, because the POSITA would want his/her newly developed experimental drug product to pass FDA requirements and become marketable, the POSITA would aim for as close to the 100% bioavailability mark as possible

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so as to easily fall within the FDA's required 80-125% (with 90% confidence interval).

434. Meezan'962 teaches a POSITA a variety of ways of increasing the bioavailability of dosage forms intended for mucosal administration, e.g., intranasal administration. Therefore, the POSITA would turn to Meezan'962 in order to optimize bioavailability of intranasal solutions. Based on the ease with which Meezan'962 achieved 98% bioavailability (simply by including 0.25% alkyl glycoside), a POSITA would easily make the necessary modifications with an expectation of successfully achieving: (i) bioavailabilities approaching 100%, and (ii) bioavailabilities falling within the ranges recited in Claims 34-36.

435. Even if the bioavailabilities in Meezan'962's Figure 1 are not accurate and/or incorrect, the POSITA would be lead to believe that such bioavailabilities could be achieved and would therefore still be motivated to achieve such bioavailabilities with an expectation of success.

436. Therefore, in my opinion, Claims 34-36 of the '876 Patent are obvious in view of the combination of Gwozdz and Meezan'962.

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XVII. GROUND 3 – CLAIMS 17-23 – AS OBVIOUS OVER GWOZDZ (EXHIBIT 1013) IN VIEW OF MEEZAN'962 (EXHIBIT 1011) FURTHER IN VIEW OF CARTT'784

437. Claims 17-23 depend, either directly or indirectly, from Claim 1. Therefore, all my discussions for Claim 1 under Ground 2 (above), are incorporated by reference to Ground 3 here.

A. Claims 17 and 18

438. Claim 17 requires the presence of about 1-20 mg benzodiazepine; Claim 18 requires that the dosage spray volume be about 10-200 µL.

439. Cartt'784 teaches dosage amounts of benzodiazepines, and diazepam in particular, in the range of about 1 to about 20 mg. *See* Cartt'784, [0063], Exhibit 1015, p. 0018.

440. Cartt'784 teaches that volume of benzodiazepines solutions should be "less than 250 µl, preferably less than 150 µl, and ideally from 25 to 100 µl". Cartt'784, [0007], Exhibit 1015, p. 0001.

441. Cartt'784 also teaches ranges of amounts and volumes for other benzodiazepines that fall within (or overlap with) the ranges recited in Claims 17 and 18, respectively. The volumes are all disclosed as being 25-

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250 µl, 50-150 µl, and about 100 µl, while the amounts of each benzodiazepine differ depending on the exact benzodiazepine:

- alprazolam – about 0.5-4 mg, preferably about 1-2 mg. [0055]-[0056], p. 0017;
- flurazepam – about 5-40 mg, preferably about 20-35 mg. [0071]-[0072], p. 0019;
- lorazepam – about 0.1-10 mg, preferably about 0.2-1 mg. [0079]-[0080], p. 0020;
- medazepam – about 0.1-10 mg, preferably about 0.2-1 mg. [0087]-[0088], p. 0021;
- mexazolam – about 0.1-10 mg, preferably about 0.2-1 mg. [0095]-[0096], p. 0022;
- midazolam – about 0.1-20 mg, preferably about 0.2-10 mg. [0104]-[0105], p. 0023; and
- temazepam – about 1-50 mg, preferably about 5-30 mg. [0112]-[0113], p. 0024.

442. Therefore, in my opinion, Claims 17 and 18 of the ‘876 Patent are obvious in view of the combination of Gwozdz, Meezan’962, and Cartt’784.

B. Claims 19-22

443. Claims 19 and 20 require that the solution be administered to at least one nostril and into each nostril, respectively. Claim 21 allows for the

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possibility (i.e., "optionally") that the solution will again be administered to the first nostril. Claim 22 allows for the possibility (i.e., "optionally") that the solution will again be administered to the first nostril and then again be administered to the second nostril.

444. Claims 21 and 22 do not limit Claim 20 (i.e., the claim from which they depend). I have been advised by counsel that optional claim elements are not actual limitations and need not be found in the prior art in order to be invalidated.

445. Regardless, and similar to Claim 19, a POSITA would readily recognize that a spray intended for nasal administration must be administered to at least one nostril. Moreover, and similar to Claim 20, a POSITA would readily recognize that humans generally have two nostrils and, therefore, would further readily recognize that a nasal spray could easily be administered to both nostrils in order to double the amount of drug being administered due to the doubling in available surface area of the nasal mucosa.

446. A POSITA would also recognize that it is possible to administer to the same nostril twice (or more), rather than (or in addition to) both nostrils. A

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POSITA would also recognize that such administrations could be done either once, twice, or several times to one or both nostrils.

447. Further, the POSITA would understand that when administering drug to both nostrils, it is generally preferable (for reasons of ease of use, comfort, and convenience) to administer the drug to the nostrils consecutively rather than concurrently. That is, it is preferable to administer the drug to one nostril, and then only after a period of time has passed (even if only a very minimal period of time), administer the drug to the second nostril.

448. Similarly, if administering to the same nostril twice, there would inherently be at least a small period of time between when the drug is administered to the first nostril and then when it is again administered to the first nostril. A POSITA would readily comprehend this inherent requirement.

449. Further, a POSITA would understand and consider that a drug could be administered multiple times into each nostril, requiring only that a period of time pass (even if a very short period of time) between each administration within the same nostril and – generally for convenience purposes – between the administration to both nostrils. The amount of time that must pass can depend on several factors, including how quickly the formulation dries in the

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nostril, the total volume being applied, the type of drug being administered, the other excipients in the formulation, etc. Determining the length of time that must be waited is well within the skill of the POSITA.

450. Moreover, ¶ [0064] of Cartt'784, partially reproduced below for convenience, discloses the elements of each of Claims 19-22:

> "In some embodiments, a first metered spray is applied to a first nostril and if necessary a second metered spray is applied to a second nostril. In some optional embodiments, a third metered spray is applied to the first nostril. In some further embodiments, a fourth metered spray is applied to the second nostril. In some embodiments, additional metered sprays are applied to alternating nostrils until the full target therapeutic dose has been administered to the patient. In some embodiments, there is a time increment of from several seconds to 5 minutes, preferably about 10 seconds to about 1 minute, between applications of benzodiazepine drug to the same nostril. This allows time for the drug to cross the nasal mucosa and enter the blood stream. Multiple applications of metered sprays to each nostril, optionally separated by a time interval, allows administration of a full therapeutic dose in increments small enough to permit full absorption of the

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> benzodiazepine drug into the blood stream and avoid loss of drug down the back of the throat."

Cartt'784, [0064], Exhibit 1015, p. 0018; *see also* [0031], [0033], [0035], [0039], [0042], [0045], [0056], [0072], [0080], [0088], [0096], [0105], [0113], on pp. 0004-0009, 0011, 0013, 0017, 0019-0024.

451. Therefore, in my opinion, Claims 19-22 of the '876 Patent are obvious in view of the combination of Gwozdz, Meezan'962, and Cartt'784.

C. Claim 23

452. Claim 23 requires that the solution be administered either before symptoms begin or after symptoms begin.

453. In my opinion, this is not a limiting claim element because there is no other time when symptoms may occur. When the solution is administered, either symptoms have already occurred and the solution is being administered in response to the symptoms, or symptoms have not yet occurred and the solution is being administered prophylactically. There is no other option.

454. Notwithstanding, Cartt'784 discloses that its invention can be used to, e.g., prevent the occurrence or re-occurrence of a seizure disorder:

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> "In some embodiments, the invention further provides methods of administering a benzodiazepine to a patient, comprising nasally administering an effective amount of the benzodiazepine to the patient, wherein the effective amount of the composition is effective to treat seizure, protect against seizure, reduce or ameliorate the intensity of seizure, reduce or ameliorate the frequency of seizure, and/or prevent occurrence or re-occurrence of seizure."

Cartt'784, [0028], Exhibit 2015, p. 0003; *see also* [0031], [0033], [0035], [0037], [0039], [0040], [0042], [0043], [0045], [0046], [0059], [0067], [0075], [0083], [0091], [0099], [0108], [0116], [0136] on pp. 0004-0014, 0017-0022, 0024, 0025, 0028.

455. Therefore, in my opinion, Claim 23 of the '876 Patent is obvious in view of the combination of Gwozdz, Meezan'962, and Cartt'784.

XVIII. CONCLUDING OPINION

456. Based on the foregoing, it is my opinion that Claims 1-36 of the '876 Patent are obvious over Sonne in view of Meezan'962.

457. It is my further opinion that Claims 1-16 and 24-36 of the '876 Patent are obvious over Gwozdz in view of Meezan'962.

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458. It is my further opinion that Claims 17-23 of the '876 Patent are obvious over Gwozdz in view of Meezan'962 and further in view of Cartt'784.

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

Executed on this, the 6th day of December, 2018.

Nicholas A. Peppas, Sc.D.

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XIX. APPENDIX A – CLAIMS CHART

A. Ground 1 – Claims 1-36 – Sonne (Exhibit 1013) in View Of Meezan'962 (Exhibit 1011)

CLAIMS U.S. Patent No. 9,763,876 B2	REFERENCES Sonne (Exhibit 1013) Meezan'962 (Exhibit 1011)
1. **[1a-i]** A method of treating a patient with a disorder which is treatable with a benzodiazepine drug, comprising:	**[1a-i]** **Sonne:** "[T]he invention…provide[s] a method of treatment of a human or non-human animal subject by delivery of a substantially insoluble or sparingly soluble biologically active agent,…" 6:41-44.
[1a-ii] administering to one or more nasal mucosal membranes of a patient a pharmaceutical solution for nasal administration consisting of	**[1a-ii]** **Sonne:** "[C]ompositions according to the invention may be administered to the mucosal membranes for example in the nose…Nasal,…administrations are particularly preferred." 3:54-59.

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	Sonne: "The compositions of the invention may be used directly as solutions of the bioactive agent in the tocopherol solvent." 3:60-61. **Sonne:** "Thus for example the compositions may take the form of…solutions,…sprays,…" 6:32-35. DS11 Solutions (Exhibit 1050) are all solutions. **Meezan'962:** "[A] method of increasing absorption of a low molecular weight compound into the circulatory system of a subject by administering the compound via the…nasal,…delivery route…" [0008]. **Meezan'962:** "A 'therapeutic composition'…can be compounded…with the usual non-toxic, pharmaceutically acceptable carriers for…solutions,…" [0049].

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[1b] benzodiazepine drug,	**[1b]** **Sonne:** "Representative active agents from a range of different therapeutic groups are listed below, by way of exemplification… Anxiolytics, sedatives & hypnotics: diazepam, nitrazepam, flurazepam," and thirteen other specifically listed benzodiazepines. 5:3-5 and 5:34-38. DS11 Solutions (Exhibit 1050) all include benzodiazepine (diazepam).
[1c] one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w);	**[1c]** **Sonne:** "compositions of the invention may contain from 1 to 99.99% (w/w) preferably 20 to 99.99%, most preferably 40 to 99.99% (w/w) of the tocopherol or tocopherol derivative solvent." 5:55-58. PO never established criticality for tocopherol amounts. *See* Peppas, ¶61; *see also* M.P.E.P. § 2144.05(I), first and second paragraphs, and (II)(A); *Ineos USA LLC*, 783 F.3d at 869-871; *Galderma Labs., L.P.*, 737 F.3d at 739.

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	DS11 Solutions contain 40% or 65% α-tocopherol.
[1d] ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w);	**[1d]** **Sonne: "**Viscosity can be reduced by addition of co-solvents such as ethanol". 3:65-66. **Sonne:** "The formulations according to the invention may be optimized with respect to bioadhesion, sprayability and viscosity, as desired. Thus for example, the following co-solvents may be added:…alcohols such as ethanol,…or benzyl alcohol". 6:47-53; *see also Blue Calypso, LLC,* 815 F.3d at 1344. DS11-A, -B have combined 55% ethanol/benzyl alcohol; DS11-C has combined 30% ethanol/benzyl alcohol; DS11-D has combined 29.75% ethanol/benzyl alcohol.

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[1e] and an alkyl glycoside.	**[1e]** **Meezan'962:** "The invention relates generally to non-irritating, non-toxic compositions providing enhanced bioavailability and more specifically to alkyl glycoside…compositions for delivery of therapeutic agents to a subject." [0002]. DS11-D includes dodecyl maltoside, an alkyl glycoside.
2. **[2]** The method of claim 1, wherein the natural or synthetic tocopherols or tocotrienols is Vitamin E.	**[2]** **Sonne:** "Tocopherols are a range of natural and synthetic compounds, also known by the generic term Vitamin E…As used herein, the term 'tocopherol' includes all such natural and synthetic tocopherol or Vitamin E compounds." 3:5-6, 3:14-15. DS11 solutions all include α-tocopherol; PO admitted that α-tocopherol is a form of vitamin E. *See* '876 Patent, 33:8-13 and 33:20-23.

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3. **[3]** The method of claim 1, wherein the benzodiazepine drug is selected from the group consisting of: alprazolam, brotizolam, chlordiazepoxide, clobazam, clonazepam, clorazepam, demoxazepam, diazepam, flumazenil, flurazepam, halazepam, midazolam, nordazepam, medazepam, nitrazepam, oxazepam, lorazepam, prazepam, quazepam, triazolam, temazepam, loprazolam, or any pharmaceutically-acceptable salts thereof, and any combinations thereof.	[**3**] *See* discussion for **[1b]**. DS11 Solutions (Exhibit 1050) all include diazepam, a benzodiazepine. **Meezan'962**: POSITA would apply Meezan'962 to benzodiazepine formulations. Peppas, ¶¶222, 228, 236.
4. **[4]** The method of claim 3, wherein the benzodiazepine drug is diazepam, or a pharmaceutically-acceptable	**[4]** **Sonne:** "Representative active agents from a range of different therapeutic groups are listed below…diazepam". 5:3-5, 5:34; *see*

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salt thereof.	*also* Figs. 1-2; Examples 1-3, 7-11, 22-23; Claims 5, 8, 13, 19, 24, 28. DS11 Solutions (Exhibit 1050) all include diazepam.
5. **[5]** The method of claim 1, wherein the solution contains about 1 to about 20% (w/v) of benzodiazepine.	**[5]** **Sonne:** "The active substance may be present in an amount of from about 0.0001% to 50% of the total composition, preferably 0.001% to 40% (w/w)." 5:52-54; *see also* Examples 1-3, 7-10, 19, 22-23. PO never established criticality for benzodiazepine amounts. *See* Peppas, ¶¶62-63; *see also* M.P.E.P. § 2144.05(I), first and second paragraphs, and (II)(A); *Ineos USA LLC*, 783 F.3d at 869-871; *Galderma Labs., L.P.*, 737 F.3d at 739. DS11 Solutions all include 5% benzodiazepine (diazepam).

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6. **[6]** The method of claim 5, wherein the solution contains about 1 to about 20% (w/v) of diazepam.	**[6]** *See* discussions for **[4]** and **[5]**. DS11 Solutions all include 5% diazepam.
7. **[7]** The method of claim 1, wherein the one or more natural or synthetic tocopherols or tocotrienols are selected from the group consisting of: α-tocopherol,β-tocopherol, γ-tocopherol, δ-tocopherol, α-tocotrienol, β- tocotrienol, γ-tocotrienol, δ-tocotrienol, tocophersolan, any isomers thereof, any esters thereof, any analogs or derivatives thereof, and any combinations thereof.	**[7]** **Sonne:** "α-Tocopherol…is the most active and widely distributed in nature, and has been the most widely studied. Other members of the class include beta, gamma, and delta tocopherols…" 3:7-12; *see also* Examples 3, 7-10, 17-19, 22-23. DS11 Solutions all include α-tocopherol.

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8. **[8]** The method of claim 1, wherein the solution contains ethanol from 1 to 25% (w/v) and benzyl alcohol from 1 to 25% (w/v). [As claim 1 requires "ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w)", **the combination of ethanol and benzyl alcohol permitted ranges from 10% to 50%.]**	**[8]** *See* discussion for **[1d]**. DS11-C and -D contain 19% and 18.75% ethanol, respectively, and 11% benzyl alcohol.
9. **[9]** The method of claim 8, wherein the benzodiazepine drug is present in the pharmaceutical solution in a concentration of from about 10 mg/mL to about 250 mg/mL. [Equivalent to 1.0-25%.]	**[9]** **Sonne:** "The active substance may be present in an amount of from about 0.0001% to 50% of the total composition, preferably 0.001% to 40% (w/w)." 5:52-54; *see also* Examples 1-3, 7-10, 19, 22-23. DS11 Solutions all include 5% diazepam, i.e., 50 mg/mL.

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10. **[10]** The method of claim 9, wherein the benzodiazepine drug is present in the pharmaceutical solution in a concentration of from about 20 mg/mL to about 50 mg/mL.	**[10]** *See* discussions for **[9]**.
11. **[11]** The method of claim 1, wherein the one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, is in an amount from about 45% to about 85% (w/w).	**[11]** *See* discussions for **[1c]**. DS11-C and -D Solutions contain 65% α-tocopherol.
12. **[12]** The method claim 11, wherein the one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, is in an amount from about 60% to about 75% (w/w).	**[12]** *See* discussions for **[11]**. DS11-C and -D Solutions contain 65% α-tocopherol.

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13. **[13]** The method of claim 1, wherein the ethanol and benzyl alcohol is in a combined amount from about 15% to about 55% (w/w).	**[13]** *See* discussions for **[1d]**. DS11-A, -B have combined 55% ethanol/benzyl alcohol; DS11-C has combined 30% ethanol/benzyl alcohol; DS11-D has combined 29.75% ethanol/benzyl alcohol.
14. **[14]** The method of claim 13, wherein the ethanol and benzyl alcohol is in a combined amount from about 25% to about 40% (w/w).	**[14]** *See* discussions for **[1d]**. DS11-C has combined 30% ethanol/benzyl alcohol; DS11-D has combined 29.75% ethanol/benzyl alcohol.
15. **[15]** The method of claim 1, wherein the solution comprises ethanol from 10 to 22.5% (w/v) and benzyl alcohol from 7.5 to 12.5% (w/v). [Thus the solution contains from 17.5% to 35% alcohols.]	**[15]** *See* discussions for **[1d]**. DS11-C and -D contain 19% and 18.75% ethanol, respectively, and 11% benzyl alcohol.

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16. **[16]** The method of claim 1, wherein the solution is in a pharmaceutically-acceptable spray formulation.	**[16]** **Sonne:** "Thus for example the compositions may take the form of… sprays,…" 6:32-35. **Sonne:** "The formulations according to the invention may be optimized with respect…sprayability…" 6:47-48. DS11-A, -B, -C, -D are sprays.
17. **[17]** The method of claim 16, wherein the benzodiazepine is administered in a therapeutically effective amount from about 1 mg to about 20 mg.	**[17]** **Sonne:** "The investigation was carried out in order to estimate irritation after nasal application of 10 mg of diazepam." 14:65-66. **Sonne:** "FIG. 1 is a graph showing mean serum concentrations (ng/ml) against time (minutes) after intranasal administration of 2.5 mg diazepam." 7:15-17.

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	DS11 Solutions contain 5% benzodiazepine/diazepam. As in **[18]** below, Sonne discloses 100 µL volumes. 100 µL of 5% benzodiazepine/diazepam solutions equates to 5 mg benzodiazepine/diazepam. *See* Peppas, ¶304.
18. **[18]** The method of claim 17, wherein said pharmaceutical solution is in a pharmaceutically-acceptable spray formulation having volume from about 10 µL to about 200 µL.	**[18]** **Sonne:** "administration of drugs with very low water solubility to the nose is difficult, because of the limited volume which is acceptable for the nose (about 100 µl)." 7:25-28; *see also* 2:30-33, 10:12-14.
19. **[19]** The method of claim 18, wherein the administration of the pharmaceutical solution comprises spraying at least a portion of the therapeutically effective amount of the benzodiazepine into at least one	**[19]** **Sonne:** "The investigation was carried out in order to estimate irritation after nasal application of 10 mg of diazepam; 100 mg of the preparation from Example 8 in each nostril." 14:65-67.

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nostril.	A POSITA would recognize that intranasal dosage forms, e.g., sprays, can be administered into one or both nostrils. Peppas, ¶308.
20. **[20]** The method of claim 18, wherein the administration of the pharmaceutical solution comprises spraying at least a portion of the therapeutically effective amount of the benzodiazepine into each nostril.	**[20]** *See* discussion for **[19]**.
21. The method of claim 20, wherein the administration of the pharmaceutical solution comprises **[21a]** spraying a first quantity of the pharmaceutical solution into the first nostril,	**[21a-b]** *See* discussion for **[19]**.

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[21b] spraying a second quantity of the pharmaceutical solution into a second nostril, and	
[21c] optionally after a pre-selected time delay, spraying a third quantity of the pharmaceutical solution into the first nostril.	**[21c]** Not required / Non-limiting claim element. A POSITA would recognize that intranasal dosage forms, e.g., sprays, can be administered several times to one or both nostrils. Peppas, ¶¶308-309, 312.
22. **[22]** The method of claim 21, further comprising, optionally after a pre-selected time delay, administering at least a fourth quantity of the pharmaceutical solution to the second nostril.	**[22]** *See* discussion for **[19]** and **[21c]**.
23. **[23]** The method of claim 21, wherein nasal administration of the	**[23]** **Sonne:** "Alprazolam is a benzodiazepine which is used for the treatment of e.g.

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pharmaceutical solution begins at any time before or after onset of symptoms of a disorder which is treatable with the pharmaceutical solution.	anxiety…" 12:18-20. **Sonne:** "Midazolam is a benzodiazepine tranquiliser with a sedative effect e.g., and is used for the treatment of anxiety and tension states, and as a sedative and for premedication." 12:47-49. A POSITA would understand that administration always occurs either before or after symptoms begin. Peppas, ¶320.
24. **[24]** The method of claim 1, wherein the solution contains at least about 0.01% (w/w) of an alkyl glycoside.	**[24]** **Meezan'962:** Alkyl glycosides "are typically present at a level of from about 0.01% to 20% by weight. More preferred levels of incorporation are from about 0.01% to 5% by weight, from about 0.01% to 2% by weight, from about 0.01% to 1%, most preferably from about 0.01% to 0.125% by weight." [0070].

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	DS11-D Solution includes 0.25% alkyl glycoside (dodecyl maltoside). **Sonne:** Example 10 includes 2% cetearyl glucoside in diazepam nosedrop emulsion. 10:55-66.
25. **[25]** The method of claim 24, wherein the solution contains about 0.01% to 1% (w/w) of an alkyl glycoside.	**[25]** **Meezan'962:** Alkyl glycosides "are typically present at a level of…from about 0.01% to 1%, most preferably from about 0.01% to 0.125% by weight." [0070]. DS11-D Solution includes 0.25% alkyl glycoside (dodecyl maltoside).
26. **[26]** The method of claim 25, wherein the solution contains about 0.01% to 1% (w/w) of dodecyl maltoside.	**[26]** *See* discussion for **[25]**. **Meezan'962:** "Alkyl glycosides of the present invention can include, but are not limited to: alkyl glycosides, such as…dodecyl-…β-D-maltoside,…" [0056];

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	see also [0058], [0061], [0092], [0155]-[0158], Table I on p. 0019. DS11-D Solution includes 0.25% dodecyl maltoside.
27. The method of claim 1, wherein the solution consists of **[27]** **[27a]** diazepam, **[27b]** vitamin E, **[27c]** ethanol, **[27d]** benzyl alcohol and **[27e]** dodecyl maltoside.	**[27]** DS11-D includes all recited ingredients. **[27a]** *See* discussion for **[4]**. **[27b]** *See* discussion for **[2]**. **[27c-d]** *See* discussion for **[1d]**. **[27e]** *See* discussion for **[26]**.

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28. The method of claim 1, wherein the solution consists of	
[28a] about 56.47% (w/v) vitamin E,	**[28a]** DS11-D includes about 65% α-tocopherol (vitamin E). A POSITA would experiment with various α-tocopherol amounts including about 56.47%, especially because PO never demonstrated criticality regarding α-tocopherol amounts. Peppas, ¶61.
[28b] about 10.5% (w/v) benzyl alcohol,	**[28b]** DS11-D includes about 11% benzyl alcohol which is about 10.5%. Peppas, ¶335. Further, a POSITA would experiment with various benzyl alcohol amounts including about 10.5%, especially because PO never demonstrated criticality regarding benzyl alcohol amounts. Peppas, ¶¶52-57.
[28c] about 10% (w/v) diazepam,	**[28c]** DS11-D includes about 5% diazepam. A POSITA would experiment with various of diazepam amounts including about 10%, especially because

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	PO never demonstrated criticality regarding diazepam amounts. Peppas, ¶¶62-63.
[28d] about 0.25%(w/v) dodecyl maltoside,	**[28d]** DS11-D includes about 0.25% dodecyl maltoside.
[28e] q.s. dehydrated ethanol.	**[28e]** DS11-D includes about 18.75% ethanol; "q.s. dehydrated ethanol" = about 22.78%. *See* Peppas, ¶331. A POSITA would experiment with various ethanol amounts including about 22.78%, especially because PO never demonstrated criticality regarding ethanol amounts. Peppas, ¶¶52-57. Moreover, ethanol is generally q.s.'ed so an exact amount is not targeted. Peppas, ¶269.
29. The method of claim 1, wherein the solution consists of	
[29]	**[29]** DS11-D includes all recited ingredients.

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[29a] diazepam, **[29b]** alkyl glycoside, **[29c]** vitamin E, **[29d]** ethanol, and **[29e]** benzyl alcohol.	**[29a]** *See* discussion for **[4]**. **[29b]** *See* discussion for **[1e]**. **[29c]** *See* discussion for **[2]**. **[29d-e]** *See* discussion for **[1d]**.
30. The method of claim 1, wherein the solution consists of **[30a]** diazepam from 5 to 15% (w/v), **[30b]** dodecyl maltoside from about 0.01 to 1% (w/v),	**[30a]** *See* discussion for **[5]**. DS11 Solutions all include 5% diazepam. **[30b]** *See* discussion for **[26]**; *see also* **[24]** and **[25]**. DS11-D Solution includes 0.25% dodecyl maltoside.

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[30c] vitamin E from 45 to 65% (w/v),	**[30c]** *See* discussion for **[1c]**. DS11-C and -D Solutions contain 65% α-tocopherol (vitamin E).
[30d] ethanol from 10 to 25% (w/v) and benzyl alcohol from 5 to 15% (w/v). [Thus, the solution contains from 15% to 40% alcohols.]	**[30d]** *See* discussion for **[1d]**. DS11-C and -D contain 19% and 18.75% ethanol, respectively, and 11% benzyl alcohol; total of 30% and 29.75% alcohol, respectively. Note: DS11-D meets every limitation.
31. **[31]** The method of claim 1, wherein the solution consists of diazepam from 5 to 15% (w/v), dodecyl maltoside from 0.01 to 1% (w/v), vitamin E from 45 to 65% (w/v), ethanol from 10 to 25% (w/v)and benzyl alcohol from 5 to 15% (w/v).	**[31]** *See* discussion for **[30a-d]**. Note: DS11-D meets every limitation.

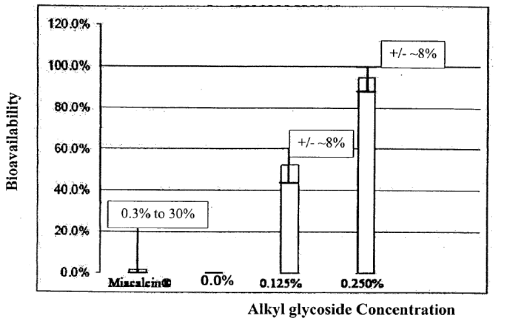
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32. The method of claim 1, wherein the solution consists of	Note: DS11-E Solution meets every limitation.
[32a] diazepam from 9 to 11% (w/v),	**[32a]** *See* discussion for **[4]** and **[5]**. DS11-C, -D Solutions contain 5% diazepam. A POSITA would increase diazepam by about 5% while simultaneously reducing vitamin E by about 5%. Peppas, ¶347; *see also* ¶¶338-341.
[32b] dodecyl maltoside from 0.1 to 0.5% (w/v),	**[32b]** *See* discussion for **[24]-[26]**. DS11-D Solution includes 0.25% dodecyl maltoside.
[32c] vitamin E from 50 to 60% (w/v),	**[32c]** *See* discussion for **[1c]**. DS11-C, -D Solutions contain 65% α-tocopherol (vitamin E). A POSITA can easily decrease α-tocopherol by about 5% while simultaneously increasing diazepam by about 5%. Peppas, ¶347; *see also* ¶¶338-341; *see also* **[32a]**.

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[32d] ethanol from 15 to 22.5% (w/v) and benzyl alcohol from 7.5 to 12.5% (w/v). [Thus the alcohol content is from 22.5% to 35%.]	**[32d]** *See* discussion for **[1d]**. DS11-C and -D contain 19% and 18.75% ethanol, respectively, and 11% benzyl alcohol; total of 30% and 29.75% alcohol, respectively.
33. **[33]** The method of claim 1, wherein the solution consists of diazepam 10% (w/v), dodecyl maltoside from 0.15 to 0.3% (w/v), vitamin E from 50 to 60% (w/v), ethanol from 17 to 20% (w/v) and benzyl alcohol from 10 to 12% (w/v).	**[33]** *See* discussion for **[32a-d]**. Note: DS11-E Solution meets every limitation.
34. **[34]** The method of claim 1, wherein said treatment achieves bioavailability that is from about 80 to 125% of that achieved with the same benzodiazepine administered intravenously.	**[34]** **Sonne:** tested pharmacokinetics/dynamics of intranasal diazepam formulations, including reporting various data. 7:15-18 and 13:56-14:58. PO admits bioavailabilities can be calculated from

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	such data. '876 Patent, 4:57-59; *see also* Peppas, ¶350. A POSITA would seek to optimize bioavailabilities of Sonne's formulations and would therefore look to Meezan'962, as discussed above. Meezan'962 achieved 98% bioavailability (90% + 8% variance) for intranasal formulations using alkyl glycosides. Meezan'962, [0150]-[0151]; *see also* Peppas, ¶¶235, 353, 427; *see also* Meezan'962 Fig. 1: Patent Application Publication Mar. 2, 2006 Sheet 1 of 3 US 2006/0046962 A1  FIG. 1

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	Meezan‘962 taught routine optimization of drug pharmacokinetics by testing experimental formulations, determining bioavailabilities as compared to intravenous formulations, and adjusting dosages to increase AUC if necessary. Meezan‘962, [0109]. Meezan‘962 achieved 98% bioavailability: “Thus, the alkyl glycoside of the invention enhances absorption and increases the bioavailability of the drug.” Meezan‘962, [0150]; *see also* [0151]. “Even more interesting, alkyl glycosides of the invention in the range of about 0.01% to about 6% have increased bioavailability (see FIG. 1). Meezan‘962, [0149]. Meezan‘962 taught alkyl glycosides are useful with “small molecule organic drug molecules” and “anti-seizure agents (topiramate, zonisamide)”. Meezan‘962, [0004], [0052]. Therefore, a POSITA

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	would apply Meezan'962 to benzodiazepines. *See* Peppas, ¶¶222, 228, 236. Regardless of whether Meezan'962 actually achieved such bioavailabilites, a POSITA would believe such bioavailabilities are achievable. Therefore, the POSITA would be motivated to experiment with and optimize the ingredients in DS11-D, using the teachings of Meezan'962, with an expectation of successfully achieving useful bioavailabilities in the 80%-125% range, including bioavailabilities approaching 100%.
35. **[35]** The method of claim 34, wherein said treatment achieves bioavailability that is from about 90 to 110% of that achieved with the same benzodiazepine administered intravenously.	**[35]** *See* discussion for **[34]**. Meezan'962 achieved 98% bioavailability (90% + 8% variance) for intranasal formulations using alkyl glycosides. Meezan'962, [0150]-[0151] and Fig. 1; *see also* Peppas, ¶¶235, 353, 427.

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36. **[36]** The method of claim 35, wherein said treatment achieves bioavailability that is from about 92.5 to 107.5% that obtained with the same benzodiazepine administered intravenously.	**[36]** *See* discussion for **[34-35]**.

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B. Ground 2 – Claims 1-16 and 24-36 – Gwozdz (Exhibit 1013) in View of Meezan'962 (Exhibit 1011)

CLAIMS 1-16, 24-36 U.S. Patent No. 9,763,876 B2	REFERENCES Gwozdz (Exhibit 1014) in view of Meezan'962 (Exhibit 1011)
1. **[1a-i]** A method of treating a patient with a disorder which is treatable with a benzodiazepine drug, comprising:	**[1a-i]** **Gwozdz:** "the present invention relates to methods of treatment of a patient with these pharmaceutical solutions." 4:24-26. **Gwozdz:** "Exemplary hydrophobic or lipophilic therapeutic agents which can be solubilized in accordance with the present invention include…benzodiazepines such as Diazepam" and fourteen other benzodiazepines. 8:6-13.
[1a-ii] administering to one or more nasal mucosal membranes of a patient a pharmaceutical solution for nasal administration consisting of	**[1a-ii]** **Gwozdz:** "Pharmaceutical solutions of the instant invention are particularly useful in formulations to be administered to mucosal membranes, i.e. the nasal mucosa…" 9:19-21.

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	Meezan‘962: “[A] method of increasing absorption of a low molecular weight compound into the circulatory system of a subject by administering the compound via the…nasal,…delivery route…” [0008]. **Meezan‘962:** “A ‘therapeutic composition’…can be compounded…with the usual non-toxic, pharmaceutically acceptable carriers for…solutions,…The carriers,…can include…other carriers suitable for use in manufacturing preparations, in solid, semisolid, or liquid form.” [0049].
[1b] benzodiazepine drug,	**[1b]** **Gwozdz:** “Exemplary hydrophobic or lipophilic therapeutic agents which can be solubilized in accordance with the present invention include…benzodiazepines such as Diazepam” and fourteen other benzodiazepines. 8:6-13.

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	Meezan'962: POSITA would understand Meezan'962 as being applicable to benzodiazepine formulations. Peppas, Exhibit 1041, ¶¶222, 228, 236.
[1c] one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w);	**[1c]** **Gwozdz:** "a pharmaceutical solution is formed by dissolving a therapeutic agent in a tocopherol and/or a tocotrienol…" 5:12-14. **Gwozdz:** "Tocopherols and/or tocotrienols for use in accordance with the present invention include…" 5:33-6:15. **Gwozdz:** "the tocopherol(s) and/or tocotrienol(s) is in an amount from about 30% to about 99% (w/w)". 4:18-19; 7:8-10; *see also* 7:20-25 (60-99% or approximately 70-90% alpha-tocopherol). 5:55-58. PO never established criticality for tocopherol amounts. *See* Peppas, Exhibit 1041, ¶61; *see also* M.P.E.P. § 2144.05(I), first and second paragraphs,

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	and (II)(A); *Ineos USA LLC*, 783 F.3d at 869-871; *Galderma Labs., L.P.*, 737 F.3d at 739.
[1d] ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w);	**[1d]** **Gwozdz:** "a pharmaceutical solution is formed by dissolving a therapeutic agent in a tocopherol and/or a tocotrienol and an alcohol…" 5:12-14. **Gwozdz:** "Examples of alcohol(s) for use in the present invention include, but are not limited to ethanol,…benzyl alcohol, and any isomers thereof, and any combinations thereof." 6:16-19. **Gwozdz:** "In some embodiments,…the alcohol(s) and/or glycol(s) is in an amount from about 1% to about 70% (w/w)." 4:17-21; 7:8-11; *see also* 7:20-24 (1-40% or approximately 10-30% ethanol). PO never established criticality for tocopherol amounts. *See* Peppas, Exhibit 1041, ¶61; *see also* M.P.E.P. § 2144.05(I), first and

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	second paragraphs, and (II)(A); *Ineos USA LLC*, 783 F.3d at 869-871; *Galderma Labs., L.P.*, 737 F.3d at 739.
[1e] and an alkyl glycoside.	**[1e]** **Meezan'962:** "The invention relates generally to non-irritating, non-toxic compositions providing enhanced bioavailability and more specifically to alkyl glycoside…compositions for delivery of therapeutic agents to a subject." [0002].
2. **[2]** The method of claim 1, wherein the natural or synthetic tocopherols or tocotrienols is Vitamin E.	**[2]** **Gwozdz:** Tocopherols/tocotrienols are "also known by the generic names tocols or vitamin E." 5:33-6:2.
3. **[3]** The method of claim 1, wherein the benzodiazepine drug is selected from the group consisting of: alprazolam, brotizolam,	[**3]** **Gwozdz**: "benzodiazepenes [sic] such as Diazepam, alpraxolam, bromazepam, chlordiazepoxidem, clonazepam, estazolam, flunitrazepam, flurazepam,

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chlordiazepoxide, clobazam, clonazepam, clorazepam, demoxazepam, diazepam, flumazenil, flurazepam, halazepam, midazolam, nordazepam, medazepam, nitrazepam, oxazepam, lorazepam, prazepam, quazepam, triazolam, temazepam, loprazolam, or any pharmaceutically-acceptable salts thereof, and any combinations thereof.	lorazepam, lormetazepam, mexazolam, nitrazepam, oxazepam, temazepam, and triazolam". 8:9-13. **Meezan'962**: POSITA would understand Meezan'962 as being applicable to benzodiazepine formulations. Peppas, Exhibit 1041, ¶¶222, 228, 236.
4. **[4]** The method of claim 3, wherein the benzodiazepine drug is diazepam, or a pharmaceutically-acceptable salt thereof.	**[4]** **Gwozdz:** "benzodiazepenes [sic] such as Diazepam". 8:9-10; *see also* 1:19, 7:12-19.

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5. **[5]** The method of claim 1, wherein the solution contains about 1 to about 20% (w/v) of benzodiazepine.	**[5]** **Gwozdz:** "combining tocopherol and ethanol has been found to provide solubility of the Diazepam approaching the 10% level. By way of illustration, at 70% tocopherol:30% ethanol (200 proof), Diazepam is soluble to greater than or equal to 8% and at 95% tocopherol:5% ethanol (200 proof), Diazepam is soluble at greater than or equal to 9%." 7:14-19.
6. **[6]** The method of claim 5, wherein the solution contains about 1 to about 20% (w/v) of diazepam.	**[6]** *See* discussions for **[4]** and **[5]**.
7. **[7]** The method of claim 1, wherein the one or more natural or synthetic tocopherols or tocotrienols are selected from the group consisting of: α-tocopherol,β-tocopherol, γ-	**[7]** **Gwozdz:** "[a]lpha-tocopherol is the most abundant and active form of this family of compounds…Other members of this family include beta-, gamma-, and delta-tocopherol, alpha-, beta-, gamma-, and

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tocopherol, δ-tocopherol, α-tocotrienol, β- tocotrienol, γ-tocotrienol, δ-tocotrienol, tocophersolan, any isomers thereof, any esters thereof, any analogs or derivatives thereof, and any combinations thereof.	delta-tocotrienols, tocopsoralen, alpha-tocopherol derivatives and/or analogs such as…as well as isomers thereof and esters thereof. Use of the phrase tocopherol(s) and/or tocotrienol(s) herein is meant to be inclusive of any member of this family alone or in combination." 6:2-13.
8. **[8]** The method of claim 1, wherein the solution contains ethanol from 1 to 25% (w/v) and benzyl alcohol from 1 to 25% (w/v). [As claim 1 requires "ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w)", **the combination of ethanol and benzyl alcohol permitted ranges from 10% to 50%.]**	**[8]** *See* discussion for **[1d]**.

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9. **[9]** The method of claim 8, wherein the benzodiazepine drug is present in the pharmaceutical solution in a concentration of from about 10 mg/mL to about 250 mg/mL. [Equivalent to 1.0-25%.]	**[9]** **Gwozdz:** "combining tocopherol and ethanol has been found to provide solubility of the Diazepam approaching the 10% level. By way of illustration, at 70% tocopherol:30% ethanol (200 proof), Diazepam is soluble to greater than or equal to 8% and at 95% tocopherol:5% ethanol (200 proof), Diazepam is soluble at greater than or equal to 9%." 7:14-19.
10. **[10]** The method of claim 9, wherein the benzodiazepine drug is present in the pharmaceutical solution in a concentration of from about 20 mg/mL to about 50 mg/mL.	**[10]** *See* discussions for **[9]**. A POSITA could easily reduce the percentage of dissolved diazepam simply by including less diazepam in the formulation. Peppas, Exhibit 1041, ¶¶390-391.

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11. **[11]** The method of claim 1, wherein the one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, is in an amount from about 45% to about 85% (w/w).	**[11]** *See* discussions for **[1c]**.
12. **[12]** The method claim 11, wherein the one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, is in an amount from about 60% to about 75% (w/w).	**[12]** *See* discussions for **[1c]**.
13. **[13]** The method of claim 1, wherein the ethanol and benzyl alcohol is in a combined amount from about 15% to about 55% (w/w).	**[13]** *See* discussions for **[1d]**.

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14. **[14]** The method of claim 13, wherein the ethanol and benzyl alcohol is in a combined amount from about 25% to about 40% (w/w).	**[14]** *See* discussions for **[1d]**.
15. **[15]** The method of claim 1, wherein the solution comprises ethanol from 10 to 22.5% (w/v) and benzyl alcohol from 7.5 to 12.5% (w/v). [Thus the solution contains from 17.5% to 35% alcohols.]	**[15]** *See* discussions for **[1d]**.
16. **[16]** The method of claim 1, wherein the solution is in a pharmaceutically-acceptable spray formulation.	**[16]** **Gwozdz:** "Advantageously, diluting a tocopherol or tocotrienol with an alcohol or glycol dramatically reduces the inherent viscosity of the tocopherol or tocotrienol thereby allowing for generation of sprayable formulations." 6:29-7:2.

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17-23. (*see Ground 2, below)*	
24. **[24]** The method of claim 1, wherein the solution contains at least about 0.01% (w/w) of an alkyl glycoside.	**[24]** **Meezan'962:** Alkyl glycosides "are typically present at a level of from about 0.01% to 20% by weight. More preferred levels of incorporation are from about 0.01% to 5% by weight, from about 0.01% to 2% by weight, from about 0.01% to 1%, most preferably from about 0.01% to 0.125% by weight." [0070].
25. **[25]** The method of claim 24, wherein the solution contains about 0.01% to 1% (w/w) of an alkyl glycoside.	**[25]** **Meezan'962:** Alkyl glycosides "are typically present at a level of…from about 0.01% to 1%, most preferably from about 0.01% to 0.125% by weight." [0070].

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26. **[26]** The method of claim 25, wherein the solution contains about 0.01% to 1% (w/w) of dodecyl maltoside.	**[26]** *See* discussion for **[25]**. **Meezan'962:** "Alkyl glycosides of the present invention can include, but are not limited to: alkyl glycosides, such as…dodecyl-…β-D-maltoside,…" [0056]; *see also* [0058], [0061], [0092], [0155]-[0158], Table I on p. 0019.
27. The method of claim 1, wherein the solution consists of **[27]** **[27a]** diazepam, **[27b]** vitamin E, **[27c]** ethanol, **[27d]** benzyl alcohol and **[27e]** dodecyl maltoside.	**[27]** **[27a]** *See* discussion for **[4]**. **[27b]** *See* discussion for **[2]**. **[27c]** *See* discussion for **[1d]**. **[27d]** *See* discussion for **[1d]**. **[27e]** *See* discussion for **[26]**.

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	[27a-d] Gwozdz: Specifically teaches combination diazepam, tocopherols (i.e., vitamin E), and alcohols (including ethanol and benzyl alcohol combinations). *See, e.g.*, 6:16-19, 7:3-19.
28. The method of claim 1, wherein the solution consists of **[28a]** about 56.47% (w/v) vitamin E,	**[28a]** **Gwozdz** discloses tocopherols in amounts of about 30-99%; alpha-tocopherol in amounts of 60-99%. 4:17-19, 7:8-10 and 20-22. A POSITA would be motivated to experiment with various amounts of α-tocopherol including amounts of about 56.47%, especially because PO has never demonstrated any criticality regarding amounts of α-tocopherol. Peppas, Exhibit 1041, ¶61.

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[28b] about 10.5% (w/v) benzyl alcohol, [along with q.s. ethanol, about 33.28% alcohols]	**[28b]** **Gwozdz:** discloses alcoholic combinations of ethanol and benzyl alcohol. 6:16-19. Alcohol/ combinations of alcohol may be present in amounts of about 1-70%, ethanol may be present in amounts of 1-40% or 10-30%. 4:19-21, 7:10-11 and 20-24. A POSITA would be motivated to experiment with various amounts of benzyl alcohol and ethanol, including amounts of about 10.5% and 22.78%, respectively, especially because PO has never demonstrated any criticality regarding amounts, or relative amounts, of alcohols. Peppas, Exhibit 1041, ¶¶52-57.
[28c] about 10% (w/v) diazepam,	**[28c]** **Gwozdz:** It is possible to make diazepam solutions "approaching the 10% level". 7:14-19.

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[28d] about 0.25%(w/v) dodecyl maltoside,	**[28d]** **Meezan'962:** Dodecyl maltoside is a specifically preferred alkyl glycoside. [0061]. 0.25% is a preferred amount of alkyl glycoside, and, therefore, of dodecyl maltoside. [0150], [0151], [0158], [0167]; *see also* Fig. 1; *see also* Peppas, Exhibit 1041, ¶¶365-367.
[28e] q.s. dehydrated ethanol.	**[28e]** *See* discussion for **[28b]**. Ethanol is generally q.s.'ed so that an exact amount is not necessarily targeted. Peppas, Exhibit 1041, ¶269.
29. The method of claim 1, wherein the solution consists of	
[29a] diazepam,	**[29a]** *See* discussion for **[1b and 4]**.
[29b] alkyl glycoside,	**[29b]** *See* discussion for **[1e]**.
[29c] vitamin E,	**[29c]** *See* discussion for **[2]**.

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[29d] ethanol, and **[29e]** benzyl alcohol.	**[29d]** *See* discussion for **[1d]**. **[29e]** *See* discussion for **[1d]**.
30. The method of claim 1, wherein the solution consists of **[30a]** diazepam from 5 to 15% (w/v), **[30b]** dodecyl maltoside from about 0.01 to 1% (w/v), **[30c]** vitamin E from 45 to 65% (w/v), **[30d]** ethanol from 10 to 25% (w/v) and benzyl alcohol from 5 to 15% (w/v). [Thus, the solution contains from 15% to 40% alcohols.]	 **[30a]** *See* discussion for **[5]**. **[30b]** *See* discussion for **[26]**; *see also* **[24, 25, 28d]**. **[30c]** *See* discussion for **[1c]**. **[30d]** *See* discussion for **[1d]**.

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31. **[31]** The method of claim 1, wherein the solution consists of diazepam from 5 to 15% (w/v), dodecyl maltoside from 0.01 to 1% (w/v), vitamin E from 45 to 65% (w/v), ethanol from 10 to 25% (w/v)and benzyl alcohol from 5 to 15% (w/v). [Note – Claim 30 recites dodecyl maltoside from **about** 0.01 to 1% (w/v).]	**[31]** *See* discussion for **[30a-d]**.
32. The method of claim 1, wherein the solution consists of **[32a]** diazepam from 9 to 11% (w/v), **[32b]** dodecyl maltoside from 0.1 to 0.5% (w/v),	**[32a]** *See* discussion for **[4, 5, 28c]**. **[32b]** *See* discussion for **[24, 25, 26, 28d]**.

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[32c] vitamin E from 50 to 60% (w/v), **[32d]** ethanol from 15 to 22.5% (w/v) and benzyl alcohol from 7.5 to 12.5% (w/v). [Thus the alcohol content is from 22.5% to 35%.]	**[32c]** *See* discussion for **[1c]**. **[32d]** *See* discussion for **[1d]**.
33. **[33]** The method of claim 1, wherein the solution consists of diazepam 10% (w/v), dodecyl maltoside from 0.15 to 0.3% (w/v), vitamin E from 50 to 60% (w/v), ethanol from 17 to 20% (w/v) and benzyl alcohol from 10 to 12% (w/v).	**[33]** *See* discussion for **[32a-d]**.

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34. **[34]** The method of claim 1, wherein said treatment achieves bioavailability that is from about 80 to 125% of that achieved with the same benzodiazepine administered intravenously.	**[34]** **Gwozdz:** "In accordance with the present invention, solutions of one or more tocopherols and/or tocotrienols and one or more alcohols and/or glycols are used in the solubilization of hydrophobic or lipophilic therapeutic agents thereby providing increased bioavailability of the therapeutic agent." 7:3-8. **Meezan'962:** achieved 98% bioavailability (90% + 8% variance) for intranasal formulations using alkyl glycosides. [0150]-[0151]; *see also* Peppas, Exhibit 1041, ¶¶235, 427, 434; *see also* Meezan'962 Fig. 1:

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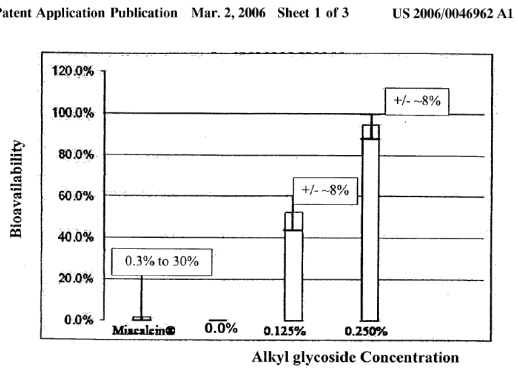


FIG. 1

Meezan'962: taught routine optimization of drug pharmacokinetics by testing experimental formulations, determining bioavailabilities as compared to intravenous formulations, and adjusting dosages to increase AUC if necessary. [0109].

Meezan'962: achieved 98% bioavailability: "Thus, the alkyl glycoside of the invention enhances absorption and increases the bioavailability of the drug." [0150]; *see also* [0151].

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	Meezan'962: "Even more interesting, alkyl glycosides of the invention in the range of about 0.01% to about 6% have increased bioavailability (see FIG. 1)." [0149]. **Meezan'962:** taught alkyl glycosides are useful with "small molecule organic drug molecules" and "anti-seizure agents (topiramate, zonisamide)". [0004], [0052]. Therefore, a POSITA would apply Meezan'962 to benzodiazepines. *See* Peppas, Exhibit 1041, ¶¶222, 228, 236. Regardless of whether Meezan'962 actually achieved such bioavailabilites, a POSITA would believe such bioavailabilities are achievable. Therefore, the POSITA would be motivated to experiment with and optimize Gwozdz's teachings, using the disclosure of Meezan'962, with an expectation of successfully achieving useful bioavailabilities in the 80%-125% range, including bioavailabilities approaching 100%.

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35. **[35]** The method of claim 34, wherein said treatment achieves bioavailability that is from about 90 to 110% of that achieved with the same benzodiazepine administered intravenously.	**[35]** *See* discussion for **[34]**. **Meezan'962:** achieved 98% bioavailability (90% + 8% variance) for intranasal formulations using alkyl glycosides. [0150] and Fig. 1; *see also* Peppas, Exhibit 1041, ¶¶222, 228, 236.
36. **[36]** The method of claim 35, wherein said treatment achieves bioavailability that is from about 92.5 to 107.5% that obtained with the same benzodiazepine administered intravenously.	**[36]** *See* discussion for **[34]**. **Meezan'962:** achieved 98% bioavailability (90% + 8% variance) for intranasal formulations using alkyl glycosides. [0150] and Fig. 1; *see also* Peppas, Exhibit 1041, ¶¶222, 228, 236.

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C. Ground 3 – Claims 17-23 – Gwozdz (Exhibit 1013) in View of Meezan'962 (Exhibit 1011) Further in View of Cartt'784 (Exhibit 1015)

CLAIMS 17-23 U.S. Patent No. 9,763,876 B2	REFERENCES Gwozdz (Exhibit 1014) in view of Meezan'962 (Exhibit 1011), in view of Cartt'784 (Exhibit 1015)
17. **[17]** The method of claim 16, wherein the benzodiazepine is administered in a therapeutically effective amount from about 1 mg to about 20 mg.	**[17]** *See* discussion for **[16]** in Ground 1. **Cartt'784:** "The dosage of diazepam may vary by indication, however it is expected that a therapeutic dose will be in the range of about 1 to about 20, preferably about 2 to about 10 mg per dose". [0063]; *see also* [0055], [0071], [0079], [0087], [0095], [0104], [0112] for dosing ranges of other benzodiazepines falling within/overlapping with recited range.

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18. **[18]** The method of claim 17, wherein said pharmaceutical solution is in a pharmaceutically-acceptable spray formulation having volume from about 10 µL to about 200 µL.	**[18]** **Cartt'784:** "Nasal preparations are generally administered in metered sprays having volumes of less than 250 µl, preferably less than 150 µl, and ideally from 25 to 100 µl." [0007]. **Cartt'784:** "As a nasal formulation, diazepam may be administered in 25 to 250 µl metered sprays. In some preferred embodiments, diazepam is administered in 50 to 150 µl, especially about 100 µl, metered sprays." [0064]; *see also* [0056], [0072], [0080], [0088], [0096], [0105], [0113] for same volume ranges for other benzodiazepines.

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19. **[19]** The method of claim 18, wherein the administration of the pharmaceutical solution comprises spraying at least a portion of the therapeutically effective amount of the benzodiazepine into at least one nostril.	**[19]** **Cartt'784:** "In some embodiments…administering a therapeutically effective amount of the composition to at least one nostril." [0031]; *see also* [0033], [0035], [0039], [0042], [0045]. A POSITA would recognize that intranasal dosage forms, e.g., sprays, are intended to be administered into one or both nostrils. Peppas, Exhibit 1041, ¶¶445-446.
20. **[20]** The method of claim 18, wherein the administration of the pharmaceutical solution comprises spraying at least a portion of the therapeutically effective amount of the benzodiazepine into each nostril.	**[20]** *See* discussion for **[19]**. **Cartt'784:** "In some embodiments, at least a portion of the therapeutically effective amount of the composition to each nostril." [0031]; *see also* [0033], [0035], [0039], [0042], [0045].

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21. The method of claim 20, wherein the administration of the pharmaceutical solution comprises	
[21a] spraying a first quantity of the pharmaceutical solution into the first nostril,	**[21a-b]** *See* discussion for **[19 and 20]**.
[21b] spraying a second quantity of the pharmaceutical solution into a second nostril, and	
[21c] optionally after a pre-selected time delay, spraying a third quantity of the pharmaceutical solution into the first nostril.	**[21c]** Not required / Non-limiting claim element. *See In re Johnston*, 435 F.3d at 1384; M.P.E.P. §§ 2103(I)(C), fourth paragraph, and 2143.03, third paragraph. A POSITA would recognize that intranasal dosage forms, e.g., sprays, can be administered more than once to one or both nostrils. Peppas, Exhibit 1041, ¶¶446, 448-449.

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	[21a-c] Cartt'784: "In some embodiments, the method comprises administering a first quantity of the composition to a first nostril, administering a second quantity of the composition to a second nostril, and optionally after a pre-selected time delay, administering a third quantity of the composition to the first nostril." [0031]; *see also* [0033], [0035], [0039], [0042], [0045].
22. **[22]** The method of claim 21, further comprising, optionally after a pre-selected time delay, administering at least a fourth quantity of the pharmaceutical solution to the second nostril.	**[22]** *See* discussion for **[19, 20, and 21c]**. **Cartt'784:** "In some embodiments, the method further comprises optionally after a pre-selected time delay, administering at least a fourth quantity of the composition to the second nostril." [0031]; *see also* [0033], [0035], [0039], [0042], [0045].

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23. **[23]** The method of claim 21, wherein nasal administration of the pharmaceutical solution begins at any time before or after onset of symptoms of a disorder which is treatable with the pharmaceutical solution.	**[23]** **Cartt'784:** "Among the beneficial therapeutic effects that may be imparted by acute nasal dosing of benzodiazepine anticonvulsants are: reduction in the severity of the seizure (e.g. general relaxation of the muscles, reduction in seizure-induced anxiety experienced by the patient and a general impartation of a feeling of well-being to the patient), reduction in the duration of the seizure, reduction in the probability that the patient will experience a repeat seizure, an increase in the interval between the current seizure and the next seizure." [0060], [0068]; *see also* [0003], [0061], [0069]. A POSITA would understand there is no other time to administer, i.e., either symptoms have begun or have not yet begun. Peppas, Exhibit 1041, ¶453.

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Dipl. Eng. (Chem. Eng.), National Technical University of Athens, Greece, 1971.
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Honorary Doctorates

Doc. Hon. Causa, University of Ghent, Belgium, 1999.
Pharm. D. Hon. Causa, University of Parma, Italy, 1999.
Doc. Hon. Causa, University of Athens, Greece, 2000.
Hon. Prof., Sichuan University, People's Republic of China, 2012
Doc. Hon. Causa, University of Ljubljana, Slovenia, 2012.
Doc. Hon. Causa, University of Patras, Greece, 2015.
Doc. Hon. Causa, National Technical University of Athens, Greece, 2016.
Hon. Prof., Peking Union Medical College, People's Republic of China, 2017.
Hon. Prof., PLA Hospital and Medical School, People's Republic of China, 2018.
Doc. Hon. Causa, University of Santiago de Compostela, Spain, 2018.
Hon. Prof., Beihang University, People's Republic of China, 2017

Professional Experience

University of Texas, Department of Chemical Engineering, Cockrell Family Regents Chair #6, 2014-, tenured 50%
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University of Texas, Department of Biomedical Engineering, Fletcher Stuckey Pratt Chair, 2003-14, tenured 50%.
University of Texas, Department of Surgery and Perioperative Care, Dell Medical School, 2016-, courtesy.
University of Texas, Department of Pediatrics, Dell Medical School, 2017-, tenured, joint, 0%.
University of Texas, Division of Molecular Pharmaceutics and Drug Delivery, College of Pharmacy, Professor, 2003-, courtesy.
University of Texas, Department of Biomedical Engineering, Chair of the Department, 2009-15.
University of Texas, Texas Materials Institute, Professor, 2003-.

Purdue University, School of Chemical Engineering, Showalter Distinguished Professor, 1993-2002.
Purdue University, Department of Biomedical Engineering, Showalter Distinguished Professor, 1999-2002.
Purdue University, School of Chemical Engineering, Professor, 1982-2002.
Purdue University, School of Chemical Engineering, Associate Professor, 1978-82.
Purdue University, School of Chemical Engineering, Assistant Professor, 1976-78.

Beihang University, Beijing, People's Republic of China, *Honorary Professor*, May 2018-present.
PLA Hospital and Medical School, Beijing, People's Republic of China, *Honorary Professor*, January 2018-.
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Sichuan University, Chengdu, People's Republic of China, *Honorary Professor*, June 2012-present.
Nanyang Technological University, Singapore, *Visiting Professor*, January 2005.
Free University of Berlin, Germany, *Mercator Visiting Professor*, Jan-June 2001.
University of Santiago de Compostela, Spain, *Visiting Professor*, February-March 2001.
Complutense University, Madrid, Spain, *Visiting Professor*, March-April 2001.
University of Naples, Italy, *Visiting Professor,* Department of Materials Engineering, May 1996.
Hoshi University, Tokyo, Japan, *Visiting Professor*, Jan.-March 1994; March 1995; March 1997.
Hebrew University, Jerusalem, Israel, *Visiting Professor*, March-May 1994.
University of Parma, Italy, Faculty of Sciences, *Adjunct Professor*, 1987-88; 1993-94.
University of Paris XI, France, Faculty of Pharmacy,*Visiting Professor*, May-December 1986.
California Institute of Technology, Department Chemical Engineering, *Visiting Professor*, March-July 1983.
University of Geneva, Switzerland, Faculty of Sciences, *Visiting Professor*, Sept.1982-Feb. 1983.

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Research Center for National Defense, Research Associate, 1974-75.
Shell Co., Rotterdam, The Netherlands, Summer 1970.
Beso Co., Patras, Greece, Summers 1968 and 1969.

Member of Academies

National Academy of Engineering (2006)
National Academy of Medicine (2008)
American Academy of Arts and Sciences (2017)
National Academy of Inventors (2014)
Chinese Academy of Engineering (2018)
French Academy of Pharmacy (Académie Nationale de Pharmacie) (2005)
Royal Academy of Spain (Academia Real) (2011)
Academy of Athens, Greece (2013)
Academy of Medicine, Engineering and Science of Texas (2006)
International Academy of Medical and Biological Engineering (2016)

Awards and Honors

2018 ***Elected to the Chinese Academy of Engineering***
2018 *Elected Honorary Professor, Beihang University, Beijing*
2018 ***Honorary Doctorate, University of Santiago de Compostela, Spain***
2018 *Elected Honorary Professor, PLA Hospital and Medical School, Beijing, China*
2018 *Associate Editor, Science Advances, AAAS/Science*
2017 Editor, *Regenerative Biomaterials, Oxford University Press.*
2017 *Elected Honorary Professor, Peking Union Medical College*
2017 ***Elected to the American Academy of Arts and Sciences***
2017 ***Inaugural Pioneer of Nanotechnology Award, Johns Hopkins University.***
2017 ***One of the five "Medicine Makers of 2017" World wide.***
2017 ***List of 100 Best Materials Scientists in the World.***
2017 ***Life Achievements and Service, Controlled Release Society***
2016 ***Honorary Doctorate, National Technical University of Athens, Greece***
2016 ***Elected to the International Academy of Medical and Biological Engineering***
2016 ***Robert A. Pritzker Distinguished Lecture Award, Biomedical Enginering Society***
2016 ***Elected to the National Materials and Manufacturing Board, NRC***
2015 ***International Award, European Society for Biomaterials, Krakow, Poland***
2015 ***Controlled Release Society Award for Life Contributions, Edinburgh, Scotland***
2015 ***Honorary Doctorate, University of Patras***
2014 ***Giulio Natta Medal, Polytechnic School of Milan, Italy***

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2014 Best paper award for 2013, Journal of Drug Delivery Science & Technology
2014 ***Applied Polymer Science Award, American Chamical Society***
2013 ***Elected to the Academy of Athens, Greece***
2013 Fellow, Royal Society of Chemistry, UK
2014 ***Nanoscale Science and Engineering Award, AIChE***
2013 ***Distinguished Scientist Award, International Journal of Nanomedicine***
2013 ***Benjamin Garver Lamme Excellence in Engineering Education Award, ASEE***
2012 ***Founders Award, National Academy of Engineering***
2012 ***Honorary Doctorate, University of Ljubljana, Slovenia***
2012 Elected Honorary Professor, Sichuan University
2012 Hocott Distinguished Engineering Research Award, University of Texas at Austin
2012 ***Elected to the Royal Academy of Spain (Academia Real)***
2012 Nature and BioNIUM Distinguished Researcher and Educator Award, Nature Conferences
2011 Fellow, American Chemical Society
2011 Excellence in Surface Science Award, Surface in Biomaterials Foundation
2010 ***Distinguished Achievement Award,*** Biomedical Engineering Society
2010 ***Acta Biomaterialia Gold Medal***
2010 Inaugural Fellow, Controlled Release Society
2010 ***William H Hall Award for Contributions to Society, Society for Biomaterials***
2010 ***Distinguished Scientist, Southern Universities Research Association***
2010 ***Maurice Marie Janot Award, Pharmaceutical Sciences, APGI***
2010 George Mitchell Award for Excellence in Graduate Research, University of Texas
2009 Alan S Michaels Distinguished Lectureship in Medical & Biological Engineering, MIT
2009 Appointed Editor-in-Chief, SFB/Wiley Biomaterials Books Series
2008 ***Elected to the Institute of Medicine of the National Academy of Sciences***
2008 Premio Romulo Garza, Best Research published in 2008, Mexico
2008 ***Founders Award, American Institute of Chemical Engineers***
2008 ***"One Hundred Chemical Engineers of the Modern Era", American Institute of Chemical Engineers***
2008 Appointed Associate Editor of the *AIChE Journal*
2008 Elected to the Board of the Biomedical Engineering Society
2008 Elected President, International Union of Sicieties of Biomaterials Science and Engineering
2008 Fellow, American Society for Engineering Education
2008 Inaugural fellow, Materials Research Society
2008 Selected as a HighlyCited® ISI Researcher
2008 ***Pierre Galletti Award, American Institute of Medical and Biological Engineering***
2007 ***Institute Lecturer, American Institute of Chemical Engineers***
2007 ***Carreer Research Excellence Award, University of Texas***
2007 Most Outstanding ChE Faculty Member, Engineering Student Council, University of Texas
2006 ***Jay Bailey Award, Biological Engineering Society, American Institute of Chemical Engineers***
2006 ***William H. Walker Award, American Institute of Chemical Engineers***
2006 Best Paper Award, European Controlled Release Meeting
2006 ***Dow Chemical Engineering and Lctureship Award, American Society for Engineering Education***
2006 ***Elected to the National Academy of Engineering***
2006 ***Elected to the Academy of Medicine, Engineering and Science of Texas***
2006 Elected Chair of College of Fellows, American Institute of Medical And Biological Engineering
2006 Consulting Editor, *Pharmaceutical Research*
2005 Inaugural Fellow, Biomedical Engineering Society
2005 Best Paper Award, International Meeting of the Microencapsulation Society
2005 Distinguished Scientist Award, Houston Society of Engineering in Medicine and Biology
2005 ***Founders Award of the Society for Biomaterials***
2005 Whitaker Graduate Student Award, Society for Biomaterials
2005 ***Elected Member of the French Academy of Pharmacy (Académie Nationale de Pharmacie)***
2004 *Research Excellence Award for Best Research Paper (highest UT research recognition), Univ Texas*
2003 Materials Research Society Graduate Research Award
2003 Capsugel Award for Best Graduate Student Research in Controlled Drug Delivery

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2003 Nagai Foundation Award for Research
2003 Appointed to the Nanotechnology Technical Advisory Board to the President's Council of Advisors on Science and Technology
2002 Outstanding Chemical Engineer Award, School of Chemical Engineering, Purdue University
2002 Distinguished Service Award, Department of Biomedical Engineering, Purdue University
2002 ***Dale E. Wurster Award in Pharmaceutics, American Association of Pharmaceutical Scientists***
2002 Graduate Student Award for Outstanding Research, Biomedical Engineering Society
2002 Graduate Student Award of the IEEE Engineering in Medicine and Biology Society
2002 Newsmaker of the Year, American Chemical Society
2002 Graduate Student Award, IEEE Engineering in Medicine and Biology Society
2002 ***Eurand Award for Outstanding Contributions in Oral Drug Delivery, Controlled Release Society***
2002 Pioneer in Biomedical Engineering, IEEE Engineering in Medicine and Biology Society
2002 Elected President-elect of the Society for Biomaterials
2002 *Sigma Xi Award, (highest Purdue research recognition), Purdue University*
2002 Chorafas Foundation Award for Best Dissertation
2002 Best Graduate Student Paper Award, Materials Research Society
2001 Editor, *New Drugs*
2001 Mercator Visiting Professor, Free University of Berlin
2001 Visiting Professor, University of Santiago de Compostela
2001 Visiting Professor, Complutense University of Madrid
2000 ***General Electric, Senior Research Award, American Society for Engineering Education***
2000 *Herbert McCoy Award (highest Purdue research recognition), Purdue University*
2000 J. Heller Award, Best Research for 1999, Controlled Release Society
2000 APV Award, Best Ph.D. Thesis, International Pharmaceutical Association
2000 Best Paper Award, European Journal of Pharmaceutics and Biopharmaceutics
2000 ***Honorary Doctorate, University of Athens, Greece***
2000 Fellow, American Association for the Advancement of Science
2000 Elected Director of the American Institute of Chemical Engineers
1999 ***Research Achievement Award in Pharmaceutical Technology, American Association of Pharmaceutical Scientists***
1999 ***Honorary Doctorate, Doctor of Pharmacy, University of Parma, Italy***
1999 Best Paper Award, Midwestern Meeting, American Association of Pharmaceutical Scientists
1999 Editor, *Advances in Chemical Engineering*
1999 Marion B. Scott Award, Purdue University
1999 ***Honorary Doctorate, University of Ghent, Belgium***
1998 Best Paper Award, Materials Research Society
1998 Fellow, American Physical Society
1997 Whitaker Best Paper Award, International Society for Artificial Organs
1997 Fellow, American Institute of Chemical Engineers
1996 Best Paper Award, Bioengineering Division, American Institute of Chemical Engineers
1996 Visiting Professor, University of Naples
1996 Best Doctoral Dissertation Award, Purdue University
1996 Whitaker Best Paper Award, Institute of Electrical and Electronic Engineers
1995 Best Paper Award, Materials Division, American Institute of Chemical Engineers
1995 Best Paper Award, Bioengineering Division, American Institute of Chemical Engineers
1995 APV Medal for Distinguished Pharmaceutical Contributions, International Pharmaceutical Association
1994 Best Paper Award, Annual Meeting American Institute of Chemical Engineers
1994 Best Session Award, Annual Meeting American Institute of Chemical Engineers
1994 Award and Honorary Membership, Italian Society of Medicine and Natural Sciences
1994 ***Food, Pharmaceutical and Bioengineering Award, American Institute of Chemical Engineers***
1994 Fellow, Biomaterials Science and Engineering, Society for Biomaterials
1994 Visiting Professor, Hoshi University
1994 Visiting Professor, Hebrew University
1994 Potter Award, Best Engineering Teacher, Purdue University
1994 Shreve Prize, Best Chemical Engineering Teacher, Purdue University

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1993 Showalter Distinguished Professor of Chemical and Biomedical Engineering
1993 Best Paper Award, Materials Division, American Institute of Chemical Engineers
1993 Unilever Award, Best Polymer Doctoral Thesis, American Chemical Society
1992 ***George Westinghouse Award, American Society for Engineering Education***
1992 ***Clemson Award for Basic Research in Biomaterials, Society for Biomaterials***
1992 Founding Fellow, American Institute of Medical and Biological Engineering
1992 Best Paper Award, Materials Division, American Institute of Chemical Engineers
1992 Controlled Release Society, Service Award
1991 ***Founders Award for Outstanding Research, Controlled Release Society***
1991 Victor LaMer Award, Best Colloids Doctoral Thesis, American Chemical Society
1991 Best Graduate Research Paper, Society of Adhesion
1991 Best Paper Award, Midwestern Meeting, American Association of Pharmaceutical Scientists
1991 Named *Polymer Science Pioneer* by the Journal *Polymer News*
1991 Editor, *European Journal of Pharmaceutics and Biopharmaceutics*
1991 Rene Maurice Gattefossé Medal, Academy of the Alpilles
1990 A.I.Ch.E. Service Award
1990 Fellow, American Association of Pharmaceutical Scientists
1989 A.I.Ch.E. Service Award
1988 ***Curtis McGraw Award for Outstanding Research, American Society for Engineering Education***
1988 Elected Chairman of the Materials Engineering and Sciences Division of AIChE
1987 Elected President of the Controlled Release Society
1987 Visiting Professor, University of Parma
1986 Visiting Professor, University of Paris XI
1985 Shreve Prize, Best Chemical Engineering Teacher, Purdue University
1985 Potter Award, Best Engineering Teacher, Purdue University
1985 Controlled Release Society, Service Award
1984 ***Materials Engineering and Sciences Award, American Institute of Chemical Engineers***
1983 Visiting Professor, California Institute of Technology
1982 Zyma Foundation Award for the Advancement of Medical and Biological Sciences
1982 Shreve Prize, Best Chemical Engineering Teacher, Purdue University
1982 A.I.Ch.E. National Best Counselor Award
1982 Editor, *Biomaterials*
1982 Visiting Professor, University of Geneva
1980 ***Western Electric Fund Award, American Society for Engineering Education***
1980 Shreve Prize, Best Chemical Engineering Teacher, Purdue University
1980 Contributing Editor, *Polymer News*
1978 Potter Award, Best Engineering Teacher, Purdue University
1978 Shreve Prize, Best Chemical Engineering Teacher, Purdue University
1971 Chryssoverghion Award, Best Student, University-wide, N.T.U. Athens

Endowed/Honorary Lectureships

2018 Plenary Lecturer, Spanish-Portuguese CRS Meeting, Coimbra, Portugal.
2017 Plenary Lecturer, 5th Nano Today Conference, Kona, HI.
2017 ***Plenary Lecturer***, Xiang Shan Scientific Conference, Beijing, China.
2017 Invited Lecturer, Polymer Gels in Materials Science, Materials Research Society, Boston, MA.
2017 Invited Lecturer, Biomaterials for Regenerative Engineering, Materials Research Society, Boston, MA
2017 ***Master Lecturer***, Shanghai Jiao Tong University, Shanghai, China.
2017 Plenary Lecturer, International Forum on Innovation and Emerging Industries Development, Shanghai.
2017 ***Plenary Lecturer***, European Society for Biomaterials, Athens, Greece.
2017 Plenary Lecturer, Service to CRS Award Lecturer, Boston, MA.
2017 ***Master Lecturer***, Peking Union Medical College, Beijing, China.
2017 Plenary Lecturer, Biomedical Engineering Society of China, Beijing, China.
2017 Distinguished Lecturer, University of Florida, Gainsville, Florida.
2017 ***Inaugural Pioneer of Nanotechnology Award Lecturer,*** Johns Hopkins University, Baltimore, MD.

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2016 ***Plenary Lecturer***, World Life Science Conference Beijing, China
2016 ***Pritzker Distinguished Lecturer***, Biomedical Engineering Society, Minneapolis, MN
2016 ***Plenary Lecturer***, Research Forum on Frontiers in Materials, Sichuan University, Chengdu, China.
2016 ***Lowrie Lecturer***, Ohio State University, Columbus, OH
2016 College of Engineering Distinguished Lecturer, University of California Davis, Davis, CA
2016 ***Pritzker Lecturer***, Illinois Institute of Technology, Chicago, Illinois.
2016 Plenary Lecturer, NanoDay 2016, Bilkent University, Ankara, Turkey
2016 ***TAMEST Materials Lecturer***, TAMEST, Dallas, TX
2015 ***Plenary Lecturer***, Chinese Biomaterials Congress, Haiku, China
2015 Invited Lecturer, US-China Entrepreneurship Symposium, Guangzhou, China
2015 ***International Award Lecturer***, European Society for Biomaterials, Krakow, Poland
2015 Plenary Lecturer, 10th Panhellenic Research Congress of Chemical Engineering, Patras, Greece
2015 Simpson Querrey Institute for BioNanotechnology Lecturer, Northwestern, Evanston, IL
2015 ***Katz Lecturer***, City College of New York, NY
2015 ***Kelly Lecturer***, 50th Anniversary, Purdue University, West Lafayette, IN
2015 ***Johnson & Johnson Lecturer***, Rutgers University, Piscataway, NJ
2015 ***Reilly Lecturer***, University of Notre Dame, South Bend, IN
2015 ***Invited Lecturer***, Chinese Academy of Engineering, Beijing, China
2015 ***National Academy of Inventors Lecture***, Pasadena, CA
2014 Strategic Research Theme Lecturer, Univerity of Hong Kong.
2014 ***Giulio Natta Lecture,*** Polytechnic School of Milan, Italy
2014 *Sangalli Lecture**,*** University of Milan, Milan, Italy
2014 ***Gaden Memorial Lecture***, Columbia University, New York, NY.
2014 ***Materials Today Asia Plenary Lecturer***, Hong Kong
2014 Keynote Lecture, US-China Symposium on Nanobiology and Nanomedicine, Washington, DC
2014 Plenary Lecturer, International Institute for Nanotechnology, Northwestern, Evanston, IL
2014 ***Plenary Lecturer***, Recovery of Biological Products XVI, Rostock, Germany
2014 ***Polymer Award Address***, American Chemical Society, Dallas, TX
2014 ***Kammermeyer Lecturer***, University of Iowa, Iowa City, IA
2014 ***Skalak Lecturer***, University of California at San Diego, CA
2013 ***Hoffman Lecturer***, University of Washington, Seattle, WA
2013 ***Plenary Lecturer***, 5th Asian Arden Conference, Nagoya, Japan
2013 International Journal of Nanomedicine Lecturer, MRS Meeting, Boston, MA
2013 ***Plenary Lecturer***, 19th International Symposium on Microencapsulation, Pamplona, Spain
2013 ***Plenary Lecturer***, 25th European Society for Biomaterials Meeting, Madrid, Spain
2013 ***Plenary Lecturer***, 4th International Conference on Biomolecular Engineering, Ft Lauderdale, FL
2013 ***Parr Lecturer***, University of Illinois, Urbana-Champaign, IL
2013 ***Ruckenstein Lecturer***, University of Buffalo, Buffalo, NY
2013 ***Distinguished Lecturer***, College of Engineering, Michigan Tech, Houghton, MI
2013 Keynote Speaker, 4th International Conference on Biomolecular Engineering, Miami, FL
2012 Keynote Speaker, Symposium New Innovations in Polymers and Biomaterials, Maui, HI
2012 Plenary Lecturer, 9th International Polymer Conference (IPC2012), Kobe, Japan
2012 ***Founders Award Lecture***, National Academy of Engineering, Washington, DC
2012 Plenary Lecturer, NanoBioSeattle, Seattle, WA
2012 ***Plenary Lecturer***, 9th World Congress of Biomaterials, Chengdu, China
2012 Plenary Lecturer, The Areces Foundation, Madrid, Spain
2012 ***The Berkeley Lectures***, University of California, Berkeley, CA
2012 Plenary Lecturer, Miami 2012 Winter Symposium: Nanotechnology in Biomedicine, Miami, FL
2012 Plenary Lecturer, 6th International Symposium on Intelligent Drug Delivery, Seoul, S. Korea
2011 ***UNC/Eisai Distinguished Lecturer*** in Drug Delivery, Univ North Carolina, Chapel Hill, NC
2011 Award Lecturer, Excellence in Surface Science, Surface in Biomaterials Foundation, Minneapolis,MN
2011 Centennial Lecture, Centennial, School Chemical Engineering, Purdue University, West Lafeyette, IN
2011 Plenary Lecturer, 7th International Symposium on Controlled Release Systems, Istanbul, Turkey
2011 ***Wohl Memorial Lecturer***, University of Delaware, Newark, DE.
2011 ***Payatakes Lecturer***, University of Houston, Houston, TX.

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2011 ***Bashore Lecturer***, Auburn University, Auburn, AL.
2011 ***Skinner and Lautenschlager Memorial Lecturer***, Northwestern University, Evanston, IL
2011 Plenary Lecturer, 10th Congress of the Spanish Society of Industrial Pharnmacy, Madrid, Spain
2010 ***BMES Distinguished Achievement Lecturer,*** Annual Meeting of the BMES, Austin, TX
2010 ***Plenary Lecturer***, 37th Annual Meeting of the Controlled Release Society, Portland, OR
2010 Plenary Lecturer, 3rd International Meeting on Pharmacy & Pharmaceutical Sciences, Istanbul, Turkey
2010 Plenary Lecturer, Grand Challenges Summit of the National Academy of Engineering, Seattle, WA
2010 Distinguished Lecturer, Imperial College, London, England
2010 Distiguished Lecturer, Collège de France, Pris, France
2010 ***Maurice-Marie Janot Award Lecturer***, 7th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Valletta, Malta
2010 Plenary Lecturer, 1st Global Congress on NanoEngineering for Medicine and Biology, Houston, TX
2009 Honorary Lecturer, Series in Biomaterials, AIChE, Nashville, TN
2009 CMA Stine Lecturer, AIChE, Nashville, TN
2009 Plenary Lecturer, 2nd PharmSciFair, Nice, France.
2009 ***Alan Michaels Lecturer***, Massachusetts Institute of Technology, Cambridge, MA
2009 Kewaunee Lecturer, Duke University, Durham, NC
2009 Missouri Academy of Chemical Engineers Lecturer, Rolla, MO
2008 Plenary Lecturer, 11th Mediterranean Congress of Chemical Engineering, Barcelona, Spain
2008 Plenary Lecturer, 6th International Conference of the Chemical Societies of the SE European Countries
2008 ***Rohm and Haas Lecturer,*** University of Massachusetts, Amherst, MA
2008 ***Merck Lecturer,*** University of Puerto Rico, Mayagüez, PR
2008 ***Galletti Award Lecturer,*** American Institute for Medical and Biological Engineering
2008 Plenary Lecturer, International Conference on Cellular and Molecular Engineering, Singapore
2008 59th Institute Lecture, Annual AIChE Meeting, Salt Lake City, UT
2007 Plenary Lecturer, National Biotechnology Conference, AAPS, San Diego, CA
2007 Plenary Lecturer, 9th Greek Scientific Chemical Engineering Conference, Athens, Greece
2008 Plenary Lecturer, 31st Annual Meeting of the Society for Biomaterials, Chicago, IL
2007 Plenary Lecturer, Pharmaceutical Sciences World Congress, Amsterdam, The Netherlands
2006 ***Dow Distinguished Lectureship, American Society for Engineering Education, Chicago, IL***
2005 Plenary Lecturer, 3rd World Congress on Biomimetics, Artificial Muscles & Bionanotechnology, Lausanne, Switzerland
2005 Plenary Lecturer, European Polymer Congress, Moscow, Russia
2005 Plenary Lecturer, Society for Biomaterials Meeting, Memphis, TN
2005 Plenary Lecturer, Third World Congress on Drug Absorption, Transport and Delivery, Barcelona, Spain.
2005 Plenary Lecturer, Annual event of the American Institute of Medical and Biological Engineering, Washington, DC
2004 Plenary Lecturer, European Materials Research Society Meeting, Warsaw, Poland
2004 Plenary Lecturer, 20th Japanese Drug Delivery Systems Meeting, Tokyo, Japan.
2004 Gattefossé Lecturer, Gattefossé Meeting, Lyon, France
2004 Plenary Lecturer, NIH/NSF Transport in Biological Systems Panel, Washington, DC
2003 Plenary Lecturer, NIH/NSF Bionanotechnology Panel, Washington, DC
2003 Plenary Lecturer, 4th Annual BioMEMS and NanoTech Meeting, Washington, DC
2003 Gattefossé Lecture, 37th Galenic Days Meeting, St. Rémy, France
2003 ***Harry G. Fair Distinguished Lecturer***, University of Oklahoma, Norman, Oklahoma
2003 ***Larson-Ruth Distinguished Lecturer***, Iowa State University, Ames, Iowa
2002 Plenary Lecturer, Biomedical Engineering Society Meeting, Houston.
2002 Plenary Lecturer, ACS Meeting, Boston.
2002 Plenary Lecturer, International Pharmaceutical Technology Symposium, Istanbul, Turkey.
2002 Plenary Lecturer, 29th International Symposium of Controlled Release of Bioactive Agents, Seoul, Korea.
2002 Plenary Lecturer, Particles 2002, Orlando.
2002 Plenary Lecturer, World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Florence, Italy.
2002 ***Merck Distinguished Lecturer***, Rutgers University.

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2001 Plenary Lecturer, 6th International Symposium on Polymers for Advanced Technologies, Eilat, Israel.
2000 Plenary Lecturer, North American Membrane Society Meeting, Boulder, Colorado.
2000 Plenary Lecturer, 6th World Congress of Biomaterials, Kamuela, Hawaii.
2000 Plenary Lecturer, Symposium on Biomedical Polymers for the 21st Century, Boston.
2000 ***Bayer Distinguished* Lecturer**, University of Pittsburgh.
1999 Plenary Lecturer, Drug Delivery for the Third Millennium, Pisa, Italy.
1999 Plenary Lecturer, Central European Symposium on Pharmaceutical Technology, PortoRoz, Slovenia.
1998 Plenary Lecturer, 90th Anniversary, American Institute of Chemical Engineers, Miami.
1998 Plenary Lecturer, International Pharmaceutical Conference, Portugal.
1998 Plenary Lecturer, International Pharmaceutical Technology Symposium, Istanbul, Turkey.
1997 Plenary Lecturer, Academy of Pharmaceutical Sciences and Technology, Tokyo, Japan.
1997 Plenary Lecturer, Japanese Drug Delivery Society, Sapporo, Japan.
1996 Plenary Bioengineering Lecturer, American Institute of Chemical Engineers, Chicago.
1996 Plenary Lecturer, POVAL Meeting, Kyoto, Japan.
1995 IUPAC Plenary Lecturer, Prague, Czech Republic.
1994 Hoshi Distinguished Lecturer, Tokyo, Japan.
1994 Plenary Lecturer, International Pharmaceutical Technology Conference.
1993 Plenary Lecturer, Materials Research Society.
1993 Nichiban Distinguished Lecturer, Tokyo, Japan.
1992 Plenary Lecturer, World Congress of Biomaterials, Berlin, Germany.
1992 Plenary Lecturer, ISOPOW-V, Valencia, Spain.
1991 ***Distinguished Lecturer***, Ontario Center for Materials Research, Toronto.
1991 Horizons Distinguished Lecturer, Kimberly-Clark, Roswell, Georgia.
1990 Distinguished Lecturer, Kimberly-Clark, Neenah, Wisconsin.
1990 Plenary Lecturer, Italian Chemical Society, Bressanone, Italy.
1988 ***Minnetonka Distinguished Lecturer***, University of Minnesota, Minneapolis, Minnesota.
1987 Inaugural Lecturer, University of Pavia, Pavia, Italy.
1987 ***Warren McCabe Distinguished Lecturer***, North Carolina State University, Raleigh, North Carolina.
1986 Plenary Lecturer, Danish Society of Polymer Technology, Copenhagen, Denmark.
1986 Plenary Lecturer, Fourth International Conference on Pharmaceutical Technology, Paris, France.
1985 Plenary Lecturer, Swedish Academy of Sciences, Stockholm, Sweden.
1983 Zyma Foundation Lecturer, Nyon, Switzerland.
1980 Plenary Lecturer, European Controlled Release Symposium, Geneva, Switzerland.

Advisory Boards

- Department of Chemical Engineering, Princeton University, 2010- .
- Department of Chemical and Biomolecular Engineering, Tulane University, 2015- .

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Editorial Boards

Currently Editor and Associate Editor

- Regenerative Biomaterials (2015-17); **Editor-in-Chief (2017-)** Oxford University Press
- Science Advances (2018-); **Associate Editor** in charge of Nanomedicine, AAAS/Science.
- Cell and Molecular Bioengineering (2013-); **Associate Editor** (2013-) Springer
- Regenerative Engineering and Translational Medicine (2015-); **Associate Editor** (2015-) Springer
- Biomedical Microdevices (2007-); **Associate Editor** (2008-) Elsevier

Science Journals

- Science Advances (2018-); **Associate Editor** in charge of Nanomedicine, AAAS/Science.

Chemical Engineering Journals

- Engineering, Chinese Academy of Engineering Journal (2015-)
- AIChE Journal; **Associate Editor** (2008-11)
- Current Opinion in Chemical Engineeting (2010-)
- Industrial & Engineering Chemistry (2006-09)
- Research (2005-08)
- Advances in Chemical Engineering; **Editor** (1999-03)
- Chemical Engineering Progress (1991-93)

Biomedical Engineering Journals

- Current Opinion in Biomedical Engineeting (2016-)
- Bioengineering and Translational Medicine (2015-).
- Cambridge University Texts in Biomedical Engineering; **Associate Editor** (2005-)
- Cell and Molecular Bioengineering (2013-); **Associate Editor** (2013-)
- Bioresearch Open Access (2012-)
- Advanced Healthcare Materials (2013-)
- Bioengineering and Translational Medicine (2015-)
- Chinese Academy Engineering Journal (2015-)
- Regenerative Engineering and Translational Medicine (2015-); **Associate Editor** (2015-)

Nanotechnology Journals

- ACS Nano (2013-)
- Biomedical Microdevices (2007-); **Associate Editor** (2008-)
- International Journal of Nanomedicine (2005-)
- Nanomedicine (2005-)
- Dictionary of Nanoscience and Nanotechnology (2009-)

Biomaterials and Tissue Enginering Journals

- Regenerative Biomaterials (2013-17); **Editor-in-Chief (2017-)**
- Regenerative Engineering (2015-17); **Associate Editor (2015-)**
- SFB/Wiley Biomaterials Book Series; **Editor-in-Chief** (2009-12)
- Hydrogels Handbook; **Editor** (2008-12)
- Biomaterials Science (2012-)
- Journal of Biomaterials Science, Polymer Edition (1987-)
- Encyclopedia of Biomaterials and Biomedical Engineering (2002-)
- Macromolecular Bioscience (2008-)
- Biomaterials (1980-04); **Editor** (1982-2001)
- Methods in Tissue Engineering (1999-)
- Tissue Engineering (1994-2008)
- Tissue Engineering Books, Academic Press (1995-)
- Biomedical Materials (1985-99)

Pharmaceutical and Medical Journals

- Acta Pharmaceutica Sinica (2017-)
- Pharmaceutical Research (2005-); **Consulting Editor** (2006-12)
- Journal of Biopharmaceutics and Biotechnology (2005-)
- International Journal of Pharmaceutics (2003-)
- Journal of Controlled Release (1983-)

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- Les Annales Pharmaceutiques Françaises (2008-)
- Encyclopedia of Controlled Drug Delivery (1997-)
- Advanced Drug Delivery Reviews (1992-)
- Journal of Drug Delivery Science and Technology (1987-)
- AAPS PharmSci (1998-)
- AAPS PharmSciTech (2000-)
- Expert Opinion on Drug Delivery (2004-)
- Acta Pharmaceutica Sciencia (2006-)
- Annals Academie Nationale de Pharmacie (2008-)
- European Journal of Pharmaceutics and Biopharmaceutics, **U.S. Editor** (1992-94); (1992-)
- Marmara Pharmaceutical Journal (2009-)

Polymer Journals

- Progress in Polymer Science (2007-)
- Journal of Applied Polymer Science (1976-)
- Polymer Gels and Networks (1993-99)
- Polymer News (1980-92)

Citations

Who's Who in America
Who's Who in Engineering
American Men and Women of Science
Who's Who in Technology
Who's Who in Medicine
Who's Who in American Education
International Who's Who in Engineering.
Who's Who in Frontier Science and Technology
Who's Who in Finance and Business
Who's Who in the South and Southwest
Who's Who in the Midwest
Personalities of America
Who's Who in Technology Today
1000 World Leaders of Scientific Influence
Who-Is-Doing-What in Drug Delivery
American Hellenic Who's Who
Who's Who in Music (1993)

Professional Societies and Positions Held

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National Academy of Engineering (NAE)

NAE Bioengineering Section, Section 2 Chair (2015-17), Chair-Elect (2013-15), Section 2 Past Chair (2017-19)
NAE Awards Committee (2010-11)
Recruiting Committee, ChE section (2007-10)

National Academy of Medicine (NAM)

NAM Engineering, Sciences Section, Section 1 Chair (2015-17), Chair-elect (2013-15)
NAM Membership Committee (2013-17)
NAM Subcommittee on International Members (2015-16)

American Academy of Arts and Sciences

National Academy of Inventors (NAI)

NAI Fellow Selection Committee (2016-)
NAI Fellow Advisory Board (2016)

Academy of Medicine, Engineering and Science of Texas (TAMEST)

Awards Committee of O'Donnell Award, Medicine Section (2008-09)

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Chair, Awards Committee, of O'Donnell Award, Medicine Section (2009-2011)
Organizing Committee, Annual meeting (2016)

International Academy of Medical and Biological Engineering

Académie Nationale de Pharmacie (France)

Editorial Committee, Academy Journal (2008-)

Academia Real Nacional (Spain)

Academy of Athens (Greece)

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American Institute of Medical and Biological Engineering (AIMBE)

Chair, College of Fellows (2007-08)
Chair, Fellows Selection Committee (2008-10)
Organizing Committee of 2005, 2007, 2008, 2009 and 2012 Meetings
SFB Representative to the Council of Societies (2004)
AIChE Representative to the Council of Societies (1995-2012)
Public Policy Committee (1996-2004)
Fellows Committee (1993, 1998-00, 2006-08)
Program Committee (1993, 2000-02)
Foreign Fellows Committee (1994)
Founding Fellow

American Institute of Chemical Engineers (AIChE)

Chairman, AIChE Awards Committee (2011-13)
Vice Chairman, AIChE Awards Committee (2009-10)
Member, AIChE Awards Committee (2006-2009)
Director (2000-02)
Member, Bioengineering Task Force (2002-05)
Member, Nominating Committee (2001-02)
Member, Board Award Committee (2001-02)
Member, Council of Technology (2000-02)
Member, RANTC (2000-)
Liaison with Bioengineering Division (2000-02)
Fellow (1998)
Chairman, Materials Division (1988-90)
First Vice-Chairman, Materials Division (1986-88)
Chairman, Nominating Committee, Materials Division (1991-92, 1994-95)
Chairman, Awards Committee, Materials Division (1991-92)
Program Chairman, Materials Division (1986-88)
Director, Materials Division (1981-82; 1984-86)
Vice Chairman, Committee on Polymers, Area 8a (1994-95)
Chairman, Committee on Polymers, Area 8a (1995-97)
Director, Food, Pharmaceuticals and Bioengineering Division (1994-97)
Chairman, New Materials Committee (1983-87)
Member, Awards Committee of Materials Division (1981-83; 85-88)
Member, History of Chemical Engineering Committee (1989-92)
Member, AIChE Chemical Engineering Education Projects Committee (1979-88)
Editorial Committee, "Chemical Engineering Faculties" (1984-87)
Editor, Materials Newsletter (1978-80)
Member, Committee on Engineering Fundamentals in Life Science, Area 15d/e (1977-)
Member, Committee on Biomaterials, Area 8b (1980-); Chairman (1980-84)
Member, Continuing Education Committee (1986-88)
Organizer, Topical Conference on Biomaterials (1997)
Organizer, Topical Conference on Biomaterials, Drug Delivery and Tissue Engineering (2003)
Organizer, Topical Conference on Medical Engineering, Drug Delivery and Therapeutic Systems (2006)
Nanotechnology Forum (2002-)
Chair, Bionanotechnology Area 22b (2002-05)
Organizer, Topical Conference on Bionanotechnology (2004)
Organizer, Topical Conference on Bionanotechnology (2005)

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American Physical Society (APS)
Fellow (1997)
American Chemical Society (ACS)
Fellow (2011)
Chairman, Program Committee*, *Division of Industrial Engineering Chemistry (1982-84)
Member, Program Committee, Division of IEC (1979-82; 85-89)
Chairman, Organizing Committee of Winter Symposia of IEC (1979-81), Member (1982-85)
Member, Murphree Award Committee (1983-86)
Member, Technical Program Committee, Division of Polymer Chemistry (1980-82)
Member, Education Committee, Division of Polymer Chemistry (1982-86)
Materials Research Society (MRS)
Inaugursal Felow (2008)
Coordinator (1993-97)
Member, External Affairs Committee (1995-98)
American Diabetes Association (ADA)
American Association for the Advancement of Sciences (AAAS)
AAAS Council (2015-16)
Past-Chair, Engineering Section (2015-16)
Chair, Engineering Section (2014-15)
Chair-elect, Engineering Section (2013-14)
Fellow (1999)
American Association of Pharmaceutical Scientists (AAPS)
Member Committee for Selection of Meritorious Manuscript Award (2004-06); ***Chair*** 2005
Fellow (1990)
Review Panel PPD Division (1990-91)
Strategic Alliance/Globalization Committee (1995-02)
Resource Fellow on Controlled Release (1992-02)
Controlled Release Society (CRS)
Fellow (2010)
President (1987-88)
Past President (1988-89)
Board of Trustees (1988-93)
Chairman, By-laws Committee (1988-89)
President-elect (1986-87)
Vice-President (1985-86)
Governor (1984-85)
Organizer, First Workshop and Exhibition of Controlled Release in Consumer Products (1990)
Organizer, Second Workshop and Exhibition of Controlled Release in Consumer Products (1992)
Organizer, Third Workshop and Exhibition on Controlled Release in Consumer Products (1993)
Program Chairman, 20th International Meeting on Controlled Release of Bioactive Materials (1993)
Program Chairman, 12th International Meeting on Controlled Release of Bioactive Materials (1985)
Chairman, Committee on Consumer Products (1990-92)
Member, Strategic Planning Committee (1991-94)
Chairman, Global Network Subcommittee (1993-95, 96-98)
Chairman, Premier Organization Status Subcommittee (1991-92)
Chairman, Heller Award Committee (1997-2000)
Member, Founders Award Committee (1991-97)
Member, Nominating Committee (1991-92)
Member, Awards Committee (1985-87)
Member, Pennwalt Award Committee (1984-85)
Newsletter Editor (1985-86)
Newsletter Columnist (1988-92)
Chairman, Committee (1985-86)
Chairman, Education Committee (1985-86)
Biomedical Engineering Society (BMES)
Member of the Board (2008-11)

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Fellow (2005)
Chairman, Affiliations Committee (2006-08)
Chairman, By-laws Committee (1992-97)
Chair, Fellows Committee (2010-12)
Member, Fellows Committee (2008-12)
Member, Whitaker Awards Committee (1993-95)
Member, Awards Committee (1988-91)

North American Membrane Society (NAMS)

International Union of Societies of Biomaterials Science and Engineering

President (2008-16)

Society for Biomaterials

President (2003-04)
Past President (2004-05)
President-Elect (2002-03)
Chair, Past Presidents Committee (2004-05)
Member SFB Council (2002-05, 2013-14)
Chair, Awards and Nominations Committee (2004-05, 2013-14)
Chair, Meetings Committee (2003-05)
Chair, Long Range Planning Committee (2002-03)
Chair, Liaison Committee (2006-)
Editor-in-Chief, Society for Biomaterials/Wiley Book Series (2009-)
Delegate to International Union of Biomaterials Societies (2006-)
Fellow, International Union of Biomaterials Societies (1993-)
Representative to AIMBE (2004)
Secretary, Executive Committee of Fellows (1997-02)
Chairman, Controlled Release Special Interest Group (1995-97)
Program Chairman, Ophthalmological Biomaterials Special Interest Group (2000-01)
Member, Awards and Nominations Committee (1996-98)
Nominating Committee (1986-88)

Tissue Engineering Society (TERMIS)

American Society for Engineering Education (ASEE)

Fellow (2008)
Westinghouse Award Committee (1993)
Dow Award Committee (2007-09)

New York Academy of Sciences (NYAS)

Society of Plastics Engineers (SPE)

Director, Medical Plastics Division (1980-86)
Member, Program Committee (1984-86)
Member, Technical Volumes Committee (1979-81)
Vice Chairman, National Committee of SPE Student Chapters (1979-80)

Adhesion Society

Sigma Xi

President, Purdue Chapter (1995-96)
Vice President, Purdue Chapter (1994-95)
Past President, Purdue Chapter (1996-97)
Chairman, Awards Committee (1996-97)

Phi Kappa Phi

Council of BME Chairs

Chair (2011-12)
Chair-elect (2010-11)
Past Chair (2012-13)
Nominating Committee (2011-13)
Long Range Planning Committee (2010-13)

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Companies Founded

Mimetic Solutions, Lexington, KY (2006-12)
Appian Laboratories, Austin, TX (2007- 17)
CoraDyn Biosystems, Austin, TX (2007-13)

Advisory Boards

Pharmacontrol Corp., Englewood Cliffs, NJ (1982-86)
Health-Chem Corp., Hercon Div., S. Plainfield, NJ (1984-89)
Cygnus Therapeutic Systems, Redwood City, CA (1986-92)
Enzytech Controlled Therapeutics, Cambridge, MA (1990-92)
Neomorphics, Boston, MA (1991-92)
Cambrex Hydrogels, East Rutherford, NJ (1992-94)
Biogel Technology, Indianapolis, IN (1992-2002)
Advanced Polymer Systems, Menlo Park, CA (1993-2002)
B.F. Goodrich, Brecksville, OH (1996-99)
Mimetic Solutions, Lexington, KY (2006-12)
Appian Laboratories, Austin, TX (2007-17)
CoraDyn Biosystems, Austin, TX (2007-11)
NanoMedical Systems, Austin, TX (2010-11)

Consultant

Panmarine Co., Piraeus, Greece (1974-77)
Rostone Corp., Lafayette, IN (1976-78)
M2M Manufacturing Co., Goshen, IN (1976-79)
American Can Co., Neenah, WI (1977-79)
E.I. duPont de Nemours, Wilmington, DE (1978-80)
Medicornea Inc., Lebanon, IN (1978-84)
Pharmacontrol Corp., *Board of Associates*, Englewood Cliffs, NJ (1982-86)
Zyma S.A., Nyon, Switzerland (1982-84)
Whitbread & Co., Luton, UK (1983-84)
IMC Corp., Terre Haute, IN (1983-87)
Health-Chem Corp., Hercon Div., *Scientific Advisory Board*, S. Plainfield, NJ (1984-89)
Schering Corp., New York, NY (1984-87)
Smith, Kline and French Co., Philadelphia, PA (1985-87)
Interx, Lawrence, KS (1985-87)
Owens-Corning, Conroe, TX (1985-88)
Brown & Williamson Tobacco Corp., Louisville, KY (1986-88)
Cygnus Therapeutic Systems, *Advisory Board*, Redwood City, CA (1986-)
Rhone-Poulenc Co., St. Fons, France (1986-92)
Nova Pharmaceuticals, Baltimore, MD (1987-89)
Athena Neurosciences, Menlo Park, CA (1988-91)
Dow Chemical Co., Midland, MI (1988-93)
Aegis Funds, Lexington, MA (1989-92)
Woodard, Emhardt, Naughton, Moriarty and McNett, Indianapolis, IN (1989-93)
Kaye, Scholer, Fierman, Hays and Handler, New York, NY (1989-91)
Ethyl Corporation, Baton Rouge, LA (1990-91)
C.R. Bard, Tewksbury, MA (1990-91)
Vistakon, Jacksonville, FL (1990-91)
Heritage Research Corporation, Goshen, IN (1990-92)
Enzytech Controlled Therapeutics, *Advisory Board*, Cambridge, MA (1990-92)
Boston Scientific, Spencer, IN (1991-94)

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Neomorphics, *Advisory Board*, Boston, MA (1991-92)
Baker and Botts, Houston, TX (1991-93)
Dowell Schlumberger, Tulsa, OK (1991- 93)
Biogel Technology, Indianapolis, IN (1992-02)
American Cyanamid, Princeton, NJ (1992-95)
Monsanto Agricultural Division, St. Louis, MO (1992-94)
Cambrex, *Advisory Board*, East Rutherford, NJ (1992-95)
Alkermes, Cambridge, MA (1993-94)
Advanced Polymer Systems, *Advisory Board*, Redwood City, CA (1993-2002)
Howmedica, East Rutherford, NJ (1993-95)
Ventritex, Sunnyvale, CA (1995)
ConvaTec, Princeton, NJ (1995)
UroMed, Needham, MA (1995-2001)
Alcon Laboratories, Fort Worth, TX (1996-03)
B.F. Goodrich, Brecksville, OH (1996-2001)
Monsanto/Ceregen, St. Louis, MO (1996)
ALZA Corp., Palo Alto, CA (1996-97)
Mentor Corp., Santa Barbara, CA (1996-2000)
Covington & Burling, Washington, DC (1996-98)
Morris, Nichols, Arsht & Tunnell, Wilmington, DE (1997-2001)
Kellogg, Battle Creek, MI (1998-2000)
Innotech, Newtown, CT (1998-2001)
Oblon, Spivak, McClelland, Maier & Neustadt, Arlington, VA (1998-2001)
Kenyon & Kenyon, Washington, DC (1998-2001)
Welsh & Katz (1999-2003)
Cor Therapeutics, South San Francisco, CA (1999-2002)
Aventis, Frankfurt, Germany (1999-01)
Hopgood, Calimafde, Judlowe and Mondolino, New York, NY (2000-03)
Kirkland and Ellis, New York, NY (2001-)
Patterson, Bellknap, Well and Tyler, New York, NY (2001-05)
Ciba Vision, Duluth, GA (2002-03)
Pennie & Edmonds LLP (2002-03)
Biomade, Groningen, The Netherlands (2002-04)
Schering Plough, Kenilworth, NJ (2003-04)
Amano Enzymes, Elgin, IL (2003-)
Kaye Scholer LLP, New York, NY (2005)
Alkerma, King of Prussia, PA (2006)
Genzyme, Waltham, MA (2007-12)
Mitsubishi Chemical Company (2006-12)
Ciba Vision, Duluth, GA (2010-13)
Millbank, New York, NY (2011-)
Hoffman & Baron, Parsippany, NJ (2013-)
Quinn Emanuel Urquhart & Sullivan, LLP, New York, MY (2016-17)

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International Committees

1. Member of the Program Committee of Area 15e, Engineering Fundamentals in Life Sciences, AIChE, 1977-.
2. Member of the Steering Committee of the AIChE Materials Engineering and Sciences Division, 1978 - 1982 .
3. Member of the Membership Committee (1978-79) and the Technical Program Committee (1977-78, 1981-82) of the Division of Polymer Chemistry of the American Chemical Society.
4. Vice Chairman of the National Committee of SPE Student Chapters, 1979-1980.
5. Member of the Chemical Engineering Education Projects Committee of AIChE, 1979-88.
6. Chairman of the Organizing Committee of the American Chemical Society/ Industrial Engineering Chemistry Division Winter Symposia, 1979-82.
7. Member of the Technical Program Committee of the Division of Industrial and Engineering Chemistry of the American Chemical Society, 1979-86.
8. Technical Program Chairman for the Materials Division Sponsored Symposia at the 87th National AIChE Meeting, Boston, August, 1979.
9. Technical Program Chairman for the Materials Division Sponsored Symposia at the 72nd Annual AIChE Meeting, San Francisco, November, 1979.
10. Director of the Division of Medical Plastics of the Society of Plastic Engineers, 1979-1982; 1983-86.
11. Technical Program Chairman for the Materials Division Sponsored Symposia at the 90th National AIChE Meeting, Houston, March 1981.
12. Technical Program Chairman for the IEC Division sponsored Symposia at the Annual ACS Meeting, New York, August 1981.
13. Member of Awards Committee for the Materials and Polymers AIChE Award, 1981-1983; 1985-88.
14. Director of the Materials Sciences Division of AIChE, 1981-1982; 1984-86.
15. Member of Scientific and Organizing Committee of IUPAC Macromolecules Meeting, Athens, August 1982. Chairman of the "Diffusion in Polymers" Symposia.
16. Chairman of the National Program Committee of the Division of Industrial and Engineering Chemistry of ACS, 1982-84.
17. Member of US Delegation in US-Taiwan Polymer Conference and Working Group, Berkeley, November 1983.
18. Chairman of the New Materials Subcommittee of the Materials Sciences Division of AIChE, 1983-88.
19. Member of Scientific Committee of 2nd International Conference on Polymers in Medicine, Capri, Italy, June 1984.
20. Governor of the Controlled Release Society, 1984-85.
21. Member of the Program Committee of the Medical Plastics Division of SPE, 1984-86.
22. Technical Program Chairman for the Materials Division Sponsored Symposia at the National AIChE Meeting, Houston, March 1985.
23. Vice-President of the Controlled Release Society, 1985-86.
24. Technical Program Chairman and Organizer of the 12th International Conference on Controlled Release of Bioactive Materials, Geneva, July 1985.
25. Technical Program Chairman for the Materials Division Sponsored Symposia of the Annual AIChE Meeting, Boston, August 1986.
26. President-elect of the Controlled Release Society, 1986-87.
27. First Vice Chairman of the Materials Division of AIChE, 1986-88.
28. Technical Program Chairman of the Materials Division of AIChE, 1986-88.
29. Member of the Scientific Committee of the 10th European Society of Biomaterials Meeting, Bologna, September 1986.
30. Organizer and Member of Scientific Committee of Biointeractions '87, Cambridge, England, July 1987.
31. Technical Program Chairman of the Materials Division Sponsored Symposia of the Annual AIChE Meeting, New York, November 1987.
32. Technical Program Chairman of the Materials Division - Sponsored Symposia of the Annual AIChE Meeting, Washington, November 1988.
33. Chairman of the Materials Division of AIChE, 1988-90.

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34. Organizer of Diffusion '89, Parma, Italy, May 1989.
35. Organizing Committee, First European Controlled Release Meeting, Uidschendam, March 1990.
36. Organizing Committee, Fifth International Symposium on Aboveground StorageTanks, Houston, June 1990.
37. President of the Controlled Release Society, 1986-87.
38. Organizing Committee, Fisrt European Controlled Release Meeting, Noordwijk, March 1990
39. Organizer, First Workshop and Exhibition on Controlled Release in Consumer Products, Cincinnati, October 1990.
40. NSF Panel for NSF Fellowships 1990-93.
41. Organizing Committee, Second European Controlled Release Meeting, Noordwijk, March 1992.
42. Organizer, Symposium on Pulsatile Drug Delivery, Köningswinter, May 1992.
43. Organizer, Second Workshop and Exhibition on Controlled Release in Consumer Products, Secaucus, NJ, May 1992.
44. Organizing Committee, Sixth International Symposium on Drug Delivery, Salt Lake City, UT, February 1993.
45. Organizer and Chairman, Symposium on Hydrogels of American Chemical Society, Denver, CO, March 1993.
46. Organizer and Chairman of the 20th International Conference on Controlled Release of Bioactive Materials, Washington, July 1993.
47. Organizer of Biointeractions '93, Leiden, September 1993.
48. Organizer and Chairman, Third Workshop on Controlled Release in Consumer Products, Geneva, October 1993.
49. Organizer and Chairman, Symposium on Biomaterials, Materials Research Society, Boston, November 1993.
50. Organizing Committee, Third European Controlled Release Meeting, March 1994.
51. Organizer, Third Workshop and Exhibition on Controlled Release in Consumer Products, Chicago, IL, September 1994.
52. Organizing Committee, Seventh International Symposium on Drug Delivery, Salt Lake City, UT, February 1995.
53. Organizing Committee, Materials Research Society Meeting, San Francisco, CA, April 1995.
54. International Scientific Board, First World Meeting on Pharmaceutical Technology, Budapest, Hungary, May 1995.
55. Scientific Advisory Board, First Spanish Portuguese Conference on Controlled Drug Delivery, Santiago de Compostela, Spain, September 1995.
56. Organizing Committee, Fourth European Controlled Release Meeting, Noordwijk, March 1996.
56. Organizing Committee, 23rd International Conference on Controlled Release of Bioactive Materials, Kyoto, Japan, July 1996.
57. International Advisory Board, Third Jerusalem Conference on Pharmaceutical Sciences and Clinical Pharmacology, Jerusalem, Israel, September 1996.
58. Organizing Committee, International Pharmaceutical Technology Symposium, Ankara, Turkey, September 1996.
59. Advisory Board, Eighth Panhellenic Pharmaceutical Conference, Athens, Greece, October 1996.
60. International Advisory Board, Third International Symposium on Innovations in Pharmaceutical Sciences and Technology, Ahmedabad, India, February 1997.
61. Organizing Committee, Eighth International Symposium on Drug Delivery, Salt Lake City, UT, February 1997.
62. Program Committee, 23rd Annual Meeting, Society for Biomaterials, New Orleans, LA, April 1997.
63. Scientific Committee, Recent Advances in Drug Delivery Systems and Pharmaceutical Technology, June 1997.
64. Organizing Committee, Fifth European Controlled Release Meeting, Noordwijk, April 1998.
65. International Advisory Board, Second World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Paris, May 1998.
66. International Program Committee, Conference on Challenges for Drug Delivery and Pharmaceutical Technology, Tokyo, June 1998.
67. Organizing Committee, Ninth International Pharmaceutical Technology Symposium, Ankara, Turkey, September 1998.

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68. Organizing Committee, US-Israel NSF Chemical Engineering Workshop, Haifa, Israel, March 1999.
69. Organizing Committee, Ninth International Symposium on Drug Delivery, Salt Lake City, UT, February 1999.
70. Advisory Board, 4th Jerusalem Conference on Pharmaceutical Sciences and Clinical Pharmacology, Jerusalem, Israel, October 1999.
71. Organizing Committee, Symposium on Drug Delivery in the Third Millennium, Pisa, Italy, October 1999.
72. Organizing Committee, 27th International Symposium on Controlled Release of Bioactive Materials, Paris, France, July 2000.
73. Organizing Committee, Sixth European Controlled Release Meeting, Noordwijk, April 2000.
74. Organizing Committee, World Congress of Biomedical Engineering, Chicago, IL, July 2000.
75. Organizing Committee, Tenth International Pharmaceutical Technology Symposium, Ankara, Turkey, September 2000.
76. Scientific Committee, Fourth Spanish-Portuguese Conference on Controlled Drug Delivery, Vittoria, Spain, September 2000.
77. International Scientific Advisory Board, Tenth International Symposium on Recent Advances in Drug Delivery, Salt Lake City, Utah, February 2001.
78. Scientific Committee, Mediterranean Meeting of Chemical Engineering, Ankara, Turkey, May 2001.
79. International Organizing Committee, 28th International Symposium on Controlled Release of Bioactive Materials, San Diego, CA, June 2001.
80. Organizing Committee, 5th International Symposium on Polymer Therapeutics: From Laboratory to Clinical Practice, Cardiff, UK, January 2002.
81. Organizing Committee, Seventh European Controlled Release Meeting, Noordwijk, April 2002.
82. Scientific Committee, Eleventh International Pharmaceutical Technology Symposium, Istanbul, Turkey, September 2002.
83. Organizer, ACS ProSpectives Conference, Boston, MA, October 2002.
84. Scientific Committee, Fifth Spanish-Portuguese Conference on Controlled Drug Delivery, Seville, Spain, November 2002.
85. International Scientific Advisory Board, Eleventh International Symposium on Recent Advances in Drug Delivery, Salt Lake City, Utah, March 2003.
86. Organizing Committee, Eighth European Controlled Release Meeting, Noordwijk, the Netherlands, April 2004.
87. Organizing Committee, European Conference on Drug Delivery and Pharmaceutical Technology, Seville, Spain, May 2004.
88. Organizing Committee, World Congres of Biomaterials Sydney, Australia, April 2004.
89. Scientific Committee, Twelveth International Pharmaceutical Technology Symposium, Istanbul, Turkey, September 2004.
90. Organizing Committee, Conference on Regenerative Medicine, Societyfor Biomaterials, Philadelphia, PA, October 2004.
91. Chair of Organizing Committee, Topical Conference on Advances in Biomaterials, Bionanotechnology, Biomimetic Systems and Tissue Engineering, AIChE Meeting, Austin, TX, November 2004.
92. Organizer, Topical Conference on Bionanotechnology, AIChE Meeting, Austin, TX, November 2004
93. International Scientific Advisory Board, Twelveth International Symposium on Recent Advances in Drug Delivery, Salt Lake City, Utah, February 2005.
94. Organizing Committee, Annual Meeting of the Society for Biomaterials, Memphis, TN, April 2005.
95. Organizer of Symposium on "Nanotechnology and Biomaterials", Society for Biomaterials, Memphis, TN, April 2005.
96. Organizer, Topical Conference on Bionanotechnology, AIChE Meeting, Cincinnati, OH, November 2005
97. Organizing Committee, Houston Society for Engineering in Biology and Medicine, Houston, TX, February 2006.
98. Organizing Committee, Ninth European Controlled Release Meeting, Noordwijk, the Netherlands, April 2006.
99. Scientific Committee, Thirteenth International Pharmaceutical Technology Symposium, Istanbul, Turkey, September 2006.

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100. Organizing Committee, Topical Conference on Bionanotechnology, AIChE Meeting, San Francisco, CA, November 2006
101. Organizer and General Chiarman, US-Japan Joint Topical Conference on Medical Engineering, Drug Delivery and Therapeutic Systems, AIChE Meeting, San Francisco, CA, November 2006
102. International Scientific Advisory Board, Thirteenth International Symposium on Recent Advances in Drug Delivery, Salt Lake City, Utah, February 2007.
103. Scientific Committee, International Meeting of APGI and ADRITELF on Innovation in Drug Delivery, Naples, Italy, September 2007.
104. International Advisory Committee, International Congress on Biohydrogels, Viareggio, Italy, November 2007.
105. Organizer and Chair of the Organizing Committee, 17th Annual Event of the American Institute of Medical and Biological Engineering, Washington, DC, February 2008.
106. Organizing Committee, Tenth European Controlled Release Meeting, Noordwijk, the Netherlands, April 2008.
107. International Scientific Advisory Board, Fourteenth International Symposium on Recent Advances in Drug Delivery, Salt Lake City, Utah, February 2009.
108. Organizing Committee, 18th Annual Event of the American Institute of Medical and Biological Engineering, Washington, DC, February 2009.
109. Advisory Committee, Annual Meeting European Society for Biomaterials, Lausanne, Switzerland, September 2009.
110. Organizing Committee, Eleventh European Controlled Release Meeting, Noordwijk, the Netherlands, April 2010.
111. International Scientific Advisory Board, Fifteenth International Symposium on Recent Advances in Drug Delivery, Salt Lake City, Utah, February 2011.
112. Organizer and Chairman, National Academy of Engineering Meeting, Engineering the Future of Health Care, Austin, TX, April 2011.
113. Organizing Committee, 20th Annual Event of the American Institute of Medical and Biological Engineering, Washington, DC, February 2011.
114. International Scientific Advisory Board, Fifteenth International Symposium on Recent Advances in Drug Delivery, Salt Lake City, Utah, February 2013.
115. International Scientific Advisory Board, 25th European Society for Biomaterials, Madrid, Spain, September 2013.
116. Organizing Committee, Workshop on Key Challenges in the Implementation of Convergence, National Research Council, Washington, DC, Fenruary 2013.
117. International Scientific Advisory Board, 10th Spanish-Portuguese Conference on Controlled Drug Delivery, Valencia, Spain, November 2013.
118. Organizer, “Integrated Cellular Systems: Building Machines with Cells”, AAAS meeting, Chicago, IL, February 2014.
119. Co-organizer, TAMEST meeting on the Future of Materials Science, Dallas, TX, January 2016.
120. Organizing Committee, “Frontiers in Materials Science”, Sichuan University, Chengdu, China, September 2016.
121. Organizing Committee, “International Symposium on Clinical Translational Medicine”, Shanghai, China, September 2016.
122. Organizing Committee, European Society for Biomaterials Meeting, Athens, Greece, September 2017.

Chair of Symposia

1. Chairman of Session, Symposium on "Chemistry and Properties of Crosslinked Polymers," ACS Meeting, San Francisco, September 1976.
2. Chairman, Symposium on "Mass Transfer in Biological Systems," AIChE Meeting, New York, November 1977.
3. Moderator, Symposium on "Biomedical Applications of Polymers," Society of Plastics Engineers Meeting, Denver, November 1977.
4. Chairman, Symposium on "Multicomponent Polymer Systems," ACS Meeting, Anaheim, March 1978.

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5. Co-Chairman, Symposium on "Heat Transfer and Thermal Regulation in Living Systems," AIChE Meeting, Miami, November 1978.
6. Chairman, Symposium on "Structure-Property Relationships in Polymeric Networks" Parts I and II, AIChE Meeting, Boston, August 1979.
7. Co-Chairman, Symposium on "Structural Influences on the Deformation Behavior of Polymeric Solids and Melts," Part II, AIChE Meeting, Boston, August 1979.
8. Chairman, Symposium on "Food Packaging Materials and Their Properties," AIChE Meeting, Boston, August 1979.
9. Chairman, Symposium on "Transport Phenomena in Artificial Organs," AIChE Meeting, San Francisco, November 1979.
10. Co-Organizer of the 1980 Winter Symposium of ACS/IEC on "Applications of Molecular Models of Polymer Dynamics".
11. Organizer and Chairman, Symposium on "Undergraduate Research in Chemical Engineering," ASEE Meeting, Amherst, MA, June 1980.
12. Organizer and Member of the Advisory Committee of 1980 IUPAC Symposium on "Interrelations between Processing, Structure and Properties of Polymeric Materials," August 1980, Athens, Greece.
13. Chairman of Session on "Theoretical Rheology," 8th International Congress of Rheology, September 1980, Naples, Italy.
14. Chairman, Symposium on "Morphology, Structure and Interactions of Biomaterials," Part I-IV, AIChE Meeting, Chicago, November 1980.
15. Chairman, Symposium on "Diffusional and Relaxational Phenomena in Glassy Polymers," AIChE Meeting, Houston, March 1981.
16. Chairman of Session, 28th International IUPAC Meeting on Macromolecules, Strasbourg, France, July 1981.
17. Chairman, Symposium on "Engineering Approaches to Diabetes," AIChE Meeting, New Orleans, November 1981.
18. Chairman of Session, International Meeting of Membranes and Membrane Processes, Perugia, Italy, May 1982.
19. Member of the Organizing Committee and Chairman of Sessions on "Diffusion in Polymers," IUPAC Meeting on Macromolecules, Athens, Greece, August 1982.
20. Chairman, Symposium on "Diffusion in Polymers," Parts I and II, AIChE Meeting, Los Angeles, November 1982.
21. Vice-Chairman, Symposium on "Biomedical Transport Phenomena III - Membranes," AIChE Meeting, Los Angeles, November 1982.
22. Chairman of Session, International Symposium on Recent Advances in Drug Delivery Systems, Park City, Utah, March 1983.
23. Chairman of AX□ Symposium in honor of E. W. Merrill, AIChE Meeting, Washington, D.C., November 1983.
24. Chairman of Session, Biointeractions 1984, London, England, January 1984.
25. Chairman of Session, Conference on Macromolecules as Drugs and as Carriers for Biologically Active Materials, New York Academy of Sciences, New York, March 1984.
26. Chairman of Session, Second World Congress of Biomaterials, Washington, D.C., May 1984.
27. Chairman of Session, 11th International Conference of Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 1984.
28. Chairman of Session, 9th International Conference on Rheology, Acapulco, Mexico, October 1984.
29. Chairman of Symposium "Characterization of Macromolecular Structures in Coals," ACS Meeting, Miami Beach, April 1985.
30. Chairman of Session, Symposium on Properties of Polymers and Drug Delivery, Swedish Academy of Pharmaceutical Sciences, Stockholm, Sweden, May 1985.
31. Member of the Organizing Committee, 2nd International Conference of Polymers in Medicine, Capri, Italy, June 3-7, 1985.
32. Technical Chairman and Organizer, 12th International Symposium on Controlled Release of Bioactive Materials, Controlled Release Society, Geneva, Switzerland, July 1985.
33. Chairman of Symposium on "Surface, Interfacial and Molecular Aspects of Polymer Bioadhesion on Soft Tissues," ACS Meeting, Chicago, September 1985.

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34. Chairman of Symposium on "Morphology, Structure and Interactions of Biomaterials," Parts I, II, III and IV, AIChE Meeting, Chicago, November 1985.
35. Chairman of Symposium on "Controlled Release," International Biomedical Engineering Symposium, Salt Lake City, January 1986.
36. Chairman of Session on "Formes Nouvelles," Fourth International Conference on Pharmaceutical Technology, Paris, France, June 1986.
37. Chairman of Session on "Oral Systems," 13th International Conference of Controlled Release of Bioactive Materials, Norfolk, Virginia, August 1986.
38. Chairman of Session, 3rd International Pharmaceutical Technology Symposium, Ankara, Turkey, September 1986.
39. Chairman, APGI Workshop on Matrix Systems, Paris, France, December 1986.
40. Chairman of Session on "Blood Compatibility," Biointeractions '87, Cambridge, United Kingdom, July 1987.
41. Chairman of Session on "Fundamentals," 14th International Conference on Controlled Release of Bioactive Materials, Toronto, Canada, August 1987.
42. Chairman of Symposium on "Diffusion in Polymers," Parts I, II and III, AIChE Meeting, New York, November 1987.
43. Chairman of Symposium on "Polymers in Microlithography," AIChE Meeting, New York, November 1987.
44. Chairman of Session, 15th International Conference on Controlled Release of Bioactive Materials, Basle, Switzerland, August 1988.
45. Chairman of Symposium on "Polymer Gels," AIChE Meeting, Washington, DC, November 1988.
46. Chairman of Session on "Drug Targeting," International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, Utah, February 1989.
47. Organizer and Chairman of International Symposium "Diffusion '89: The Theory and Applications of Diffusion in Biomedical, Pharmaceutical and Food Sciences," Parma, Italy, May 1989.
48. Chairman of Session on "Bioadhesive Applications," International CRS/APV Workshop on Bioadhesion-Possibilities and Future Trends, Leiden, The Netherlands, May 1989.
49. Chairman of Session on "Novel Formulations," Fifth International Conference on Pharmaceutical Technology, Paris, France, May 1989.
50. Chairman of Session on "Modelling," 16th International Conference on Controlled Release of Bioactive Materials, Chicago, Illinois, August 1989.
51. Organizer and Chairman of Symposium on "Biomaterials," AIChE Meeting, San Francisco, California, November 1989.
52. Chairman of Symposium on "Polymers in Microlithography," AIChE Meeting, San Francisco, California, November 1989.
53. Organizer and Chairman of Symposium on "Polymers as Biomaterials," ACS Meeting, Boston, Massachusetts, April 1990.
54. Organizer and Chairman of First International Workshop and Exhibition on Controlled Release in Consumer Products, Cincinnati, Ohio, October 1990.
55. Chairman of Session on "Biomaterials," USA-Czechoslovak Academy of Sciences Symposium on Novel Polymers, Prague, Czechoslovakia, December 1990.
56. Chairman of Session on "Triggered and Modulated Drug Delivery Systems," Fifth International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, Utah, February 1991.
57. Chairman of Session on "Hydrogels," 18th International Conference on Controlled Release of Bioactive Materials, Chicago, Illinois, July 1991.
58. Organizer and Chairman of Symposium on "Structure and Properties of Biomaterials," AIChE Meeting, Los Angeles, California, November 1991.
59. Organizer and Chairman of Symposium on "Diffusion in Polymers," AIChE Meeting, Los Angeles, California, November 1991.
60. Organizer and Chairman of Symposium on "Polymers as Biomaterials," ACS Meeting, San Francisco, California, April 1992.
61. Organizer and Chairman of Second International Workshop and Exhibition on Controlled Release in Consumer Products, Secaucus, New Jersey, May 1992.
62. Organizer and Chairman of Workshop on Pulsatile Drug Delivery Systems, Königswinter, Germany, May 1992.

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63. Chairman of Symposium on "Bioadhesion" of Second Jerusalem Meeting on Pharmaceutical Sciences and Clinical Pharmacology, Jerusalem, Israel, May 1992.
64. Organizer and Chairman of Symposium on "Bioadhesives," AIChE Meeting, Miami Beach, FL, November 1992.
65. Organizer and Chairman of "Polymers in Pharmaceutics," AAPS Meeting, San Antonio, TX, November 1992.
66. Chairman of Session on "Hydrogels," International Meeting on Prospectives of Biomaterials, Kaanapali, Hawaii, December 1992.
67. Organizer and Chairman of "Preparation and Characterization of Hydrogels," ACS Meeting, Denver, CO, March 1993.
68. Organizer and Chairman of the 20th International Symposium on Controlled Release of Bioactive Agents, Washington, DC, July 1993. Chairman of three sessions.
69. Organizer and Chairman of Symposium on "Superabsorbent Polymers," ACS Meeting, Chicago, IL, August 1993.
70. Chairman of Symposium on "Ophthalmic Applications of Polymers and Pharmaceuticals," ACS Meeting, Chicago, IL, August 1993.
71. Organizer of Biointeractions '93, Leiden, the Netherlands, August 1993.
72. Organizer and Chairman of Third International Workshop and Exhibition on Controlled Release in Consumer Products, Geneva, Switzerland, October 1993.
73. Organizer and Chairman of Symposium on "Poly(ethylene oxide) and Other Hydrogels," AIChE Meeting, St. Louis, MO, November 1993.
74. Organizer and Chairman of Symposium on "Biomaterials for Drug and Cell Delivery," MRS Meeting, Boston, MA, December 1993.
75. Chairman of Symposium, Second US-Japan Meeting on Drug Delivery, Maui, HI, December 1993.
76. Chairman of Session on "Controlled Release," 20th Annual Meeting of the Society for Biomaterials, Boston, MA, April 1994.
77. Chairman of Session on "Drug Delivery," 11th Congress of the International Society for Artificial Cells, Blood Substitutes and Immobilization Biotechnology, `Boston, MA, July 1994.
78. Chairman of Session on "Hydrogels," Society for Biomaterials Meeting, San Francisco, CA, March 1995.
79. Organizer and Chairman of Symposium on "Polymer/Inorganic Interfaces," Materials Research Society Meeting, San Francisco, CA, April 1995.
80. Chairman of Session on "Biomedical Polymers," Kagoshima, Japan, April 1995.
81. Chairman of Session on "Microparticles," World Conference on Pharmaceutical Technology, Budapest, Hungary, May 1995.
82. Chairman of Session on "Oral Delivery," First Spanish Portuguese Conference on Controlled Drug Delivery, Santiago de Compostela, Spain, September 1995.
83. Organizer and Chairman of Sessions on "Diffusion in Polymers," AIChE Meeting, Miami Beach, FL, November 1995.
84. Chairman of Session on "Drug Delivery," World Congress of Biomaterials, Toronto, Ontario, May 1996.
85. Chairman of Session on "Hydrogels," 23rd International Conference on Controlled Release of Bioactive Materials, Kyoto, Japan, July 1996.
86. Chairman of Session on "Biomedical Applications of Polymers," AIChE Meeting, Chicago, IL, November 1996.
87. Chairman of Session on "Cellular Interactions of Biomaterials," AIChE Meeting, Chicago, IL, November 1996.
88. Organizer and Chairman of Symposium on "New Biomaterials for Drug Delivery Applications," Society for Biomaterials Meeting, New Orleans, LA, April 1997.
89. Organizer and General Chairman of Topical Conference on “Biomaterials, Carriers for Drug Delivery and Scaffolds for Tissue Engineering,” AIChE Meeting, Los Angeles, CA, November 1997.
90. Chairman of Session on “Drug Delivery,” 4th US-Japan CRS Meeting, Kauai, HI, December 1997.
91. Chairman of Session on “Drug Delivery,” 24th Annual Meeting of the Society for Biomaterials, San Diego, CA, April 1998.
92. Chairman of Session on “Biofunctional Polymers in Drug Delivery,” Conference on Challenges for Drug Delivery and Pharmaceutical Technology, Tokyo, Japan, June 1998.

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93. Chairman of Session on "Drug Delivery," 9th International Pharmaceutical Technology Symposium, Ankara, Turkey, September 1998.
94. Chairman of Session, US-Turkey-Israel Conference on Chemical Engineering, Haifa, Israel, March 1999.
95. Chairman of Symposium on "Synthesis and Characterization of Polymers for Biomaterials and Drug Delivery Carriers," ACS Meeting, Anaheim, CA, March 1999.
96. Chairman of Symposium on "Drug Delivery in the Third Millennium," Pisa, Italy, October 1999.
97. Chairman of Sessions on "Drug Delivery," World Congress of Biomedical Engineering, Chicago, IL, July 2000.
98. Chairman of Session on "Chemical Engineering in Medicine and Biology: Forty Years of Successes," AIChE Meeting, Los Angeles, CA, November 2000.
99. Chairman of Session on "Polymer Design and Drug Delivery," Meeting on New Trends in Polymers for Oral and Parenteral Administration, APGI/GRTV, Paris, France, March 2001.
100. Chairman of Session on "Ophthalmological Biomaterials," Society for Biomaterials meeting, St. Paul, MN, April 2001.
101. Chairman of Session on "Oral Delivery," 6th US-Japan Symposium on Drug Delivery Systems, Lahaina, Maui, HI, December 2001.
102. Chairman of Sessions on "Biomimetic Materials," Society for Biomaterials Meeting, Tampa, FL, April 2002.
103. Chairman of Session on "Biomaterials," ACS Prospectives Meeting, Boston, MA, October 2002.
104. Chairman of Symposium on "Bionanotechnology," AIChE Meeting, Indianapolis, IN, November 2002.
105. Chairman of Symposium on "Nanotechnology in Drug Delivery", BioMEMS and NanoTech World meeting, Washington, DC, August 2003.
106. Chairman of Symposium on "Bionanotechnology," AIChE Meeting, San Francisco, CA, November 2003.
107. Chairman of Symposium on "Intelligent Biomaterials", European Materials Research Society, Warsaw, Poland, September 2004.
108. Chairman of Plenary Session of Meeting on "Biomaterials in Regenerative Medicine: the Advent of Combination Products", Society for Biomaterials, Philadelphia, PA, October 2004.
109. Chairman of Plenary Session on "Advances in Biomaterials, Bionanotechnology, Biomimetic Systems and Tissue Engineering": AIChE Meeting, Austin, TX, November 2004.
110. Chairman of Symposium on "Nanobiotechnology", AIChE Meeting, Austin, TX, November 2004.
111. Chairman of Symposium on "Transport of Biomaterial/Bionanotech Devices Through Biological Barriers", AIChE Meeting, Austin, TX, November 2004.
112. Organizer and Chairman, Symposium on "Bionanotechnology" on Topical Conference on Bionanotechnology, AIChE Meeting, Austin, TX, November 2004
113. Chairman of Symposium on "Nanotechnology and Biomaterials", Society for Biomaterials, Memphis, TN, April 2005.
114. Chairman of Symposium on "Polymer Gels", European Polymer Congress, Moscow, Russia, June 2005.
115. Chairman of Symposium on "Biomaterials", Houston Society for Engineering in Biology and Medicine, Houston, TX, February 2006
116. Chairman of Plenary Session of "US-Japan Joint Topical Conference on Medical Engineering, Drug Delivery Systems and Therapeutic Systems", AIChE Meeting, San Francisco, CA, November 2006.
117. Chairman of Symposium on the 65th Birthday of Prof. Clark Colton, AIChE Meeting, San Francisco, CA, November 2006.
118. Chairman, Symposium on "Bionanotechnology" of the Conference on Bionanotechnology, AIChE Meeting, Austin, TX, November 2007
119. Chairman of Symposium at the 9th US-Japan Symposium on Drug Delivery Systems, Lahaina, HI, December 2007.
120. Chairman of Symposium on "Novel Chemistry" of the Fourteenth International Symposium on Recent Advances in Drug Delivery, Salt Lake City, Utah, February 2009.
121. Chair, Symposium on Translation of Knowledge, 18th Annual Event of the American Institute of Medical and Biological Engineering, Washington, DC, February 2009.

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122. Chaiman of Symposium on Hydrogels, Fifteenth International Symposium on Recent Advances in Drug Delivery, Salt Lake City, Utah, February 2011
123. Chairman, National Academy of Engineering Meeting, Engineering the Future of Health Care, Austin, TX, April 2011
124. Chairman, Session at the 10th US-Japan Symposium on Drug Delivery Systems, Lahaina, HI, December 2011.
125. Chairman, Symposium on "Innovations in Medical and Biological Engineering", Annual Meeting of the American Institute of Medical and Biological Engineering, Washington, DC, February 20, 2012.
126. Chairman, Symposium, Workshop on Key Challenges in the Implementation of Convergence, National Research Council, Washington, DC, Fenruary 16, 2013.
127. Chairman, Session at the 12th US-Japan Symposium on Drug Delivery Systems, Lahaina, HI, December 2013.
128. Chairman, Symposium on "Integrated Cellular Systems: Building Machines with Cells", Annual AAAS meeting, Chicago, IL, February 2014.
129. Chairman, Symposium on "Drug Delivery", European Society for Biomaterials meeting, Krakow, Poland, September 2015.
130. Chairman, Session at the 13th US-Japan Symposium on Drug Delivery Systems, Lahaina, HI, December 2015.
131. Chairman, Symposium on "Biomaterials", Annual TAMEST meeting, Dallas, TX, 2016.
132. Chairman, Symposium on the "Future of Biomaterials", European Society for Biomaterials meeting, Athens, Greece, 2017.
133. Chairman, Session at the 14th US-Japan Symposium on Drug Delivery Systems, Lahaina, HI, December 2017.

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Federal Review Panels

1. National Institutes of Health, Biomedical Engineering Centers, October 1977.
2. National Institutes of Health, Arteriosclerosis Centers, April 1981.
3. National Science Foundation, Bureau of Engraving and Printing Panel, October 1987.
4. National Institutes of Health, Surgery & Bioengineering, Study Section, 1987-88.
5. National Institutes of Health, Surgery & Bioengineering Study Section, 1990-91.
6. National Institutes of Health, Surgery, Anesthesiology and Trauma Panel, August 1991.
7. National Institutes of Health, Small Business Administration, 1992-93.
8. National Science Foundation Fellowships, February 1992.
9. National Science Foundation Fellowships, February 1993.
10. National Science Foundation Fellowships, February 1995.
11. National Science Foundation, Technology for a Sustainable Environmental Panel, June 1995.
12. National Institutes of Health, SBIR Review Board, March 1996.
13. National Institutes of Health, SBIR Review Board, October 1998.
14. National Science Foundation, IGERT Program, June 1999.
15. National Institutes of Health, Surgery & Bioengineering Study Section, June 1999.
16. Nanotechnology Technical Advisory Group to the President's Council of Advisors on Science and Technology, 2003-06
17. National Research Council Committee on “International Benchmarking of US Chemical Engineering Research Competitiveness”, 2006-07.
18. National Institutes of Health, Challenge Grants, 2009
19. National Research Council, Key Challenges in the Implementation of Convergence, Washington, DC, February, 2013.
20. National Science Foundation Fellowships, Fall, 2015, Fall 2016, Fall 2017.

Reviewer of proposals for Research Foundations in Austria, Belgium, Germany, Japan, Portugal, Russia, Singapore, Spain, Switzerland, UK.

Participant or panelist in numerous NSF, NIH and DOE panels for review of proposals, definition of research directions and other subjects

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Lecturer

Lecturer of an one-week industrial course (20.02s) on "Controlled Release Technology" at M.I.T. (August 1980, August 1981, August 1982, July 1983, July 1984, July 1985, July 1986, July 1986, July1987, June 1988, July 1989, June 1990, July 1991, August 1992, June 1993, July 1994, July 1995, June 1996; July 1997; July 1998; July 1999; June 2000; June 2001; June 2002; June 2003; July 2004; July 2005; July 2006; July 2007; June 2008; July 2009; July 2010; July 2011; July 2012; July 2013; July 2014; June 2015; June 2016; July 2017); in Brussels, Belgium (May 1983); in Vienna, Austria (June 1984); in Paris, France (April 1986); in Copenhagen, Denmark (June 1988).

Lecturer of the industrial course on "Structure and Properties of Polymeric Materials" at Purdue (August1984, June 1985, December 1985, May 1986, May 1987, April 1988, July 1989, April 1990, May 1991); in Indianapolis (June 1992); in Geneva, Switzerland (May 1987); in Pavia, Italy (May 1988); in Parma, Italy (October 1993).

Lecturer of the Industrial Course on "Hydrogels in Biomedical and Pharmaceutical Applications" in Indianapolis (April 1991); at Purdue (May 1992).

Lecturer of Controlled Release Society workshop at Ft. Lauderdale (July 1984), Toronto (August 1987).

Lecturer of Controlled Release Society workshop on Consumer Products at Cincinnati (October 1990).

Lecturer of Controlled Release Society workshop on Biomaterials at West Palm Beach (January 1992).

Lecturer of Controlled Release Society workshop on Consumer Products at Secaucus, NJ (May 1992).

Lecturer of Controlled Release Society workshop on Consumer Products at Geneva, Switzerland (October 1993).

Lecturer of Controlled Release Society workshop on Consumer Products at Chicago, IL (September 1994).

Lecturer of Controlled Release Society workshop on Development of Hydrogel Dosage Forms at Kyoto, Japan (July 1996).

Lecturer of Controlled Release Society workshop on Protein/Peptide Controlled-Release Delivery at Baltimore (August 1996).

Lecturer in Advanced Tissue Engineering course, Rice University, Houston, TX (August 2007).

Lecturer of Biomedical Nanotechnology Course, Tecnologico de Monterrey, Monterrey, Mexico (October 2008).

Lecturer of Controlled Release workshop, Kimberly Clark, Neenah, WI (October 2012).

Lecturer on workshop Fundamentals and Applications of Controlled Release and Dug Delivery, University of Belgrade, Belgrade, Serbia (May 2013).

Teaching at the University of Texas

ChE 379/384 (U/G): "Polymerization Kinetics and Reaction Engineering," Spring 2003.
ChE 384 (G): “Topics in Polymer Science and Engineering,” Summer 2003 (a few lectures).
BME 385J (G): “Fields, Forces and Flows in Cellular and Physiological Systems”, Fall 2003.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2003.
ChE 387M (G): “Mass Transfer”, Spring 2004.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2004.
BME 385J.34 (G): “Advances in Biomaterials Science and Engineering”, Fall 2004.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2004.
ChE 322 (U): “Chemical Engineering Thermodynamics”, Spring 2005.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2005.
BME 380J.2 (G): “Quantitative Physiology”, Fall 2005.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2005.
ChE 372 (U): “Kinetics and Reaction Engineering”, Spring 2006.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2006.
BME 385J.34 (G): “Advances in Biomaterials Science and Engineering”, Fall 2006.
ChE 372 (U): “Kinetics and Reaction Engineering”, Spring 2007.
ChE 384 (G): "Polymerization Kinetics and Reaction Engineering", Spring 2007.
ChE 355 (U): “Introduction to Polymer Science”, Fall 2007.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2007.
BME 385J (G) and ChE 384 (G): “Bionanotechnology”, Spring 2008.

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ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2008.
ChE 355 (U): “Introduction to Polymer Science”, Fall 2008.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2008.
BME 382J.4 (G): “Advances in Biomaterials Science and Engineering”, Spring 2009.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2009.
ChE 355 (U): “Introduction to Polymer Science”, Fall 2009.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2009.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2010.
BME 382J.4 and ChE 384 (G): “Advances in Biomaterials Science and Engineering”, Fall 2010
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2010.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2011.
BME 382J.4 and ChE 384 (G): “Advances in Biomaterials Science and Engineering”, Fall 2011
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2011.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2012.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2012.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2013.
BME 385J and ChE 384 (G): “Fields, Forces and Flows in Cellular and Physiological Systems”, Fall 2013.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2013.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2014.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2014.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2015.
ChE 384 (G): “Advances in Biomedical Engineering”, Fall 2015.
ChE 379/384 (U/G): "Polymerization Kinetics and Reaction Engineering," Spring 2016.
ChE 384 (G): “Advances in Biomedical Engineering”, Spring 2016.
BME 382J/ChE 384T (G): “Advances in Biomaterials Science and Engineering”, Fall 2016.
ChE 372 (U): “Kinetics and Reaction Engineering”, Spring 2017.
BME 380J4/ChE 384T (G): “Fields, Forces and Flows in Cellular and Physiological Systems”, Fall 2017.
ChE 355 (U)/CH 367L(U)/ChE392P:“Introduction to Polymer Science”, Spring 2018; also as graduate course.

At UT, Peppas designed and taught eight new courses ChE 379/384, ChE 387M, ChE 322, ChE 372, BME 385J, BME 385J.34, BME 380J.2, ChE 355 and 385J. Of these five are new courses not previously offered at UT (ChE 379/384, BME 385J, BME 385J.34, BME 380J.2 and 385J).

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Teaching at Purdue University

ChE 542 (U/G): "Chemistry and Engineering of High Polymers," Spring, 1977.
ChE 624 (G): "Mass Transfer," Fall 1977.
ChE 529 (U/G): "Advanced Chemical Processes," Spring 1978.
ChE 544: "Structure and Properties of Polymeric Materials," Spring 1978.
ChE 311 (U): "Introductory Chemical Engineering Thermodynamics," Fall 1978.
ChE 529 (U/G): "Advanced Chemical Processes," Spring 1979.
ChE 543 (U/G): "Polymerization Reaction Engineering," Fall 1979.
ChE 597H (U/G): "Biomedical Engineering," Fall 1979.
ChE 544 (U/G): "Structure and Properties of Polymeric Materials," Spring 1980.
ChE 439 (U): "Reaction Kinetics and Chemical Equilibrium," Fall, 1980.
ChE 597N (U/G): "Mechanical Behavior and Processing of Polymer Solids and Fluids," Spring 1981.
ChE 624 (G): "Mass Transfer," Fall 1981.
ChE 561 (U/G): "Biomedical Engineering," Fall 1977, Fall 1978, Fall 1980, Fall 1981, Fall 1983, Fall 1984.
ChE 544 (U/G): "Structure and Properties of Polymeric Materials," Spring 1982.
ChE 697M (G): "Biomedical Phenomena," Spring 1982.
ChE 624 (G): "Mass Transfer," Fall 1983.
ChE 544 (U/G): "Structure and Properties of Polymeric Materials," Spring 1984.
ChE 697Y (G): "Macromolecular Analysis in Chemical Engineering Science," Spring 1984.
ChE 378 (U): "Heat and Mass Transfer," Fall 1984.
ChE 529 (U/G): "Advanced Chemical Processes," Spring 1985
ChE 543 (U/G): "Polymerization Reaction Engineering," Fall 1985.
ChE 697Y (G): "Macromolecular Analysis in Chemical Engineering Science," Spring 1986.
ChE 450 (U): "Design and Analysis of Processing Systems," Spring 1986.
ChE 544 (U/G): "Structure and Properties of Polymeric Materials," Spring 1987.
ChE 306 (U): "Design of Staged Separation Processes," Fall 1987.
ChE 697Y (G): "Macromolecular Analysis in Chemical Engineering Science," Spring 1988.
ChE 610 (G): "Thermodynamics," Fall 1988.
ChE 348 (U): "Reaction Kinetics and Chemical Equilibrium," Spring 1989.
ChE 378 (U): "Heat and Mass Transfer," Fall 1989.
ChE 450 (U): "Design and Analysis of Processing Systems," Spring 1990.
ChE 543 (U/G): "Polymerization Reaction Engineering," Fall 1990.
ChE 544 (U/G): "Structure and Properties of Polymeric Materials," Spring 1991.
ChE 697M (G): "Biomedical Phenomena," Spring 1991.
ChE 348 (U): "Reaction Kinetics and Chemical Equilibrium," Fall 1991.
ChE 697Y (G): "Macromolecular Analysis in Chemical Engineering Science," Spring 1992.
ChE 348 (U): "Reaction Kinetics and Chemical Equilibrium," Fall 1992.
ChE 697Z (G): "Fundamentals of Controlled Release and Pharmaceutical Engineering," Spring 1993.
ChE 597H (U): "Honors Seminar," Spring 1993.
ChE 544 (U/G): "Structure and Properties of Polymeric Materials," Fall 1993.
ChE 597H (U): "Honors Seminar," Fall 1993.
ChE 348 (U): "Reaction Kinetics and Chemical Equilibrium," Fall 1994.
ChE 597H (U): "Honors Seminar," Fall 1994.
ChE 543 (U/G): "Polymerization Reaction Engineering," Spring 1995.
ChE 597H (U): "Honors Seminar," Spring 1995.
ChE 544(U/G): "Structure and Properties of Polymeric Materials," Fall 1995
ChE 597H (U): "Honors Seminar," Fall 1995.
ChE 697M (G): "Biomedical Phenomena," Spring 1996.
ChE 610 (G): "Thermodynamics," Fall 1996.
ChE 597H (U): "Honors Seminar," Fall 1996.
BME 601(G): "Principles of Biomedical Engineering I," Fall 1996.
ChE 660 (G): "Kinetics and Reaction Engineering," Spring 1997.
ChE 644 (G): "Macromolecular Analysis," Fall 1997
BME 602(G): "Principles of Biomedical Engineering II," Spring 1998.

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ChE 660 (G): “Kinetics and Reaction Engineering,” Spring 1998.
ChE 610 (G): “Thermodynamics,” Fall 1998.
ChE 697A (G): “Polymer Science and Engineering,” Fall 1998.
ChE 348 (U): “Reaction Kinetics and Chemical Equilibrium,” Spring 1999
ChE 544 (U/G): “Structure and Properties of Polymeric Materials,” Fall 1999
ChE 697C (G): “Biomaterials Science and Engineering,” Fall 1999.
ChE 658 (G): “Biomedical Phenomena,” Spring 2000.
ChE 378 (U): “Heat and Mass Transfer,” Fall 2000.
ChE 306 (U): “Design of Staged Separation Processes,” Fall 2001.
BME 695T (G): “Biomaterials Science and Engineering,” Fall 2001.
BME 696I (G): “IGERT Seminar,” Fall 2001.
ChE 543 (U/G): “Polymerization Reaction Engineering,” Spring 2002.
BME 696I (G): “IGERT Seminar,” Spring 2002.
ChE 544 (U/G): “Structure and Properties of Polymeric Materials,” Fall 2002.

At Purdue Peppas designed and taught sixteen new courses not previously given there (ChE 303, ChE 543, ChE 544, ChE 597H, ChE 597N, ChE 644, ChE 658, ChE 644, ChE 658, ChE 697A, ChE 697C, ChE 697D, ChE 697M, ChE 697Y, BME 601, BME 602 and BME 696I). In addition, he modified extensively courses ChE 529 and ChE 624. He has taught, ChE 306 (2 times), 311(1), 378 (3), 348 (6), 450 (2), 529 (3), 542 (1), 543 (5), 544 (9), 597H (7), 597N (1), 610 (3), 624 (3), 644 (1), 658 (1), 660 (2), 697A (1), 697C (1), 697M (3), 697Y (4), 697Z (1), and BME 601 (1), 602 (1), 695T (1), 696I (2).

"Fundamentals of Polymer Science: Macromolecular Chemistry and Physics," Fall 1982. Course taught at Faculty of Sciences, University of Geneva, Switzerland.

"Advances in Polymer Science," Spring 1983. Series of 20 lectures given at the Department of Chemical Engineering, California Institute of Technology, Pasadena, California.

"Mathematical and Molecular Analysis of Diffusion in Polymers," Fall 1986. Series of 9 lectures given at the Department of Pharmacy, University of Paris-Sud, Châtenay-Malabry, France.

"Diffusion Theory," December 1986. Series of 16 lectures given at the Department of Chemical Engineering, Hacettepe University, Ankara, Turkey.

"Structure Properties and Applications of Polymeric Materials in Pharmaceutical Technology," May 1988 and October 1993. Series of 12 lectures given at the Faculty of Pharmacy, University of Parma, Parma, Italy.

Series of lectures given at the Faculty of Pharmacy, Hoshi University, Tokyo, Japan, Spring 1994.

"Diffusion in Polymers," May 1996. Series of 5 lectures given at the Department of Materials Science, University of Naples, Naples, Italy.

"Use of Hydrogels in Drug Delivery," May 1996. Series of 8 lectures at the Department of Pharmacy, University of Naples, Naples, Italy.

“Controlled Release Technology,” January and May 2001. Series of 10 lectures at the Department of Pharmacy, Free University of Berlin, Berlin, Germany.

“Controlled Release Technology: Recent Advances in Carrier Selection, Formulation, Release Modelling, Cellular and in Vivo Behavior,” March 2001. Series of 8 lectures at the School of Pharmacy, Complutense University, Madrid, Spain.

Series of six lectures at the Department of Materials Science, Nanyang Technological University, Singapore.

Lecture on “Molecularly-Imprinted Matrices and Scaffolds for Tissue Engineering” in Advanced Tissue Engineering course, Rice University, 2007.

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"Fundamentals and Applications of Controlled Release and Dug Delivery", May 2013. Series of 7 lectures at the School of Pharmacy, University of Belgrade, Belgrade, Serbia.

"Fundamentals and Applications of Biopolymers in Medical Applications and Drug Delivery". March 22-26, 2015. Series of 12 lectures at Sichuan University, Chengdu, China,

"Fundamentals and Applications of Biopolymers in Medical Applications". September 16, 2017. Series of 6 lectures at Sichuan University, Chengdu, China,

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Service at the University of Texas

1. Evolution of ChE Committee, Chair, Chemical Engineering, 2003-04.
2. Review of Curriculum Committee, Chemical Engineering, 2003-05.
3. Graduate Committee, Biomedical Engineering, 2003-09.
4. Accreditation and Assessment Committee, College of Engineering, 2003-05.
5. Degrees and Courses Committee, College of Engineering, 2003-04.
6. Executive Committee, Biomedical Engineering, 2003-05.
7. Undergraduate Curriculum Committee, Biomedical Engineering, 2003-05.
8. Intellectual Property Committee, University, 2003-09.
9. Awards Committee, Biomedical Engineering, Chair, 2004- .
10. Awards Committee, Chemical Engineering, 2003- .
11. Research Excellence Awards Committee, University-wide, 2004- .
12. Various Qualifying Examination Committees, Chemical Engineering, since 2003.
13. Chair, Area 2, Health Care, Startegic Plan, School of Engineering, 2009- .
14. Chair, BME-Law School Committee, 2010- .
15. Chair, Recruiting Committee, Biomedical Engineering, 2010- .
16. Various Medical School Committes, 2013- .
17. Chair, Engineering-wide Medical School Committee, 2013- .
18. Member, Chief of Surgery Recruitment Committee, DMS, 2014.
19. Member, Research Committee, Department of Surgery, 2016- .
20. **Member, Promotions & Tenure Committee, CSE (2016-2018).**
21. **Member, Executive Committee, Department of Pediatrics, 2016- .**
22. **Member, Executive &Tenure Committee, Department of Pediatrics, 2016- .**
23. Member, Research Committee, Department of Pediatrics, 2016- .
24. Member, Research Committee, Department of Surgery, 2016- .

Service at Purdue University

1. Dean's Advisory Committee, Schools of Engineering, 2002.
2. Dean's Research Enterprise Committee, Chair, School of Engineering, 2002.
3. Joint Committee of the Biomedical Engineering Program, 1996-02.
4. Chairman, Graduate Committee, Department of Biomedical Engineering, 1998-02.
5. Chairman, Qualifying Examinations, Department of Biomedical Engineering, 2000-02.
6. Member, Committee for McCoy Award, 2000-02.
7. Chairman, Sigma Xi Chapter, Purdue University, 1995-96.
8. Vice Chairman, Sigma Xi Chapter, Purdue University 1994-95.
9. Controlled Release Society Student Chapter, Advisor 1993-02.
10. Senator of Purdue University, June 1985-May 1988; June 1991-December 1993; Nominating Committee, June 1986-May 1988; Steering Committee, May-December 1993.
11. Committee on Faculty Relations, August 1990-June 1993.
12. New Directions Committee, August 1990-August 1998.
13. Committee on Internationalization of Purdue, April 1989-January 1990.
14. Purdue Engineer Magazine, Student Advisor, May 1989-May 1991.
15. In charge of Honors Program, September 1985-August 1987; September 1990-02.
16. Chemical Engineering Undergraduate Committee, September 1976-December 1979, August 1987-June 1990, August 1996-June 1998.
17. Chemical Engineering Graduate Committee, January 1980-August 1982; September 1985-June 1986, September 1990-02.
18. Chemical Engineering, Faculty Recruiting Committee, September 1977-August 1981; September 1983-August 1985; January 1987-02.

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19. Chemical Engineering Seminars, August 1979-May 1982; May 1983-May 1984; January 1986-May 1986.
20. Editor of Purdue University, Chemical Engineering Graduate Brochure of 1980, 1981, 1982, 1983, 1985, 1987, 1989, 1991, 1998.
21. Chemical Engineering, Awards Committee, September 1983-May 1986, January 1987-02.
22. Committee for 75th Anniversary of ChE School, September 1984-June 1986.
23. AIChE Student Chapter Counselor, June 1977-August 1982; June 1983-August 1985; January 1987-August 1987; August 1988-May 1993.
24. SPE Student Chapter Founder and Counselor, September 1978-August 1982; June 1983-August 1984.
25. Sigma Xi Chemical Engineering Representative, August 1983-93.
26. Engineering Library Coordinating Committee, September 1977-June 1979.
27. Engineering Academic Personnel Grievance Committee, September 1978-June 1980; Chairman 1978-79.
28. Engineering-Chemistry Liaison Committee, January 1980-August 1982.
29. Hellenic Student Association Counselor, September 1977-September 1979.
30. Faculty Fellow, Harrison Hall, August 1978-June 1979.

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Current Research Interests: Polymers, Materials and Nanotechnology

Diffusion in Polymers, Composites, Mathematical Modeling and Membrane Science

- Multicomponent diffusion through membranes and polymer films.
- Anomalous diffusion in polymers.
-- Physical chemistry of macromolecular networks.
- Controlled release theory and applications.
- Gel interactions
- Polymer/polymer interpenetration

Polymerization Kinetics and Reaction Engineering

- Kinetics of multimethacrylate polymerizations
- Reaction engineering of fast UV-curing reactions
- UV-crosslinkable polymers

Polymer Dissolution: Microelectronics and Optical Applications

- Etching on polymers
- Positive resists
- Polymer dissolution
- Mathematical modeling

Current Research Interests: Biomedical Engineering

Bionanotechnology
- Microfabricated devices
- Intelligent therapeutic systems
-

Controlled Drug Delivery
- Drug delivery
- Peptide and protein release systems
- Buccal and sublingual release devices
- Nasal formulations
- Modulated release using oral controlled release devices
- Temperature and pH-sensitive systems
- Mucoadhesive controlled release systems

Biomaterials
Non-thrombogenic biopolymers
- Contact and intraocular lens materials
- Artificial articular cartilage

Biointerfacial Phenomena
- Protein adsorption on polymer surfaces
- Bioadhesive systems
- Blood/polymer interactions

Nanotechnology
- Targeted nanoparticles
- Molecular recognition principles
- Recognitive systems

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160. N.A. Peppas: Book review of "Bioadhesive Drug Delivery Systems," by E. Mathiowitz, D.E. Chickering and C.M. Lehr, eds., *Pharm. Res., 17*, 248 (2000).
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170. N.A. Peppas: book review of “Biopolymers for Medical And Pharmaceutical Applications”, by A. Steinbüchel and R.H.Marchessault, eds, *Adv. Materials*, *18*, 2487 (2006).

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Presentations in National and International Meetings

1. "Kinetics of the Crystallization of Crosslinked PVA Films by Slow Evaporation of Hydrogels," 172nd National American Chemical Society Meeting, San Francisco, California, August 29 - September 3, 1976, (P).
2. "Novel Methods of Production of Crosslinked and Grafted Polystyrene with Improved Thermal Properties," 172nd National American Chemical Society Meeting, San Francisco, California, August 29 - September 3, 1976, (P).
3. "Transport of Albumin Across the Aortic Wall During Angiotensin-Induced Hypertension," 29th Annual Conference on Engineering in Medicine and Biology, Boston, Massachusetts, November 11, 1976, (A), *.
4. "Development of New PVA Biomembranes," 173rd National American Chemical Society Meeting, New Orleans, Louisiana, March 25, 1977, (P).
5. "Hydrogels for Synthetic Articular Cartilage Applications," Society of Plastics Engineers National Meeting (NATEC), Denver, Colorado, November 8, 1977, (P).
6. "Chain Entanglements and Microcrystallinity in Plasticized Poly(vinyl chloride)," 70th Annual AIChE Meeting, New York, New York, November 15, 1977, (P).
7. "The Effect of Angiotensin II in *In-vivo* Albumin Transport in Normal Rabbit Aortic Tissue," 70th Annual AIChE Meeting, New York, November 15, 1977, (P).
8. "New Hydrophilic Copolymers for Biomedical Applications," 24th Annual American Society for Artificial Internal Organs Meeting, Chicago, Illinois, April 28, 1978, (P).
9. "Novel Methods of Polymerization and Crosslinking of Styrene," 71st Annual AIChE Meeting, Miami, Florida, November 13, 1978, (P).
10. "A Reaction Engineering Approach to a Course in Industrial Chemistry," 71st Annual AIChE Meeting, Miami, Florida, November 13, 1978, (P).
11. "Does Undergraduate Research Contribute to a Chemical Engineering Curriculum?," 71st Annual AIChE Meeting, Miami, Florida, November 14, 1978, (P).
12. "Crystallization During Weathering of Packaging Films," Society of Plastics Engineers National Meeting, Chicago, Illinois, November 15, 1978, (P), *.
13. "Mathematical Analysis of Transport Properties of Flexible Fibers in Relation to Food Storage Stability, I. Water Vapor Sorption," Society of Plastics Engineers National Meeting, (NATEC), Chicago, Illinois, November 15, 1978, (P), *.
14. "Isothermal Crystallization of Crosslinked and Uncrosslinked Hydrophilic Polymers in the Presence or Absence of Solvent," 86th National AIChE Meeting, Houston, Texas, April 2, 1979, (A).
15. "Reconstruction of Vocal Cords by Intracordal Polymer Injection and Gelation," 25th Annual Society of Plastics Engineers Meeting (ANTEC), New Orleans, Louisiana, May 8, 1979, (P).
16. "Non-Gaussian Macromolecular Network Models for the Investigation of Highly Crosslinked Networks," 87th National AIChE Meeting, Boston, Massachusetts, August 20, 1979, (A).
17. "Diffusion of Macromolecules Through Model Hydrophilic Networks," 87th National AIChE Meeting, Boston, Massachusetts, August 20, 1979, (A).
18. "Diffusion Controlled Mechanisms of Crystallization of Crosslinked and Uncrosslinked Polymers," 87th National AIChE Meeting, Boston, Massachusetts, August 22, 1979, (P).
19. "Mathematical Analysis of Transport Properties of Polymer Packaging Films in Relation to Food Storage Stability. II. Non-linear Water Vapor Sorption Models," 87th National AIChE Meeting, Boston, Massachusetts, August 22, 1979, (P).
20. "Mathematical Analysis of Transport Properties of Polymer Packaging Films in Relation to Food Storage Stability. III. Sorption and Chemical Reaction of Oxygen," 87th National AIChE Meeting, Boston, Massachusetts, August 22, 1979, (P).
21. "Hydrophilic Polymeric Materials for Reconstruction of Vocal Cords," 26th International Symposium on Macromolecules IUPAC, Mainz, West Germany, September 18, 1979, (P).
22. "Transport of Macromolecules Through PVA Networks," 26th International Symposium on Macromolecules IUPAC, Mainz, West Germany, September 19, 1979, (P).
23. "Generalized Method of Prediction of Mean Activity Coefficients of Polyelectrolytes in Aqueous Solutions," 26th International Symposium on Macromolecules IUPAC, Mainz, West Germany, September 20, 1979, (P).

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24. "A Chemical Engineering Curriculum Serving the National Needs: The Greek System," 72nd Annual AIChE Meeting, San Francisco, California, November 26, 1979, (P).
25. "Migration of Environmentally Hazardous Plasticizers from Polymers," 72nd Annual AIChE Meeting, San Francisco, California, November 28, 1979, (A).
26. "Generalized Mean Activity Coefficients for Aqueous Solutions of Polyelectrolytes," 72nd Annual AIChE Meeting, San Francisco, California, November 29, 1979, (P).
27. "Diffusion of Oxygen Through Polymers for Hard and Soft Contact Lenses," National Meeting of Contact Lens Association of Ophthalmologists, Las Vegas, Nevada, January 10, 1980, (A).
28. "Modelling of Drug Diffusion Through Swellable Polymeric Systems," 179th National ACS Meeting, Houston, Texas, March 27, 1980, (P).
29. "Migration of Potentially Toxic Compounds from Plasticized Polymers," 38th Annual Meeting of Society of Plastics Engineers, New York, New York, May 7, 1980, (P).
30. "Mathematical Analysis of Transport Properties of Polymer Films for Food Packaging. IV. Prediction of Shelf-Life of Food Packages Using Halsey Sorption Isotherms," 38th Annual Meeting of Society of Plastics Engineers, New York, New York, May 8, 1980, (P).
31. "The Polymer Science and Engineering Program at Purdue University: Emphasis on Engineering Fundamentals," 38th Annual Meeting of Society of Plastics Engineers, New York, New York, May 5, 1980, (P).
32. "Polymer Gel Drying: Theory and Applications," 38th Annual Meeting of Society of Plastics Engineers, New York, New York, May 8, 1980, (A).
33. "Models and Experimental Studies on Macromolecular Crosslinked Structures of Bituminous Coals," Conference on the Chemistry and Physics of Coal Utilization of the American Physical Society, Morgantown, West Virginia, June 2, 1980, *Invited-Plenary Lecture,* (P).
34. "Practical Applications of Synthetic Membranes: Past, Present and Future," 2nd Panhellenic Congress of Chemical Engineers, Athens, Greece, June 11, 1980, (A); (not presented).
35. "Prediction of Shelf-Life of Food Products after Packaging," 2nd Panhellenic Congress of Chemical Engineers, Athens, Greece, June 12, 1980, (A); (not presented).
36. "Preparation of Students through Undergraduate Research," 88th Annual ASEE Conference, Amherst, Massachusetts, June 24, 1980, (P).
37. "Synthetic Membranes: Interrelations between Structure and Diffusive Properties," IUPAC Macromolecular Meeting, Athens, Greece, August 25, 1980, *Invited-Plenary Lecture,* (A).
38. "Polymer Structural Effects on the Oxygen Permeation of Soft Contact Lens Materials," 27th International IUPAC Macromolecular Symposium, Florence, Italy, September 11, 1980, (P).
39. "An Evaluation of New Mathematical Models for Drug Release from Matrix Tablets," First International Pharmaceutical Exhibition, Interphex 80, New York, New York, September 16, 1980, *Invited Lecture,* (P), *.
40. "Macromolecular Network Structure and its Effects on Drug and Protein Diffusion," European Controlled Release Symposium, Geneva, Switzerland, October 2, 1980, *Invited-Plenary Lecture,* (P).
41. "Physicochemical and Statistical Analysis of Crosslinked Structures in Coal Networks," ACS Coal Meeting, Pittsburgh, Pennsylvania, November 10, 1980, *Invited Lecture,* (P), *.
42. "ESCA Characterization of PVA/PNVP Copolymers for Biomedical Applications," 73rd Annual AIChE Meeting, Chicago, Illinois, November 17-20, 1980, (A); (not presented).
43. "Diffusion of Phthalic Esters Through Plasticized Polymers," 73rd Annual AIChE Meeting, Chicago, Illinois, November 17-20, 1980, (P).
44. "Solute Diffusion in Highly Swollen Gels," 73rd Annual AIChE Meeting, Chicago, Illinois, November 17-20, 1980, (P).
45. "Macromolecular Network Analysis of Bituminous Coals: Theory, Extraction and Swelling Experiments," 73rd Annual AIChE Meeting, Chicago, Illinois, November 17-20, 1980, (A), *.
46. "Teaching of Polymer Science and Engineering in Chemical Engineering Departments," 73rd Annual AIChE Meeting, Chicago, Illinois, November 17-20, 1980, (P).
47. "Teaching of Biomedical Engineering in Chemical Engineering Departments," 73rd Annual AIChE Meeting, Chicago, Illinois, November 17-20, 1980, (P).
48. "Oxygen Diffusion in Glassy Copolymers of Methyl Methacrylate and Disiloxanes," Annual Meeting of American Physical Society, Phoenix, Arizona, March 16-19, 1981, (A).
49. "Fibrinolytic Enzyme Immobilized Polymers for Blood Compatible Applications," 28th International IUPAC Macromolecular Symposium, Strasbourg, France, July 8, 1981, (A).

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50. "Case-II Transport in Plasticized PVC," 28th International IUPAC Macromolecular Symposium, Strasbourg, France, July 9, 1981, (A).
51. "Streptokinase Immobilized Hydrogels: Preparation, Characterization and Preliminary Evaluation as Blood-Compatible Materials," 3rd Congress of International Society for Artificial Organs, Paris, France, July 10, 1981, (A).
52. "Drug Release Kinetics from Hydrophobic Porous Monolithic Devices," 8th International Symposium of Controlled Release of Bioactive Materials, Ft. Lauderdale Florida, July 27, 1981, (P).
53. "Swelling-Controlled Release from Hydrophilic Polymeric Networks," 8th International Symposium of Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 27, 1981, (P).
54. "Models and Experimental Studies of Drug Release from Porous Polymeric Formulations," National AIChE Meeting, Detroit, Michigan, August 18, 1981, (A), *.
55. "Diffusive Characteristics of Polymer Membranes for Protein Separation: Polymer Physical Considerations," National AIChE Meeting, Detroit, Michigan, August 19, 1981, (P), *.
56. "Polymer Structure and Thermodynamic Considerations of Solute Transport in Polymer Membranes," ACS Annual Meeting, New York, N.Y. August 26, 1981, (A).
57. "Macromolecular Structural Changes in Bituminous Coals during Extraction and Solubilization," DOE Contractors Conference, Pittsburgh, PA, October 7, 1981 (P).
58. "Preparation and Structure of Friedel-Crafts Crosslinked Polystyrene Particles," ACS Annual Meeting, Las Vegas, Nevada, March 31, 1982, (P)
59. "Constant Solute Release Rates from Glassy Polymers," ACS Annual Meeting, Las Vegas, Nevada, April 1, 1982, (P).
60. "Macromolecular Structure and Solute Diffusion in Membranes," International Symposium on Membranes and Membrane Processes, Perugia, Italy, May 20, l982, *Invited Lecture,* (A).
61. "Diffusion of Solutes in Highly and Moderately Swollen Polymeric Networks," 29th International IUPAC Macromolecular Symposium, Amherst, Massachusetts, July 14, 1982, *Invited Lecture,* (P).
62. "Swelling Controlled Release Systems: Progress Toward Zero-Order Kinetics with Polymer Blends," 9th International Symposium of Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 21, 1982, (P), *.
63. "Solute Diffusion in Swellable Polymers," International IUPAC Macromolecular Symposium, Athens, Greece, August 30, 1982, *Invited Lecture,* (A).
64. "Macromolecular Structural Changes in Bituminous Coals during Extraction and Solubilization," DOE Contractors Conference, Pittsburgh, Pennsylvania, September 23, 1982 (P), *.
65. "Kedem-Katchalsky Analysis of Transport of Monomer Albumin Through Molecular Size Pores of Polymeric Networks," Annual AIChE Meeting, Los Angeles, California, November 16, 1982, (A).
66. "Molecular Diffusion of Monomer Albumin Through Crosslinked PHEMA Membranes," Annual AIChE Meeting, Los Angeles, California, November 17, 1982 (A).
67. "Changes of the Crosslinked Macromolecular Structure of Coal During Extraction and Solubilization," Annual AIChE Meeting, Los Angeles, California, November 19, 1982, (A), *.
68. "Polymeres biocompatibles," Symposium on "Biomateriaux, application a des formes pharmaceutiques nouvelles," Lille, France, December 13, 1982, *Invited Lecture,* (A).
69. "Release of Bioactive Agents from Swellable Polymers: Theory and Experiments," International Symposium on Recent Advances in Drug Delivery Systems, Park City, Utah, March 24, 1983, *Invited Lecture,* (A).
70. "Surface Analysis of Poly(vinyl alcohol-co-N-vinyl-2-pyrrolidone)," ACS Annual Meeting, Seattle, Washington, March 22, 1983 (P)*.
71. "Copolymers of Methyl Methacrylate and Disiloxane Derivatives," ACS Annual Meeting, Seattle, Washington, March 22, 1983, (P).
72. "Release of Drugs from Initially Glassy, Dynamically Swelling P(HEMA-co-MMA) Copolymers," ACS Annual Meeting, Seattle, Washington, March 24, 1983, (P).
73. "Thermal Analysis of Macromolecular Coal Networks," APS Annual Meeting, Los Angeles, California, March 25, 1983, (A).
74. "New Observations of the Mechanism of Solute Release from Hydrophilic Polymers," Third International Conference of Pharmaceutical Technology, Paris, France, June 1, 1983, (P) *.
75. "Modeling Drug Release from Swellable Systems," 10th International Symposium of Controlled Release of Bioactive Materials, San Francisco, California, July 25, 1983, (P) *.

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76. "Analysis of Solvent Transport Mechanisms in Macromolecular Coal Networks," International Coal Conference, Pittsburgh, Pennsylvania, August 17, 1983, (P).
77. "Equilibrium and Dynamic Swelling of Highly Crosslinked Polymeric Networks," International IUPAC Macromolecular Symposium, Bucharest, Rumania, September 6, 1983, (P) *.
78. "Equilibrium and Dynamic Behavior of Polymer Particles in Ternary Emulsion Systems," International IUPAC Macromolecular Symposium, Bucharest, Rumania, September 7, 1983, (P) *.
79. "Bioadhesive Intraoral Release Systems: Design, Testing and Analysis," 20th Annual Meeting of International Association for Dental Research, Geneva, Switzerland, September 23, 1983, (P) *.
80. "Crosslinked PVA Micromatrices for Swelling-Controlled Drug Release," International Symposium on Controlled Release Pharmaceuticals, Pavia, Italy, September 27, 1983, (A) *.
81. "Macromolecular Structural Changes in Bituminous Coals during Extraction and Solubilization," DOE Contractors Conference, Pittsburgh, Pennsylvania, October 18, 1983 (P).
82. "Modelling of Transport and Sorption in Packaging Systems for Pharmaceutical Products," Industrial Pharmacy Management Conference, University of Wisconsin, Madison, Wisconsin, October 25, 1983, *Invited Lecture*, (P).
83. "The Role of Crosslinks, Entanglements and Relaxations of the Macromolecular Carrier in the Diffusional Release of Biologically Active Materials," Conference on Macromolecules as Drugs and as Carriers for Biologically Active Materials," New York Academy of Sciences, New York, New York, March 26, 1984, *Invited Lecture* (A).
84. "Viscoelastic Properties of Bituminous Coals," ACS Annual Meeting, St. Louis, Missouri, April 12, 1984(P)*.
85. "The Molecular Weight Between Crosslinks of Selected American Coals," ACS Annual Meeting, St. Louis, Missouri, April 12, 1984 (P) *.
86. "XPS Analysis of P(VA-co-NVP)," Second World Congress on Biomaterials, Washington, D.C., April 28, 1984 (P).
87. "Bioadhesive Intraoral Release Systems," Second World Congress on Biomaterials, Washington, D.C., April 28, 1984 (P).
88. "Physical Aspects of Polymeric Drug Delivery Systems," Annual Meeting of Academy of Pharmaceutical Sciences, Montreal, Canada, May 7, 1984, *Invited Lecture*, (A).
89. "Analysis of the Structure of Highly Crosslinked Polymeric Networks," ACS Rubber Chemistry Meeting, Indianapolis, Indiana, May 8, 1984 (A) *.
90. "Anomalous Transport in Macromolecular Coal Networks," DOE Contractors Conference, Pittsburgh, Pennsylvania, June 7, 1984, (P)*.
91. "Molecular Theories and Experiments of Penetrant Transport in Coal Particles," Gordon Conference on Fuel Sciences, New Hampton, New Hampshire, July 2, 1984, *Invited Lecture*.
92. "Transport of Drugs in the Intestinal Mucus," 11th International Symposium on Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 23, 1984, (P).
93. "Controlled Release Microparticle Systems for Urinary Tract Applications," 11th International Symposium on Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 23, 1984, (P).
94. "Scaling Concepts in Controlled Release," 11th International Symposium on Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 24, 1984, (P)*.
95. "Release of Drugs from Ethylene-Vinyl Alcohol Copolymers," 11th International Symposium on Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 24, 1984, (P)*.
96. "The Swelling Interface Number as a Criterion for Zero-Order Release," 11th International Symposium on Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 24, 1984, (P)*.
97. "Modelling of Drug Release from Porous Polymers," 11th International Symposium on Controlled Release of Bioactive Materials, Ft. Lauderdale, Florida, July 24, 1984, (P).
98. "Bioadhesive Controlled Release Systems," Workshop of Controlled Release Society, Ft. Lauderdale, Florida, July 25, 1984,
99. "Relaxation-Controlled Transport of Penetrants in Glassy Polymers," 9th International Congress on Rheology, Acapulco, Mexico, October 9, 1984, (P).
100. "Importance of Macromolecular Relaxations in Solvent Transport in Coal Particles," 9th International Congress on Rheology, Acapulco, Mexico, October 10, 1984, (P)*.

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101. "Swelling Controlled Release Systems: Recent Developments and Applications," International Symposium of the International Association for Pharmaceutical Technology (APV), Bad Homburg, West Germany, November 13, 1984, (P).
102. "Preparation and Swelling Characteristics of Friedel-Crafts Crosslinked Polystyrene Particles," Annual AIChE Meeting, San Francisco, California, November 27, 1984, (A).
103. "Modelling of Suspension Copolymerization/Crosslinking of Styrene," Annual AIChE Meeting, San Francisco, California, November 27, 1984, (A)*.
104. "Drug Diffusion in Aqueous Mucin Solution: Towards Understanding of Drug Absorption by the Intestine," Annual AIChE Meeting, San Francisco, California, November 28, 1984 (A)*.
105. "Some New Observations of Penetrant Transport in Crosslinked Polystyrene," Annual AIChE Meeting, San Francisco, California, November 29, 1984, (A)*.
106. "Comparison of the Macromolecular Structure of Coals with That of Stiff Polymer Chains," Annual AIChE Meeting, San Francisco, California, November 30, 1984, (P)*.
107. "Surface, Interfacial and Molecular Aspects of Polymer Adhesion on Soft Tissues," Annual AIChE Meeting, San Francisco, California, November 30, 1984, (A).
108. "The Effect of the Crystalline Structure of Membranes on their Solute Diffusion Behavior," Annual AIChE Meeting, San Francisco, California, November 30, 1984, (A)*.
109. "Bioadhesive Polymers: Design and Performance," International Chemical Congress of Pacific Basin Societies, Honolulu, Hawaii, December 18, 1984, (A). *Invited Lecture.*
110. "Theory and Experiments with Bioadhesive Swellable Delivery Systems," International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, Utah, February 28, 1985, *Invited Lecture,* (A).
111. "Integral Methods in Polymerization Reaction Engineering," Integral Methods in Science and Engineering 1985, Arlington, Texas, March 18, 1985, (A)*.
112. "Thermoplastic and Viscoelastic Properties of Coals," ACS Annual Meeting, Miami Beach, Florida, April 29, 1985, (P).
113. "Mechanisms of Amine Transport in Coal Particles," ACS Annual Meeting, Miami Beach, Florida, April 30, 1985, (P).
114. "Dynamic Swelling of Thin Coal Sections," ACS Annual Meeting, Miami Beach, Florida, May 1, 1985, (A)*.
115. "Swelling Thermodynamics of Polymer Latex Particles by a Water-Soluble Solvent," ACS Annual Meeting, Miami Beach, Florida, May 1, 1985, (P)*.
116. "Oxygen-permeable Silicon-based Contact Lenses: An Assessment of Permeation and Wettability Problems," ACS Annual Meeting, Miami Beach, Florida, May 1, 1985, (A).
117. "Modeling of Suspension Copolymerization/Crosslinking of Styrene with Divinyl Benzene," ACS Annual Meeting, Miami Beach, Florida, May 1, 1985, (P)*.
118. "Mathematical Analysis of Transport Properties of Polymer Films for Food Packaging. V. Variable Storage Conditions," ACS Annual Meeting, Miami Beach, Florida, May 2, 1985, (P).
119. "Transport of Bioactive Agents through Polymers," Symposium on Properties of Polymers and Drug Delivery, Swedish Academy of Pharmaceutical Sciences, Stockholm, Sweden, May 9, 1985, *Invited-Plenary Lecture,* (A).
120. "Core Course Material in Polymers for Chemical Engineering Courses," 19th ACS Great Lakes Regional Meeting, West Lafayette, Indiana, June 10, 1985, (A).
121. "Models of Penetrant and Solute Transport in Glassy Polymers," 19th ACS Great Lakes Regional Meeting, West Lafayette, Indiana, June 12, 1985, (A) *.
122. "Penetrant Transport in Polystyrene," 19th ACS Great Lakes Regional Meeting, West Lafayette, Indiana, June 12, 1985, (A)*.
123. "Crosslinked Polyether-diol Micromatrices for Controlled Drug Release," 12th International Symposium on Controlled Release of Bioactive Materials, Geneva, Switzerland, July 9, 1985, (P)*.
124. "Relaxational Effects in Solute Transport and Release from Swelling-Controlled P(HEMA-co-MMA) Systems," 12th International Symposium on Controlled Release of Bioactive Materials, Geneva, Switzerland, July 9, 1985, (P).
125. "The Mathematics and Physics of Solute Transport in Continuously Swelling Hydrophilic Polymers," 12th International Symposium on Controlled Release of Bioactive Materials, Geneva, Switzerland, July 9, 1985, (P)*.

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126. "Diffusion in Swellable Drug Delivery Systems," 12th International Symposium on Controlled Release of Bioactive Materials, Geneva, Switzerland, July 9, 1985, (P)*.
127. "Polymer/Glycoprotein Chain Interpenetration in Bioadhesion," 12th International Symposium on Controlled Release of Bioactive Materials, Geneva, Switzerland, July 9, 1985, (P).
128. "Swelling of Gels of PHEMA and Release of Phenylephrin □ HCl from this Polymer," 12th International Symposium on Controlled Release of Bioactive Materials, Geneva, Switzerland, July 10, 1985, (P)*.
129. "Swelling Laws for Drug Release from Equilibrium Swollen Hydrogels," 12th International Symposium on Controlled Release of Bioactive Materials, Geneva, Switzerland, July 10, 1985, *Invited Lecture* (P).
130. "The Kinetics of Preparation of PHEMA Microparticles by Suspension Copolymerization/Crosslinking with EGDMA," 12th International Symposium on Controlled Release of Bioactive Materials, Geneva, Switzerland, July 11, 1985, (P)*.
131. "Release of Radioactive Isotopes from Stored Waste to the Ground," 12th International Symposium on Controlled Release of Bioactive Materials, Geneva, Switzerland, July 12, 1985, (P).
132. "Molecular Aspects of Polymer Adhesion on Mucus," ACS Annual Meeting, Chicago, Illinois, September 9, 1985, (A).
133. "The Effect of Degree of Crystallinity and Crystallite Size on Solute Diffusion through Membranes," ACS Annual Meeting, Chicago, Illinois, September 9, 1985, (A)*.
134. "Scaling Laws for Solute Diffusion in Equilibrium Swollen Gels," ACS Annual Meeting, Chicago, Illinois, September 10, 1985, (P)*.
135. "Bioadhesives: Fundamental Studies on Adhesion to Mucus Membranes," APS Annual Meeting, Minneapolis, Minnesota, October 21, 1985, (A).
136. "The Relaxational Aspects of Drug Release from P(HEMA-co-MMA) Copolymers," Annual AIChE Meeting, Chicago, Illinois, November 12, 1985, (A) *.
137. "The Surface of P(VA-co-NVP) Hydrogels as Revealed by Scanning Electron Microscopy," Annual AIChE Meeting, Chicago, Illinois, November 12, 1985, (A)*.
138. "Modeling of Multicomponent Transport in Swelling Polymers," Annual AIChE Meeting, Chicago, Illinois, November 13, 1985, (A) *.
139. "Kinetic Modelling of Copolymerization-Crosslinking Reactions," Annual AIChE Meeting, Chicago, Illinois, November 14, 1985, (A) *.
140. "Interfacial Phenomena Related to Bioadhesion of Polymers on the Intestinal Mucus," Annual AIChE Meeting, Chicago, Illinois, November 15, 1985, (A).
141. "Diffusion of Biological Molecules in Semidilute Gels," Annual Materials Research Society Meeting, Boston, Massachusetts, December 4, 1985, (A).
142. "New Observations of Anomalous Transport in Crosslinked Polystyrene,"= Annual Materials Research Society Meeting, Boston, Massachusetts, December 5, 1985, (A).
143. "Measurement of the Bioadhesive Force Between a Polymer Microparticle and Mucin Gel," International Biomedical Engineering Symposium, Salt Lake City, Utah, January 21, 1986, (A).
144. "Bioadhesive Controlled-Release Systems," Fourth International Conference on Pharmaceutical Technology, Paris, France, June 3, 1986, *Plenary Lecture*, (A).
145. "Influence de l' hydrosolubilite du principe actif sur la liberation a partir de microspheres de PHEMA et role joue par la nature du solvant," Fourth International Conference on Pharmaceutical Technology, Paris, France, June 4, 1986, (P) *.
146. "Relaxation-Coupled Diffusion in Glassy Polymers," Second Conference of European Rheologists, Prague, Czechoslovakia, June 18, 1986, (A).
147. "The Role of Polymer Structure in Bioadhesion to the Mucus," 13th International Symposium on Controlled Release of Bioactive Materials, Norfolk, Virginia, August 4, 1986, *Invited Lecture*, (P).
148. "Investigation of the Effects of Thickness on the Swelling Kinetics of P(HEMA-co-MMA) in Water," 13th International Symposium on Controlled Release of Bioactive Materials, Norfolk, Virginia, August 5, 1986, (P).
149. "Drug Diffusion in Heterogeneous Polymeric Systems with Impermeable Domains," 13th International Symposium on Controlled Release of Bioactive Materials, Norfolk, Virginia, August 5, 1986, (P).

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150. "Comparison of Experimental Techniques for the Measurement of the Bioadhesive Forces of Polymeric Materials with Soft Tissues," 13th International Symposium on Controlled Release of Bioactive Materials, Norfolk, Virginia, August 5, 1986, (P).
151. "The Design and Evaluation of Bioadhesive Controlled Release Systems," Third International Pharmaceutical Technology Symposium, Ankara, Turkey, September 9, 1986, *Invited Lecture,* (P).
152. "The Bioadhesive Behavior of 2-Hydroxyethyl Methacrylate-Containing Copolymer Microparticles with Aqueous Gels of Bovine Submaxillary Mucin," European Congress on Biomaterials, Bologna, Italy, September 15, 1986, (A).
153. "Dynamic Swelling of and Drug Release from Microparticles for Swelling-Controlled Release Applications," 13th Annual Meeting of the European Society of Artificial Organs, Avignon, France, September 18, 1986, (A).
154. "Macromolecular Release from Magnetically-Triggered Controlled-Release Polymer Systems," 13th Annual Meeting of the European Society of Artificial Organs, Avignon, France, September 20, 1986, (A).
155. "L'influence de la structure polymerique sur la liberation controlee des principes actifs," Journees Galeniques, Saint-Remy de Provence, France, September 26, 1986, (P).
156. "Transport of Drugs Through the Intestinal Mucus," Annual AIChE Meeting, Miami, Florida, November 6, 1986, (A).
157. "Polymer Microparticles on Biological Surfaces," Annual AIChE Meeting, Miami, Florida, November 5, 1986, (A)*.
158. "Preparation and Modelling of Water-Soluble Microparticles by Suspension Polymerization," Annual AIChE Meeting, Miami, Florida, November 7, 1986, (A)*.
159. "Membrane and Reservoir Systems," Symposium on Drug Delivery Systems, Danish Society of Polymer Technology, Copenhagen, Danemark, November 19, 1986, *Plenary Lecture,* (A).
160. "Bioadhesive Polymers," Symposium on Drug Delivery Systems, Danish Society of Polymer Technology, Copenhagen, Danemark, November 20, 1986, *Plenary Lecture,* (A).
161. "Model Experimental Study of a Transdermal System," International Symposium on Transdermal Drug Delivery Systems, New Ulm, Federal Republic of Germany, December 2, 1986, (A)*.
162. "Bioadhesive Analysis of Controlled Release Systems. I. Systems Containing Poly(acrylic acid)," APGI Colloquium, Paris, France, December 11, 1986, (A)*.
163. "Bioadhesive Analysis of Controlled Release Systems. II. Systems for Release of Metronidazole," APGI Colloquium, Paris, France, December 11, 1986, (A)*.
164. Modele d' etude experimentale d' un systeme transdermique," First International Forum on Formulation Physical Chemistry and its Applications, Nice, France, February 5, 1987, (A)*.
165. Prediction of Polymer Dissolution in Swellable Controlled Release Systems," International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, Utah, February 26, 1987, *Invited Lecture,* (A).
166. "Bioadhesion et microformes," First Scientific Meeting of the Industrial Health Group of East-Central France, Dijon, France, May 15, 1987, (A).
167. "Models of Solute Transport Through Block Copolymer Membranes," 1st Annual Meeting of the North American Membrane Society, Cincinnati, Ohio, June 2, 1987, (P)*.
168. "Hydroxyalkyl Methacrylate Copolymers for Biomedical Applications," 13th Annual Meeting of Society for Biomaterials, New York, N.Y., June 4, 1987, (P)*.
169. "The Interaction of Poly(acrylic acid)-Containing Polymeric Systems with Bovine Sublingual Mucus," Biointeractions '87, Cambridge, United Kingdom, July 8, 1987, (A).
170. "Fracture Analysis of the Bioadhesive Interactions Between Surface-swollen, Poly(acrylic Acid)-Containing Tablets and the Bovine Sublingual Tissue," 14th International Symposium on Controlled Release of Bioactive Materials, Toronto, Canada, August 3, 1987, (P)*.
171. "The Time-Dependent Behavior of the Adhesive Interactions Between Poly(acrylic Acid) and Buccal Tissue," 14th International Symposium on Controlled Release of Bioactive Materials, Toronto, Canada, August 3, 1987 (P).
172. "Coupled Diffusion/Dissolution Processes May Give Zero-Order Release of Drugs from Microspheres," 14th International Symposium on Controlled Release of Bioactive Materials, Toronto, Canada, August 3, 1987, (P).
173. "Diffusive Characteristics of Drugs in Novel Gels," 14th International Symposium on Controlled Release of Bioactive Materials, Toronto, Canada, August 3, 1987, (P)*.

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174. "The Mechanisms of Disintegration of Compressed Particle Systems," International Symposium on Perspectives in Solid Dosage Form Design, Pavia, Italy, September 28, 1987, (A)*.
175. "Suspension Polymerization of 2-Hydroxyethyl Methacrylate," Annual AIChE Meeting, New York, N.Y., November 16, 1987, (A)*.
176. "A Rational Thermodynamics Theory for Penetrant Transport in Polymers," Annual AIChE Meeting, New York, N.Y., November 16, 1987, (A)*.
177. "Testing of the Adhesive Force Between Poly(acrylic acid) and Bovine Sublingual Mucus," Annual AIChE Meeting, New York, N.Y., November 18, 1987, (A).
178. "Dissolution Analysis of Model Positive Resists," Annual AIChE Meeting, New York, N.Y., November 19, 1987, (A).
179. "Crack Healing of Polymer-Polymer Interfaces of Linear Polymers," Fall Meeting Materials Research Society, Boston, MA, December 1, 1987, (A).
180. "Effect of Chain Entanglements on the Fracture Characteristics of Polymeric Materials," Fall Meeting, Materials Research Society, Boston, MA, December 3, 1987, (A)*.
181. "Modello Fisico per la Disgregazione di Compresse," 11th Symposium of ADRITELF, Erice, Italy, March 20, 1988, (A)*.
182. "Biomaterials Needs for the Next Generation of Drug Delivery," Spring Meeting, Materials Research Society, Reno, NV, April 5, 1988, *Invited Lecture,* (A).
183. "Mechanisms of Dissolution of Compressed Tablets," Spring Meeting, Materials Research Society, Reno, NV, April 5, 1988, (A).
184. "Branching Theory in Sol-Gel Processing," Spring Meeting, Materials Research Society, Reno, NV, April 5, 1988, (P).
185. "Fracture Mechanics of Low Molecular Weight Polymers," Spring Meeting, Materials Research Society, Reno, NV, April 5, 1988, (P).
186. "The Thermodynamics of Perfume Incorporation and Release from Polymers," Spring Meeting, Materials Research Society, Reno, NV, April 5, 1988, (A).
187. "Structural Changes in Environmentally Sensitive Hydrogels," Spring Meeting, Materials Research Society, Reno, NV, April 5, 1988, (A)*.
188. "Tablet Disintegration: A Physical Model," 7th Pharmaceutical Technology Conference, London, April 14, 1988 (P)*.
189. "Synthesis and Swelling Characteristics of a Type of Hydrophilic/Hydrophobic Membranes," Second Annual Meeting, North American Membrane Society, Syracuse, NY, June 20, 1988, (P)*.
190. "Transport Properties of Water in Epoxy Resins and Composites," National Meeting, American Chemical Society, Toronto, Canada, June 9, 1988, (P)*.
191. "Application of Branching Theory to Curing Kinetics of Tetraepoxy-Diamine Systems," National Meeting, American Chemical Society, Toronto, Canada, June 9, 1988, (P)*.
192. "Measurement of the Forces Between Polymer Microparticles and Mucin Gels," National Meeting, American Chemical Society, Toronto, Canada, June 8, 1988, (A).
193. "Elements of Chemical Technology in the Byzantine University of Constantinople and in the Byzantine Empire," National Meeting American Chemical Society, Toronto, Canada, June 6, 1988, (A).
194. "Unit Processes Against Unit Operations: The Educational Fights of the Thirties," National Meeting, American Chemical Society, Toronto, Canada, June 6, 1988, (A).
195. "Academic Connections of the 20th Century U.S. Chemical Engineers: Influence of the 18th and 19th Century Swedish, French, German, and Italian Chemists," National Meeting, American Chemical Society, Toronto, Canada, June 6, 1988, (A).
196. "Delivery of Selected Principal Essential Oils Used in Flavoring," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 18, 1988, (P)*.
197. "Determination of Mesh Size in Hydrogels," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 17, 1988, (P)*.
198. "Production of Hydrophilic Homo- and Copolymer Microparticles by Suspension Polymerization," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 17, 1988, (P)*.
199. "Macromolecular Network Characteristics and their Effect on Drug Release from Crosslinked Poly(vinyl alcohol) Micromatrices," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 17, 1988, (P)*.

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200. "Swelling-controlled Release Systems of Poly(multiethylene glycol dimethacrylates) and their Copolymers," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 17, 1988, (P).
201. "Environmental Cracking of Long-term Antifouling Controlled Release Systems," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 18, 1988, (P).
202. "The Swelling Behavior of pH-Sensitive Hydrogels," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 17, 1988, (P)*.
203. "Videomicroscopic Study of the Stresses Formed in Hydrogels During Swelling," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 19, 1988, (P).
204. "Alginate Magnetic Release Systems: Crosslinked Structure, Swelling and Release Studies," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 17, 1988, (P).
205. "Drug Release from Swellable Matrices Restricted by Impermeable Film Coatings," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 18, 1988, (P)*.
206. "Gel Syneresis and Drug Release with Temperature-Sensitive Hydrogels," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 19, 1988, (P).
207. "Influence of the Composition of the Test Medium on the Adhesion of a Bioadhesive Tablet to a Bilogical Tissue," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 18, 1988, (P)*.
208. "Assessment of a New Method for the Determination of Bioadhesion," 15th International Symposium on Controlled Release of Bioactive Materials, Basle, Switzerland, August 17, 1988, (P)*.
209. "Polydimethacrylates for Laser Videodisc Applications," ACS Annual Meeting, Anaheim, California, September 26, 1988, (P).
210. "Controlled Release Polymeric Systems for Essential Oils Used in Flavoring," ACS Annual Meeting, Anaheim, California, September 27, 1988, (A).
211. "Solute Transport in Heterogeneous Polymeric Systems with Semipermeable Domains," US-Europe Symposium on Advanced Membrane Science and Technology, Ravello, Italy, October 3, 1988, \fIInvited Lecture\fR, (A).
212. "Copolymerization and Crosslinking Reactions of Hydrophilic Monomers," Annual AIChE Meeting, Washington, DC, November 19, 1988, (A)*.
213. "The Swelling Behavior of pH-Sensitive Hydrogels," Annual AIChE Meeting, Washington, DC, December 1, 1988, (A)*.
214. "Structure and Swelling Behavior of Poly(ethylene glycol-g-methacrylic acid)Networks," Annual AIChE Meeting, Washington, DC, December 1, 1988, (A)*.
215. "Preparation and Properties of Novel Methacrylate-Based Laser Videodisc Polymers," Annual AIChE Meeting, Washington, DC, November 28, 1988, (A)*.
216. "A Branching Theory for the Analysis of Certain Sol-Gel Processes," Annual AIChE Meeting, Washington, DC, November 30, 1988, (A)*.
217. "The Progress of Alkoxysilane Reactions for Sol-gel Processing," 7th International Symposium on Ceramics, Bologna, Italy, December 15, 1988, (A).
218. "DIffusive and Surface Problems During Utilization of Hydrogels in Ophthalmology," International Symposium on Advances in Biomedical Polymers, Perth, Australia, February 6, 1989, *Invited Lecture*, (P).
219. "Ampholytic Hydrogels Sensitive to Physiological Conditions," International Symposium on Advances in Biomedical Polymers, Perth, Australia, February 8, 1989, (P).
220. "Temperature Sensitive Hydrogels for Biomedical Applications," International Symposium on Advances in Biomedical Polymers, Perth, Australia, February 9, 1989, (P).
221. "Transport Characteristics of Glassy and Rubbery Polymers," Second Materials Science Symposium of the School of Optometry of the University of Missouri, St. Louis, Missouri, March 14, 1989, *Invited Lecture*.
222. "Theories of Penetrant Transport in Glassy Polymers," Annual ACS Meeting, Dallas, Texas, March 20, 1989, *Invited Lecture*, (P)*.
223. "Controlled Release of Drugs from pH-Sensitive Polymers," Annual Meeting of the Society of Biomedical Engineering, New Orleans, Louisiana, March 20, 1989 (A).
224. "Modelling the Complex Sequence of Sol-gel Processing Reactions," 91st Annual Meeting of American Ceramic Society, Indianapolis, Indiana, April 25, 1989, (A).

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225. "Drying and Stresses in Non-crystalline and Crystalline Solids Derived from Gels," 91st Annual Meeting of American Ceramic Society, Indianapolis, Indiana, April 26, 1989, (A).
226. "Controlled Release of Drugs from pH-Sensitive Polymers," Annual Meeting Biomedical Engineering Society, April 26, 1989, (A)*.
227. "Thermodynamic Investigation of Equilibrium-Swollen Heterogeneous Networks," 15th Annual Meeting of Society for Biomaterials, Lake Buena Vista, Florida, May 1, 1989, (P)*.
228. "Protein Partitioning in Hydrophilic/Hydrophobic Graft and Block Copolymer Networks," 15th Annual Meeting of Society for Biomaterials, Lake Buena Vista, Florida, May 1, 1989, (P)*.
229. "Diffusional Peptide Release," First International Meeting on the Theory and Applications of Diffusion in Biomedical, Pharmaceutical and Food Sciences, Parma, Italy, May 16, 1989, *Invited Lecture*, (A).
230. "pH-Dependent Anomalous Swelling of Glassy Polymers," First International Meeting on the Theory and Applications of Diffusion in Biomedical, Pharmaceutical and Food Sciences, Parma, Italy, May 16, 1989, (A)*.
231. "Kinetics of Mucus-Polymer Interactions," International CRS/APV Workshop on Bioadhesion-Possibilities and Future Trends, Leiden, The Netherlands, May 23, 1989, *Invited Lecture*, (P).
232. "The Higuchi Model as a Tool to Obtain Information about the Structure of Ibuprofen-loaded Ethylcellulose Microspheres," Fifth International Conference on Pharmaceutical Technology, Paris, France, June 1, 1989, (P)*.
233. "Dynamic Swelling Behavior of pH-Sensitive Swelling Controlled Release Systems," Fifth International Conference on Pharmaceutical Technology, Paris, France, June 1, 1989, (P).
234. "Gel Syneresis as a Method to Release Drugs at Prescribed Intervals," Fifth International Conference on Pharmaceutical Technology, Paris, France, June 1, 1989, (P).
235. "Drug Release Modulation by Physical Restriction of Matrix Swelling," Fifth International Conference on Pharmaceutical Technology, Paris, France, June 1, 1989, (P)*.
236. "Water Uptake and Disintegration Force Development in Pharmaceutical Tablets," Fifth International Conference on Pharmaceutical Technology, Paris, France, June 1, 1989, (P)*.
237. "Diffusion in Membranes Exhibiting Hydrophilic/Hydrophobic Phases," 16th International Symposium on Controlled Release of Bioactive Materials, Chicago, Illinois, August 8, 1989, (P).
238. "Complex-forming Hydrogels Sensitive to Physiological Conditions," 16th International Symposium on Controlled Release of Bioactive Materials, Chicago, Illinois, August 8, 1989, (P).
239. "The Response of pH-Sensitive Polymers to Successive Changes of pH or Ionic Strength in Solutions," 16th International Symposium on Controlled Release of Bioactive Materials, Chicago, Illinois, August 8, 1989, (P).
240. "Recent Advances in Modeling of Swelling-Controlled Release Systems," 16th International Symposium on Controlled Release of Bioactive Materials, Chicago, Illinois, August 8, 1989, (P).
241. "pH-Dependent Anomalous Swelling of Glassy Polymers," 16th International Symposium on Controlled Release of Bioactive Materials, Chicago, Illinois, August 8, 1989, (P)*.
242. "Programmed Insulin Delivery Using Thermosensitive Hydrogels," Annual AIChE Meeting, San Francisco, California, November 8, 1989, (P).
243. "Fractal Analysis in Polymer Structures for Information Storage Technology," Annual AIChE Meeting, San Francisco, California, November 8, 1989, (P)*.
244. "Kinetics of UV-Induced Multiethylene Glycol Dimethacrylate Polymerizations," Annual AIChE Meeting, San Francisco, California, November 8, 1989, (P)*.
245. "Copolymerization/Crosslinking Reaction of 2-Hydroxyethyl Methacrylate with Ethylene Glycol Dimethacrylate," Annual AIChE Meeting, San Francisco, California, November 8, 1989, (P)*.
246. "Modeling of Protein Adsorption on Smooth Polymeric Surfaces Based on Calculated Interaction Parameters," Annual AIChE Meeting, San Francisco, California, November 6, 1989, (P)*.
247. "Fibrinolytic Activity of pH-Sensitive Streptokinase-Immobilized Poly(methacrylic acid-g-ethyleneoxide) Microspheres," Annual AIChE Meeting, San Francisco, California, November 7, 1989, (P).
248. "Swelling/Dissolution Front Synchronization as a Method of Zero-Order Release," Annual AIChE Meeting, San Francisco, California, November 7, 1989, (P).
249. "Self-Association of Poly(ethylene glycol-g-methacrylic acid) as Studied by Nuclear Overhauser Effect and NMR Relaxation Time Measurements," Annual AIChE Meeting, San Francisco, California, November 8, 1989, (P)*.

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250. "Dynamic and Equilibrium Swelling Characteristics of Hydrophilic Copolymers with Carboxylic Functional Groups," Annual AIChE Meeting, San Francisco, California, November 8, 1989, (P).
251. "Soluble Fraction Effects on Dynamic Swelling of Hydrogels," Annual AIChE Meeting, San Francisco, California, November 7, 1989, (P)*.
252. "Development and Implementation of a Model for Penetrant Transport in Glassy Polymers," Annual AIChE Meeting, San Francisco, California, November 8, 1989, (P)*.
253. "Dynamic Penetrant Uptake and Equilibrium Sorption of Epoxy Resins," Annual AIChE Meeting, San Francisco, California, November 9, 1989, (P)*.
254. "Dissolution of Positive Resists," Annual AIChE Meeting, San Francisco, California, November 6, 1989, (P).
255. "Structural Changes in TEOS Gelation as Revealed by Compressive Creep Experiments," Annual AIChE Meeting, San Francisco, California, November 9, 1989, (P).
256. "Hydrogels of P(EO-g-MA) for Biomedical Applications," First European Symposium of Controlled Drug Delivery, the Hague, the Netherlands, March 29, 1990, (P), *Invited Lecture*.
257. "Penetrant Transport in Coal Networks," ACS Meeting, Boston, Massachusetts, April 25, 1990, (P).
258. "Modelling of Moisture Transport in Epoxy Composites," ACS Meeting, Boston, Massachusetts, April 24, 1990, (A).
259. "Mucoadhesive Polymers," ACS Meeting, Boston, Massachusetts, April 25, 1990, (A).
260. "Correlation Between Structure and Properties of Polymers and Drug Release," 10th Advanced Course on Pharmaceutical Chemistry, Italian Chemical Society, Bressanone, Italy, June 6, 1990, (P), *Invited Lecture*.
261. "Controlled Release from Bioadhesive Polymeric Systems," 10th Advanced Course on Pharmaceutical Chemistry, Italian Chemical Society, Bressanone, Italy, June 8, 1990, (P), *Plenary Lecture*.
262. "Swelling and Syneresis of Hydrogels due to Temperature, pH and Ionic Strength Changes," 33rd IUPAC Symposium on Macromolecules, Montreal, Canada, July 10, 1990, (A), *Invited Lecture*.
263. "Swelling Dimensionality and Drug Release from Swellable Matrices," Fifth International Pharmaceutical Technology Symposium, Ankara, Turkey, September 11, 1990, (P)*.
264. "Polymer Structure and Diffusion in Polymers," First Workshop on Controlled Release in Consumer Products, Cincinnati, Ohio, October 18, 1990, (P), *Invited Lecture*.
265. "Polymers and Hydrocolloids in Consumer Product Applications," First Workshop on Controlled Release in Consumer Products, Cincinnati, Ohio, October 18, 1990, (P), *Invited Lecture*.
266. "Perfume Release and Air Fresheners," First Workshop on Controlled Release in Consumer Products, Cincinnati, Ohio, October 19, 1990, (P), *Invited Lecture*.
267. "pH-Dependent Swelling Behavior of Carboxyl-Containing Copolymeric Networks," Annual AIChE Meeting, Chicago, IL, November 15, 1990, (A)*.
268. "Mathematical Modelling of Drug Release from Physiologically Sensitive Hydrogels," Annual AIChE Meeting, Chicago, IL, November 12, 1990, (A)*.
269. "Kinetics and Volume Relaxation for Polymerizations of Multiethylene Glycol Dimethacrylates," Annual AIChE Meeting, Chicago, IL, November 14, 1990, (A)*.
270. "Complexation of Polymeric Acids with Complementary Oligomeric Bases," Annual AIChE Meeting, Chicago, IL, November 14, 1990, (A)*.
271. "Modelling of Coupled Deformation and Mass Transport Processes," Annual AIChE Meeting, Chicago, IL, November 14, 1990, (A)*.
272. "Water Diffusion Kinetics in Graphite/Epoxy Composites," Annual AIChE Meeting, Chicago, IL, November 14, 1990, (A)*.
273. "A Novel Kinetic Gelation Simulation for Analysis of Free Radical Polymerizations of Multifunctional Monomers," Annual AIChE Meeting, Chicago, IL, November 14, 1990, (A)*.
274. "Imaging Polymer Interfaces by Scanning Electron Microscopy and Energy Dispersive X-Ray Analysis," Annual AIChE Meeting, Chicago, IL, November 14, 1990, (A)*.
275. "Control of Mesh and Pore Size of Bioceramics Produced by Sol/Gel Processing," Third International Symposium on Ceramics in Medicine, Terre Haute, IN, November 20, 1990, (A).
276. "Fracture Energy and Critical Strength of High Molecular Weight Glassy Polymers," Fall Meeting, Materials Research Society, Boston, MA, November 26, 1990, (P)*.
277. "Effects of Aging on Polymerization Kinetics," Fall Meeting, Materials Research Society, Boston, MA, November 27, 1990, (P)*.

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278. "Physiologically Responsive Hydrogels," USA-Czechoslovak Academy of Sciences Workshop on Novel Polymers and Properties for Biotechnology and Bioengineering, Prague, Czechoslovakia, December 13, 1990, (A), *Invited Lecture*.
279. "A Novel Kinetic Gelation Simulation for Analysis of Free Radical Polymerizations of Multifunctional Monomers," Annual American Physical Society Meeting, Cincinnati, OH, March 18, 1991, (A)*.
280. "A Model for Coupled Deformation and Mass Transport Processes in Polymers," Annual American Physical Society Meeting, Cincinnati, OH, March 18, 1991, (A)*.
281. "Chain Dynamics at a Gel/Gel Interface," Annual American Physical Society Meeting, Cincinnati, OH, March 19, 1991, (A)*.
282. "Structure of Hydrogels by Freezing-Thawing Cyclic Processing," Annual American Physical Society Meeting, Cincinnati, OH, March 19, 1991, (A)*.
283. "Swelling Dimensionality and Drug Release," 10th Pharmaceutical Technology Conference, Bologna, Italy, April 16, 1991, (P)*.
284. "Polymer Characterization and Polymerization Reaction Modeling for Advanced Dental Materials," Annual Meeting of the Society of Biomaterials, Scottdale, AZ, May 1, 1991, (A)*.
285. "Effect of Ionic Strength, Temperature and pH on the Dynamic and Equilibrium Swelling Behavior of Ionic Hydrogels," AAPS Midwest Regional Meeting, Chicago, Illinois, May 6, 1991, (A)*.
286. "Modulated Release of Peptides and Drugs Using Physio-responsive Polymers," 25th Journees Galeniques Meeting, St. Remy, France, May 31, 1991, (P), *Invited Lecturer*.
287. "The Kinetics of Adhesive Bond Development Between Polymers and Mucus," 18th International Symposium on Controlled Release of Bioactive Materials, Amsterdam, the Netherlands, July 9, 1991, (P), *Invited Lecture*.
288. "A Method of Measuring Mucoadhesive Forces on Polymeric Microparticles," 18th International Symposium on Controlled Release of Bioactive Materials, Amsterdam, the Netherlands, July 9, 1991, (P)*.
289. "Solute Release from Polyelectrolytic Networks," 18th International Symposium on Controlled Release of Bioactive Materials, Amsterdam, the Netherlands, July 9, 1991, (P).
290. "Dimensionality in Swelling of Polymer Carriers and its Importance in Drug Release," 18th International Symposium on Controlled Release of Bioactive Materials, Amsterdam, the Netherlands, July 9, 1991 (P).
291. "Swelling Force Development in Ionic Polymeric Networks," 18th International Symposium on Controlled Release of Bioactive Materials, Amsterdam, the Netherlands, July 10, 1991 (P)*.
292. "Release Behavior from pH-Sensitive Hydrogels Containing Bioactive Agents of Varying Thermodynamic Properties," 18th International Symposium on Controlled Release of Bioactive Materials, Amsterdam, the Netherlands, July 10, 1991, (P)*.
293. "Physicochemical Characteristics of Drug Diffusion in Polymers," International Workshop on Drug Delivery Systems and Pharmaceutical Technology, Buenos Aires, Argentina, September 16, 1991, (P).
294. "Design and Optimization of Controlled Release Systems," International Workshop on Drug Delivery Systems and Pharmaceutical Technology, Buenos Aires, Argentina, September 16, 1991 (P).
295. "Swelling Controlled Release Systems," International Workshop on Drug Delivery Systems and Pharmaceutical Technology, Buenos Aires, Argentina, September 18, 1991, (P).
296. "Transdermal Delivery," International Workshop on Drug Delivery Systems and Pharmaceutical Technology, Buenos Aires, Argentina, September 19, 1991, (P).
297. "Bioadhesion," First Latin American Symposium on Drug Administration Strategies and Therapeutic Systems, Buenos Aires, Argentina, September 20, 1991, (P).
298. "Release Behavior of Bioactive Agents from pH-Sensitive Hydrogels," Annual AIChE Meeting, Los Angeles, CA, November 19, 1991, (A)*.
299. "Dissolution of Glassy Polymers," Annual AIChE Meeting, Los Angeles, CA, November 19, 1991, (A)*.
300. "Dynamic Swelling of pH-Sensitive Controlled Release Systems," Annual AIChE Meeting, Los Angeles, CA, November 19, 1991, (A)*.
301. "Kinetics and Modelling of UV-Induced Multi-Ethylene Glycol Dimethacrylate Polymerizations," Annual AIChE Meeting, Los Angeles, CA, November 19, 1991, (A)*.

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302. "Water Effects on the Interfacial Shear Strength of Graphite/Epoxy Interface," Annual AIChE Meeting, Los Angeles, CA, November 19, 1991, (A)*.
303. "Synthesis and Characterization of Acrylic Acid Hydrogels for Bioadhesive Applications," Annual AIChE Meeting, Los Angeles, CA, November 19, 1991, (A)*.
304. "Physiologically-Sensitive Hydrogels in Controlled Release Applications," US-Japan Symposium on Drug Delivery Systems, Maui, HI, December 17, 1991, (A), *Invited Lecture*.
305. "Modeling of Ionic Polymers for Controlled Drug Delivery Applications," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, January 22, 1992, (A)*.
306. "Effect of Physiological Conditions on Drug Release Behavior from Ionic Polymeric Devices," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, January 22, 1992, (A)*.
307. "Poly(acrylic acid) Hydrogels for Bioadhesive Controlled Release Applications," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, January 22, 1992, (A)*.
308. "Near-field FTIR Imaging as a Method for Studying Polymer Interdiffusion in Bioadhesive Controlled Release Systems," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, January 22, 1992, (A)*.
309. "Characterization of Polymer Dissolution for Design of Polymer Implant Devices," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, January 22, 1992, (A)*.
310. "Hydrogels and Bioadhesion," CRS Workshop on Biomaterials and Controlled Release, Jupiter Beach, FL, January 30, 1992, (A), *Invited Lecture*.
311. "Interfacial Adhesion of PVC/PEMA," Annual Adhesion Society Meeting, Hilton Head, SC, February 17, 1992, (P)*.
312. "PVT Properties of Crosslinked Polystyrene/Dodecane System," Annual Meeting of American Physical Society, Indianapolis, IN, March 19, 1992, (A)*.
313. "Interdiffusion in Compatible Polymer Pairs," Annual Meeting of American Physical Society, Indianapolis, IN, March 20, 1992, (A)*.
314. "Characterization of Polymer Dissolution," Annual Meeting of American Physical Society, Indianapolis, IN, March 20, 1992, (A)*.
315. "Penetrant Transport in Ionic Polymers," Annual Meeting of American Physical Society, Indianapolis, IN, March 20, 1992, (A).
316. "Bioresponsive Hydrogels for Controlled Release of Solutes," Annual Meeting of American Chemical Society, San Francisco, CA, April 7, 1992, (P), *Invited Lecture*.
317. "Hydrogels in Medicine and Biology," Fourth World Biomaterials Congress, Berlin, Germany, April 26, 1992, (P), *Plenary Lecture*.
318. "Diffusion Release from Polymers," Second Workshop on Controlled Release in Consumer Products, Secaucus, New Jersey, May 13, 1992, (P), *Invited Lecture*.
319. "Fundamentals of pH- and Temperature-sensitive Polymers," Symposium on Pulsatile Drug Delivery, Köningswinter, Germany, May 20, 1992, (P), *Invited Lecture*.
320. "Use of Near-field FTIR Imaging to Investigate Polymer Interdiffusion in Relation to Bioadhesion of Controlled Release Systems," Second Jerusalem Conference on Pharmaceutical Sciences and Clinical Pharmacology, Jerusalem, Israel, May 28, 1992, (A), *Invited Lecture*.
321. "Bioadhesive Controlled Release Systems," Workshop on Developments in Biopharmaceutics and Pharmacokinetics, Athens, Greece, May 30, 1992, (A), *Invited Lecture*.
322. "Mechanisms of Peptide and Protein Transport in Hydrogels," 19th International Symposium on Controlled Release of Bioactive Materials, Orlando, Florida, July 29, 1992, (P), *Invited Lecture*.
323. "Characterization of Water Structure in Relation to Release Behavior of Drugs from pH-Sensitive Hydrogels," 19th International Symposium on Controlled Release of Bioactive Materials, Orlando, Florida, July 29, 1992, (P)*.
324. "Swelling Controlled Drug Release from Cationic Polymers," 19th International Symposium on Controlled Release of Bioactive Materials, Orlando, Florida, July 29, 1992, (P)*.
325. "Peptide Diffusion and Release from Polymeric Carriers," 7th Symposium on Peptide Delivery, Zermatt, Switzerland, September 29, 1992, (A), *Invited Lecture*.
326. "Photopolymerizations of Multifunctional Acrylates and Methacrylates," Annual AIChE Meeting, Miami Beach, FL, November 2, 1992, (A)*.
327. "Modeling and Characterization of Polymer Dissolution," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.

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328. "Near-field FTIR Imaging Studies of Polymer-polymer Diffusion," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A).
329. "Diffusional and Mechanical Behavior of the Dodecane/Polystyrene System," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
330. "Characterization of Polymer/Drug Interactions by ATR-FTIR," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
331. "Disintegration of Pharmaceutical Formulations," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
332. "Dynamic and Equilibrium Swelling of Polyacrylates," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
333. "Release of Essential Oils from Sweelable Polymers," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
334. "Use of ATR-FTIR Spectroscopy for the Investigation of Chain Interpenetration in Bioadhesion," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
335. "Investigation of Drug Distribution and Interaction with Polymer Microscopy," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
336. "New Hydrophilic/Hydrophobic Block and Graft Copolymers for Selective Solute Separation," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
337. "Physical and Mechanical Characterization of Polymultifunctional Acrylates and Methacrylates," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
338. "Measurement of the Concentration Profile at a Poly(vinyl chloride) and Poly(methyl methacrylate) Interface with Analytical Electron Microscopy," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
339. "Highly Crosslinked Polymers as Information Storage Systems," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*.
340. "Relaxational and Diffusional Phenomena Observed During Swelling and Release from Ionic Polymers," Annual AIChE Meeting, Miami Beach, FL, November 4, 1992, (A)*
341. "Diffusion and Sorption in Amorphous Polymer," Fifth International Symposium on Properties of Water," Peniscola, Spain, November 10, 1992, (A), *Plenary Lecturer*.
342. "Interaction of Biologically Active Molecules with Ionic Polymer Networks," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, March 1, 1993, (A)*, *Invited Lecture*.
343. "Novel Preparation Method of PVA Microparticles," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, March 1, 1993 (A)*.
344. "Synthesis and Characterization of Poly(ethylene glycol-g-methacrylic acid) Hydrogels," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, March 1, 1993, (A)*.
345. "Highly Crosslinked Polymers in Information Technology Applications," Annual ACS Meeting, Denver, CO, March 31, 1993 (P).
346. "Contemporary Issues in Hydrogels Research," Annual ACS Meeting, Denver, CO, April 1, 1993, (P), *Invited Lecture*.
347. "Complexation in P(EG-p-MAA) Hydrogels," Annual ACS Meeting, Denver, CO, April 1, 1993, (P)*.
348. "pH-Responsive Hydrogels for Controlled Drug Delivery," Annual ACS Meeting, Denver, CO, April 1, 1993, (P).
349. "Recent Advances in Transdermal and Oral Bioadhesives," Nichiban Conference, Tokyo, Japan, May 28, 1993, (A).
350. "Bioresponsive Drug Delivery Systems," International Conference on Materials for Biomedical Applications," Capri, Italy, June 10, 1993, (A), *Invited Lecture*.
351. "Dedrimers and Star Polymers for Pharmaceutical and Medical Applications," 20th International Symposium on Controlled Release of Bioactive Materials, Washington, D.C., July 27, 1993, (P), *Invited Lecture*.
352. "Thirty Years of Controlled Release Modelling," 20th International Symposium on Controlled Release of Bioactive Materials, Washington, D.C., July 26, 1993, (P).
353. Synthesis and Characterization of P(EG-g-MAA) Hydrogels," 20th International Symposium on Controlled Release of Bioactive Materials, Washington, D.C., July 27, 1993, (P)*.
354. Investigation of Poly(acrylic acid)/Mucin Bioadhesion Using ATR-FTIR Spectroscopy," 20th International Symposium on Controlled Release of Bioactive Materials, Washington, D.C., July 28, 1993, (P).

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355. "Kinetics of Photopolymerizations of Multifunctional Monomers," Annual ACS Meeting, Chicago, IL, August 1993, (P)*.
356. "The Dynamic Swelling of Ionic Networks," Annual ACS Meeting, Chicago, IL, August 1993, (P)*.
357. "Highly Swollen Copolymers of Poly(ethylene glycol-g-methacrylic acid)," Annual ACS Meeting, Chicago, IL, August 1993, (P).
358. "Near-Field FTIR and ATR-FTIR Spectroscopies for the Investigation of Diffusional Mechanisms, Annual ACS Meeting, Chicago, IL, August 1993, (P), *Invited Lecture*.
359. "Fundamentals of Controlled Release with Applications to Food Flavor Delivery," Annual ACS Meeting, Chicago, IL, August 1993, (A), *Invited Lecture*.
360. "Glassy/Rubbery Transition in Relation to Penetrant Transport and Controlled Release of Encapsulated Food Ingredients," Annual ACS Meeting, Chicago, IL, August 1993, (A), *Invited Lecture*.
361. "Controlling Protein Diffusion in Hydrogels," International Symposium on Delivery of Protein Drugs, Kyoto, Japan, September 4, 1993, (A), *Invited Lecture*.
362. "Bioadhesive Polymers," Symposium on Polymers and Bioengineering, Cambridge, MA, October 1, 1993, *Invited Lecture*.
363. "Release Mechanisms from Polymeric Carriers," First European Workshop and Exhibition on Controlled Delivery in Consumer Products, Geneva, Switzerland, October 21, 1993, (P), *Invited Lecture*.
364. "Evidence of Mucoadhesion by Chain Interpenetration at a PAA/Mucin Interface Using ATR-FTIR Spectroscopy," Annual AIChE Meeting, St. Louis, MO, November 7, 1993, (A)*.
365. "Experimental and Theoretical Studies of Diacrylate Photopolymerizations," Annual AIChE Meeting, St. Louis, MO, November 6, 1993, (A)*.
366. "Poly(methacrylic acid) Copolymer Interactions with Mucin with Applications to Mucoadhesion," Annual AIChE Meeting, St. Louis, MO, November 6, 1993, (A)*.
367. "Macromolecular Transport in Ionic Hydrogels," Annual AIChE Meeting, St. Louis, MO, November 1993, (A)*.
368. "Information Storage Systems from Highly Crosslinked Multifunctional (Meth)acrylates," Annual AIChE Meeting, St. Louis, MO, November 5, 1993, (A)*.
369. "Dissolution of Glassy Polymers," Annual AIChE Meeting, St. Louis, MO, November 6, 1993, (A)*.
370. "Comparative Studies of Oscillatory Swelling and Solute Transport in Complexing Poly(ethylene glycol-g-methacrylic acid) and Poly(acrylic acid)-containing Hydrogels," Annual AIChE Meeting, St. Louis, MO, November 6, 1993, (A), *Invited Lecture*.
371. "Environmentally Sensitive Membranes for Separation Processes," Annual AIChE Meeting, St. Louis, MO, November 7, 1993, (A)*.
372. "Intelligent Polymers as Carriers for Drug Delivery," Materials Research Society Meeting, Boston, MA, November 30, 1993, (A), *Plenary Lecture*.
373. "Poly(methacrylic acid-g-ethylene glycol) Hydrogels as pH Responsive Biomedical Materials," Materials Research Society Meeting, Boston, MA, November 30, 1993, (P)*.
374. "Temperature- and pH-Sensitive Hydrogels for Controlled Release of Antithrombotic Agents," Materials Research Society Meeting, Boston, MA, November 30, 1993, (P)*.
375. "Novel Preparation of Poly(vinyl alcohol) Microparticles Without Crosslinking Agent for Controlled Drug Delivery of Proteins," Materials Research Society Meeting, Boston, MA, November 30, 1993, (P)*.
376. "Controlled Release of Triamterene from Poly(dl-lactide-co-glycolide) Microspheres," Materials Research Society Meeting, Boston, MA, November 29, 1993, (P)*.
377. "Developments in Biomedical Research Polymers," ACS Meeting on Materials Technology for Competitive Advantage, St. Petersburgh, FL, November 22, 1993, (A), *Invited Lecture*.
378. "Dissolution of Glassy Polymers," American Physical Society Meeting, Pittsburgh, PA, March 21, 1994, (A)*.
379. "Molecular and Modelling Aspects of Dissolution of Glassy Polymers," Israeli Institute of Chemical Engineers Meeting, Beer-sheva, Israel, March 29, 1994, (A), *Invited Lecture*.
380. "Poly(methacrylic acid-g-ethylene glycol) as a pH Sensitive Biopolymer," Society for Biomaterials Meeting, Boston, MA, April 7, 1994, (P).

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381. "Recent Advances in the Development and Performance of Bioresponsive Drug Delivery Systems," 13th Pharmaceutical Technology Conference, Strasbourg, France, April 14, 1994, (A), *Plenary Lecture*.
382. "Penetrant Transport and Drug Release in pH-Sensitive Hydrogels," Midwest Meeting American Association of Pharmaceutical Scientists, Chicago, Illinois, May 23, 1994, (A)*.
383. "The Mucoadhesive Properties of Polymeric Microparticles," Midwest Meeting American Association of Pharmaceutical Scientists, Chicago, Illinois, May 23, 1994, (A)*.
384. "Moving Fronts and Drug Release from Hydrogel Matrices," 21st International Symposium on Controlled Release of Bioactive Materials, Nice, France, June 28, 1994, (P)*.
385. "Bioadhesive Interactions of PMAA and PAA with Mucin and Mucus," 21st International Symposium on Controlled Release of Bioactive Materials, Nice, France, June 29, 1994, (P).
386. "Recent Advances in Mucoadhesives for Drug Delivery," 11th Congress of ISABI, Boston, Massachusetts, July 25, 1994, (P), *Invited Lecture*.
387. "Crosslinking Methods: Applications to Controlled Release," Fourth Workshop on Controlled Delivery in Consumer Products, Chicago, IL, September 27, 1994, *Invited Lecture*.
388. "Past, Present and Future of Materials in Medicine," Meeting of Society of Medicine and Natural Sciences, Parma, Italy, October 3, 1994, *Plenary Lecture*.
389. "Future Directions in the Development of Biomaterials," Annual Meeting of the Biomedical Engineering Society, Tempe, AZ, October 15, 1994, (A), *Invited Lecture*.
390. "Mechanochemical Behavior of pH- and Temperature-Sensitive Gels," Annual Meeting of the Biomedical Engineering Society, Tempe, AZ, October 16, 1994, (A).
391. "Measurement of Chain Interpenetration at a Mucoadhesive Interface Using ATR-IR Spectroscopy," First Iranian Chemical Engineering Conference, Teheran, Iran, November 15, 1994, (A)*.
392. "Intelligent Biomaterials: Scientific Curiosity or Panacea?", Annual AIChE Meeting, San Francisco, CA, November 15, 1994, (A), *Invited Lecture*.
393. "P(NIPAAm-co-MAA) Hydrogels for Temperature-and pH-Sensitive Release of Antithrombotic Agents", Annual AIChE Meeting, San Francisco, CA, November 15, 1994, (A), *Invited Lecture*.
394. "Mechanistic Aspects and Transport Behavior during Polymer Dissolution", Annual AIChE Meeting, San Francisco, CA, November 14, 1994, (A)*.
395. "Understanding of Dissolution of Semicrystalline Polymers", Annual AIChE Meeting, San Francisco, CA, November 14, 1994, (A)*.
396. "Evidence of Mucoadhesion by Chain Interpenetration at a PAA/Mucin Interface Using ATR-FTIR Spectroscopy", Annual AIChE Meeting, San Francisco, CA, November 14, 1994, (A)*.
397. "Adhesive and Diffusive Characteristics of Novel PVA Films for Medical Applications", Annual AIChE Meeting, San Francisco, CA, November 15, 1994, (A)*.
398. "Kinetics of Multifunctional Acrylates for Information Storage Systems", Annual AIChE Meeting, San Francisco, CA, November 15, 1994, (A).
399. "Semicrystalline Polymers for Controlled Drug Delivery," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, February 16, 1995, (A)*.
400. "Release of Antithrombotic Agents," Indianapolis/Cincinnati Meeting, AAPS, Indianapolis, IN, February 16, 1995, (A)*.
401. "New Interpolymer Complexes, Star Polymers and Ionic Hydrogels in Drug Delivery Applications," Seventh International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 28, 1995, (P), *Invited Lecture*.
402. "Pulsatile Release of Antithrombotic Agents from pH- and Temperature Sensitive Hydrogels," Seventh International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 28, 1995, (A)*.
403. "Polymer Dissolution: A Modeling Attempt to "Couch" Molecular Theories in a Phenomenological Framework," American Physical Society Meeting, San Jose, CA, March 22, 1995, (A)*.
404. "Recent Advances in Modeling and Physicochemical Behavior of Swellable Polymers, Biomaterials, and Drug Delivery Systems," 5th Iketani Conference and International Symposium on Biomedical Polymers, Kagoshima, Japan, April 19, 1995, (P), *Invited Lecture*.
405. "Zero Order Release by Partial Coating of HPMC Matrix Tablets with Permeable and Semipermeable Films," First World Congress of Pharmaceutics and Biopharmaceutics, Budapest, Hungary, May 9, 1995, (P)*.

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406. "Bioadhesive Poly(vinyl alcohol) as a Carrier for Controlled Release of Growth Factors and Proteins," First World Congress on Pharmaceutics and Biopharmaceutics, Budapest, Hungary, May 9, 1995, (P).
407. "Mucoadhesive Properties of Hydrophilic Polymeric Microparticles," 35th Symposium of AFI, Italian Pharmaceutical Association, Riccione, Italy, June 9, 1995, (A)*.
408. "Control and Modeling of Drug Delivery Devices for the Treatment of Diabetes," American Control Conference, Seattle, June 22, 1995, (P)*.
409. "Fickian and non-Fickian Diffusion in Swellable Gels," 36th IUPAC Microsymposium on High-Swelling Gels, Prague, Czech Republic, July 10, 1995, (A), *Plenary Lecture*.
410. "Transport in Hydrophilic Polymer Gels: Applications in Controlled Release," 22nd International Symposium of Controlled Release of Bioactive Materials, Seattle, WA, August 1, 1995, (P)*.
411. "Effect of Dissolution on Lamellar Thickness Distribution of Semi-Crystalline Poly(vinyl alcohol)," Annual ACS Meeting, Chicago, IL, August 24, 1995, (P)*.
412. "Development of a Dissolution-controlled, Zero-order Release, Drug Delivery System," Annual ACS Meeting, Chicago, IL, August 21, 1995, (P)*.
413. "Recent Developments in Insulin Delivery and Control Using Hydrogel Systems," Spanish Portuguese Conference on Controlled Drug Delivery, Santiago de Compostela, Spain, September 25, 1995, (P), *Invited Lecture*.
414. "Chain Disentanglement and Reptation Mechanisms During Polymer Dissolution," Annual AIChE Meeting, Miami Beach, FL, November 13, 1995, (A)*.
415. "A New Model for Dissolution of Semicrystalline Polymers," Annual AIChE Meeting, Miami Beach, FL, November 13, 1995, (A)*.
416. "Transport in Swellable Polymer Systems for Controlled Drug Release," Annual AIChE Meeting, Miami Beach, FL, November 13, 1995, (A)*.
417. "Rate Behavior in Solution Polymerization of Acrylic Acid," Annual AIChE Meeting, Miami Beach, FL, November 13, 1995, (A)*.
418. "Swelling/Deswelling Behavior in pH-Responsive Hydrogels of Ethylene Glycol Poly(Methacrylic acid) Copolymers," Annual AIChE Meeting, Miami Beach, FL, November 13, 1995, (A)*.
419. "Glucose-responsive Gels for the Release of Insulin," Annual AIChE Meeting, Miami Beach, FL, November 13, 1995, (A)*.
420. "Intelligent Hydrogel Systems for Protein and Drug Release with Feedback Control," 3rd US-Japan Symposium on Drug Delivery Systems, Maui, HI, December 18, 1995, (A), *Invited Lecture*.
421. "A Self-Consistent Diffusivity Approach to Understand Polymer Dissolution," American Physical Society Meeting, St. Louis, MO, March 19, 1996, (A)*.
422. "Modeling of Dissolution of Semicrystalline Polymers," American Physical Society Meeting, St. Louis, MO, March 19, 1996, (A)*.
423. "Modification of Drug Release Profiles and Swelling Behavior in Poly(vinyl alcohol) due to the Presence of a Crystalline Phase," American Chemical Society Meeting, New Orleans, LA, March 26, 1996, (P)*.
424. "On the Mechanisms of Water Transport and Drug Release from Swellable Hydrogels," American Chemical Society Meeting, New Orleans, LA, March 27, 1996, (P)*.
425. "Solid State NMR Spectroscopy for Characterization of Acrylate Reaction," American Chemical Society Meeting, New Orleans, LA, March 26, 1996, (P).
426. "Radiation Crosslinked Poly(ethylene oxide) Hydrogels Show Insignificant Diffusional Screening Effects," American Chemical Society Meeting, New Orleans, LA, March 26, 1996, (P).
427. "An Experimental Study of Acrylic Acid Crosslinking Polymerizations," American Chemical Society Meeting, New Orleans, LA, March 27, 1996, (P)*.
428. "Molecular Aspects of the Swelling Behavior of Interpolymer Complexing Hydrogels," American Chemical Society Meeting, New Orleans, LA, March 27, 1996, (P)*.
429. "Glucose-responsive Complexation Hydrogels," American Chemical Society Meeting, New Orleans, LA, March 27, 1996, (P)*.
430. "Kinetics of UV Polymerization of Acrylic Acid," American Chemical Society Meeting, New Orleans, LA, March 27, 1996, (P)*.
431. "Release of Insulin from Glucose-Sensitive Hydrogel," American Chemical Society Meeting, New Orleans, LA, March 27, 1996, (P)*.

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432. "Design of New Biomaterials for Drug Delivery: Tailoring the Structure to Specific Delivery Needs and Release Requirements," European Course on New Forms and New Routes of Administration of Drugs, Parma, Italy, March 30, 1996, (A), *Plenary Lecture*.
433. "Mucoadhesive PVA Hydrogels for Release of Wound Healing Drugs," Fifth World Biomaterials Congress, Toronto, Canada, June 1, 1996, (P).
434. "Recent Advances on Characterization, Morphology and Structural Modification of PVA with Emphasis on Diffusional and Adhesive Characteristics," 108th Poly(vinyl alcohol) Meeting, Kyoto, Japan, July 6, 1996, (A), *Plenary Lecture*.
435. "Mucoadhesive PEG-tethered Microparticulate Systems for Gastrointestinal and Vaginal Drug Delivery," 23rd International Symposium on Controlled Release of Bioactive Materials, Kyoto, Japan, July 9, 1996 (P).
436. "Oral Delivery Devices from Freeze/Thawed PVA Hydrogels," 23rd International Symposium on Controlled Release of Bioactive Materials, Kyoto, Japan, July 9, 1996 (P).
437. "Mucoadhesive PVA Films Produced by Freezing/Thawing Processes for the Release of Small Molecular Weight Solutes and for Wound Healing Systems," 23rd International Symposium on Controlled Release of Bioactive Materials, Kyoto, Japan, July 9, 1996 (P).
438. "Unique Swelling-Controlled Release Systems Based on Temperature- and pH-Sensitive Terpolymers for Fibrinolytic Enzyme Delivery," 23rd International Symposium on Controlled Release of Bioactive Materials, Kyoto, Japan, July 10, 1996 (P).
439. "Oscillatory Drug and Protein Release by a Complexation/Decomplexation Mechanism," 23rd International Symposium on Controlled Release of Bioactive Materials, Kyoto, Japan, July 10, 1996, (P)*.
440. "Robust Model-Based Control of Insulin Pumps and Devices," 23rd International Symposium on Controlled Release of Bioactive Materials,Kyoto, Japan, July 10, 1996, (P)*, *Plenary Lecture*.
441. "Investigation of Drug/Polymer Interactions in the Hydrated State," Conference on Advances in Controlled Delivery, Baltimore, MD, August 19, 1996, (P)*.
442. "Crystal Dissolution-Controlled Release Systems: A Novel Technology for Facile Programmed Release of Drugs," Conference on Advances in Controlled Delivery, Baltimore, MD, August 20, 1996, (P).
443. "Independent Effects of pH and Monomer Concentration on the Kinetics of Acrylic Acid Solution Polymerization," American Chemical Society Meeting, Orlando, FL, August 26, 1996, (P)*.
444. "Network Formation by Chain Polymerization of Liquid-Crystalline Monomers," Polymer Networks 96 Meeting, Doorn, The Netherlands, September 4, 1996, (A)*.
445. "Model Predictive Control for Infusion Pump Insulin Delivery," 18th Annual International Conference IEEE, Engineering in Medicine and Biology Society, Amsterdam, The Netherlands, November 2, 1996, (P)*.
446. "Influence of Molecular Parameters of Glassy Crosslinked Polymer on Swelling-Controlled Solute Release Profiles," Annual AIChE Meeting, Chicago, IL, November 12, 1996, (A)*.
447. "Insulin Delivery Using Model-Based Control of Insulin Infusion Pumps," Annual AIChE Meeting, Chicago, IL, November 12, 1996, (A)*.
448. "New Directions in Drug Delivery," Annual AIChE Meeting, Chicago, IL, November 12, 1996, (A), *Invited Lecture*.
449. "Understanding Polymer Dissolution Using Self-Consistent Diffusion Coefficient Models and Comparison with Magnetic Resonance Imaging Analysis," Annual AIChE Meeting, Chicago, IL, November 13, 1996, (A)*.
450. "Characterization of PVA Prepared by Freezing/Thawing Techniques," Annual AIChE Meeting, Chicago, IL, November 13, 1996, (A).
451. "A Calorimetric Evaluation of the pH- and Conversion-Dependent Kinetics of (Meth)acrylic Acid Solution Polymerization," Annual AIChE Meeting, Chicago, IL, November 14, 1996, (A)*.
452. "Dissolution Mechanism of Thin Semicrystalline Polymer Films," Annual AIChE Meeting, Chicago, IL, November 14, 1996, (A)*.
453. Crystal Dissolution Controlled Drug Delivery Systems: A New Method of Drug or Protein Delivery," Annual AIChE Meeting, Chicago, IL, November 15, 1996, (A)*.
454. "Glucose-Sensitive, Poly(ethylene glycol)-Grafter Copolymer Networks for Feedback Responsive Insulin Delivery," Annual AIChE Meeting, Chicago, IL, November 15, 1996, (A)*.

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455. "Interpolymer Complexation in Polyelectrolyte Biopolymers," Annual AIChE Meeting, Chicago, IL, November 15, 1996, (A)*.
456. "Preparation, Swelling Behavior, and Insulin Release from Glucose-Responsive Complexation Hydrogels," Annual AIChE Meeting, Chicago, IL, November 15, 1996, (A)*.
457. "Preparation and Characterization of pH-Sensitive, Cationic Hydrogels," Annual AIChE Meeting, Chicago, IL, November 15, 1996, (A)*.
458. "Design of New Biomaterials for Drug Delivery: Tailoring the Structure to Specific Delivery Needs and Release Requirements," UK CRS Meeting, Manchester, United Kingdom, January 6, 1997, (A), *Invited Lecture*.
459. "Application of pH Responsive Polymer to an insulin Oral Dosage Form," 12th Annual Meeting Academy Pharmaceutical Sciences and Technology, Ohmiya, Japan, April 41997, (P)*.
460. "Novel Networks and Gels Containing Increased Amounts of Grafted and Crosslinked Poly(ethylene glycol)," American Chemical Society Meeting, San Francisco, CA, April 15, 1997, (P)*.
461. "Preparation and Characterization of Random Copolymers of Acrylic Acid and Multifunctional Acrylates," American Chemical Society Meeting, San Francisco, CA, April 15, 1997, (P)*.
462. "Computer Simulations of Liquid-Crystalline Diacrylate Monomer Polymerization," American Chemical Society Meeting, San Francisco, CA, April 15, 1997, (P)*.
463. "A Complexation/Decomplexation Mechanism in pH-Responsive Copolymer Networks," American Chemical Society Meeting, San Francisco, CA, April 15, 1997, (P)*.
464. "Graft Copolymers of PEO-PPO-PEO Triblock Polyethers on Bioadhesive Polymer Backbones: Synthesis and Properties," American Chemical Society Meeting, San Francisco, CA, April 15, 1997, (P)*.
465. "Molecular Analysis of the Dissolution of Glassy Polymers," American Chemical Society Meeting, San Francisco, CA, April 15, 1997, (P)*.
466. "Preparation and Characterization of Glucose-Sensitive P(MAA-g-EG) Hydrogels," American Chemical Society Meeting, San Francisco, CA, April 15, 1997, (P)*.
467. "Graft Copolymers of PEO-PPO-PEO Triblock Polyethers on Bioadhesive Polymer Backbones for use as Drug Delivery Carriers," American Chemical Society Meeting, San Francisco, CA, April 15, 1997, (P)*.
468. "Pulsatile Drug Delivery Systems Based on Interpolymer Complexing Biopolymer Networks," Society for Biomaterials Meeting, New Orleans, LA, May 3, 1997, (P)*.
469. "Drug Delivery Systems Controlled by Polymer Carrier Dissolution: Formulation and Performance," Society for Biomaterials Meeting, New Orleans, LA, May 3, 1997, (P).
470. "Recent Applications in Therapeutic pH- and Temperature-Sensitive Systems," First Argentinian CRS International Symposium, Buenos Aires, Argentina, May 13, 1997, (P), *Invited Lecture*.
471. "Peptide and Protein Diffusion in Polymeric Systems," First Argentinian CRS International Symposium, Buenos Aires, Argentina, May 13, 1997, (P), *Invited Lecture*.
472. "Oral Drug Delivery Using Swellable and pH-Sensitive Systems," First Greek CRS Conference, Athens, Greece, May 26, 1997, (P), *Invited Lecture*.
473. "Analysis of Swelling-Controlled Release Systems for Optimization of Drug Delivery," 24th International Symposium on Controlled Release of Bioactive Materials, Stockholm, Sweden, June 17, 1997, (P)*.
474. "Magnetic Resonance Imaging Analysis of Soluble Drug Delivery Carriers," 24th International Symposium on Controlled Release of Bioactive Materials, Stockholm, Sweden, June 17, 1997, (P).
475. "Drug Concentration Profiles During Release from Hydrophilic Matrices," 24th International Symposium on Controlled Release of Bioactive Materials, Stockholm, Sweden, June 17, 1997, (P)*.
476. "Design of Oral Controlled Drug Delivery Systems for Insulin," 11th World Congress of the International Society for Artificial Organs, Providence, RI, July 1, 1997 (A)*.
477. "Variable-rate Implantable Insulin Infusion Pumps: Closed-loop Maintenance of Normoglycemia Under Patient Variability for Type I Diabetes," 11th World Congress of the International Society for Artificial Organs, Providence, RI, July 1, 1997 (A)*.
478. "Poly(ethylene glycol)-Tethered Controlled Release Systems with Improved Mucoadhesive Behavior: Preparation and Studies with ATR-FTIR Spectroscopy," Japanese Drug Delivery Systems Society Meeting, Sapporo, Japan, July 11, 1997(P), *Plenary Lecture*.

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479. "Biomaterials for Developing Pharmaceutical Preparations of High Quality of Life," Annual Meeting of Academy of Pharmaceutical Sciences and Technology, Kitamazu, Chiba, Japan, July 14, 1997 (P), *Plenary Lecture*.
480. "Protein Delivery from Novel Bioadhesive Complexation Hydrogels," Alfred Benzon Symposium, Copenhagen, Denmark, August 19, 1997 (A), *Invited Lecture*.
481. "Self-diffusion and Molecular Mobility in PVA-based Dissolution-Controlled Systems for Drug Delivery," Fourth International Meeting of Recent Advancesin Magnetic Resonance Applications to Porous Media, Trondheim, Norway, September 2, 1997 (A)*.
482. "Complexation Graft Copolymers as Oral Drug Delivery Systems," American Chemical Society Meeting, Las Vegas, NV, September 9, 1997 (P)*.
483. "Novel Copolymeric Acrylate Networks for Sustained Solute Delivery," American Chemical Society Meeting, Las Vegas, NV, September 10, 1997, (P)*.
484. "Preparation and Characterization of PEG-Containing pH-Sensitive, Cationic Hydrogels for Drug Delivery Applications," American Chemical Society Meeting, Las Vegas, NV, September 10, 1997, (P).
485. "Morphology of Poly(Vinyl Alcohol) Gels Prepared by a Freezing/Thawing Process," American Chemical Society Meeting, Las Vegas, NV, September 10, 1997, (A).
486. "Time and Frequency Domain Analysis of Blood Glucose Regulation Algorithms," 19th IEEE Engineering in Medicine and Biology Conference, Chicago, IL, November 1, 1997, (A)*.
487. "The Importance of the Drug Diffusion Front in Drug Delivery Kinetics from Swellable Matrices," American Association of Pharmaceutical Scientists Meeting, Boston, MA, November 4, 1997, (A)*
488. "Design of Oral Delivery Systems for Peptides and Proteins Using Complexation Graft Copolymer Networks," Annual AIChE Meeting, Los Angeles, CA, November 18, 1997, (P)*.
489. "Molecular and Release Characteristics of Dissolution-Controlled Drug Delivery Systems," Annual AIChE Meeting, Los Angeles, CA, November 18, 1997, (P)*.
490. "Glucose-Sensitive Cationic Hydrogels: Preparation Characterization and Modeling of Swelling Properties," Annual AIChE Meeting, Los Angeles, CA, November 18, 1997, (P)*.
491. "Analysis of Insulin Administration and Absorption from Ocular/Lacrimal/Nasal Systems with or without Enhancers," Annual AIChE Meeting, Los Angeles, CA, November 18, 1997, (P)*.
492. "Control Analysis of Pancreas Models for Optimal Insulin Delivery," Annual AIChE Meeting, Los Angeles, CA, November 18, 1997, (P)*.
493. "Protein and Drug Transport in PVA/PAA Composite Membranes Prepared by Freezing/Thawing Techniques," Annual AIChE Meeting, Los Angeles, CA, November 18, 1997, (P).
494. "Probing the Network Structure of Highly Crosslinked Ionizable Polymers," Annual Physical Society Meeting, Los Angeles, CA, March 18, 1998, (A)*.
495. "Network Structure and Diffusion in Highly Crosslinked Ionizable Polymers," Annual Physical Society Meeting, Los Angeles, CA, March 18, 1998, (A)*.
496. "NMR Imaging Analysis of Self-Diffusion and Molecular Mobility During Dissolution of Water-Soluble Polymers," Annual Physical Society Meeting, Los Angeles, CA, March 18, 1998, (A)*.
497. "NMR Study of Interpolymer Complexation in Polyelectrolyte Gels Using the Nuclear Overhauser Effect," Annual Physical Society Meeting, Los Angeles, CA, March 18, 1998, (A)*.
498. "Analysis of the Complexation/Decomplexation Behavior of Polyelectrolyte Gels," Annual Physical Society Meeting, Los Angeles, CA, March 18, 1998, (A)*.
499. "Physicochemical and Mathematical Factors Influencing Drug Delivery," Annual Society for Biomaterials Meeting, San Diego, CA, April 21, 1998, (A), *Invited Lecture*.
500. "Novel Bioadhesive Complexation Gels for Oral Peptide Delivery," Annual Society for Biomaterials Meeting, San Diego, CA, April 23, 1998, (P)*.
501. "Interpretation of Drug Release Kinetics and Drug Concentration Profiles in HPMC Gels," Second World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Paris, France, May 26, 1998, (P)*.
502. "Poly(ethylene glycol)-containing Hydrogels in Drug Delivery," Conference on Challenges for Drug Delivery and Pharmaceutical Technology, Tokyo, Japan, June 10, 1998, (P), *Invited Lecture*.
503. "Application of pH-Responsive Polymers to Insulin Oral Dosage Forms," Conference on Challenges for Drug Delivery and Pharmaceutical Technology, Tokyo, Japan, June 11, 1998, (P)*, *Invited Lecture*.

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504. "Nasal Administration and Bioadhesive Polymers in Rabbits," Conference on Challenges for Drug Delivery and Pharmaceutical Technology, Tokyo, Japan, June 11, 1998, (P)*.
505. "Polymer Relaxation in Swellable Matrices Contributes to Drug Release," 25th International Symposium on Controlled Release of Bioactiive Materials, Las Vegas, Nevada, June 22, 1998, (P).
506. "Pure PVA Hydrogels Using Freezing/Thawing Techniques as Carriers for Drug Delivery," 25th International Symposium on Controlled Release of Bioactiive Materials, Las Vegas, Nevada, June 22, 1998, (P)*.
507. "Insulin Release from pH-Sensitive Cationic Hydrogels," 25th International Symposium on Controlled Release of Bioactiive Materials, Las Vegas, Nevada, June 23, 1998, (P)*.
508. "Molecular Design of Ionizable PEG-Containing Networks for Extended Solute Release," 25th International Symposium on Controlled Release of Bioactiive Materials, Las Vegas, Nevada, June 23, 1998, (P).
509. "Drug Transport Analysis in Complex Networks Using Molecular Probes," 25th International Symposium on Controlled Release of Bioactiive Materials, Las Vegas, Nevada, June 24, 1998, (P)*.
510. "Modelling of Controlled Release Systems for Consumer Products," 25th International Symposium on Controlled Release of Bioactiive Materials, Las Vegas, Nevada, June 23, 1998, (P).
511. "Synthesis and Characterization of Poly(ethylene glycol) Star Polymer Gels for Medical and Pharmaceutical Applications," 25th International Symposium on Controlled Release of Bioactiive Materials, Las Vegas, Nevada, June 24, 1998, (P)*.
512. "Novel PNIPAAm/PMAA Interpenetrating Polymer Networks," 25th International Symposium on Controlled Release of Bioactiive Materials, Las Vegas, Nevada, June 24, 1998, (P)*.
513. "Solid-state NMR Investigation of Interpolymer Complexation in Swollen Copolymer Networks," Annual American Chemical Society Meeting, Boston, MA, August 27, 1998, (P)*.
514. "Long-term Morphological Changes in Freeze-thawed PVA Hydrogels," Annual American Chemical Society Meeting, Boston, MA, August 27, 1998, (P)*.
515. "Structure and Solute Size Exclusion of Poly(N-isopropylacrylamide)/Poly(methacrylic acid) Interpenetrating Polymeric Networks," Annual American Chemical Society Meeting, Boston, MA, August 27, 1998, (P)*.
516. "Contract Research Organizations and Their Role and Importance," Symposium on New Drug Developments in Pharmaceutical Sciences and Drug Registration, Istanbul, Turkey, September 5, 1998.
517. "Macromolecules as Excipients," 9th International Pharmaceutical Technology Symposium, Ankara, Turkey, September 8, 1998 (A), *Plenary Lecture*.
518. "Excipients for Food, Cosmetic and Consumer Applications," 9th International Pharmaceutical Technology Symposium, Ankara, Turkey, September 8, 1998 (A), *Plenary Lecture*.
519. "Poly(ethylene glycol) Star Polymer Hydrogels," Sixth Annual Chemical Engineering Graduate Student Symposium, Lexington, Kentucky, September 18, 1998, (P)*.
520. "Kinetics and Modeling of UV Polymerizations Initiated with an Iniferter," Sixth Annual Chemical Engineering Graduate Student Symposium, Lexington, Kentucky, September 18, 1998, (P)*.
521. "Novel pH-Sensitive Hydrogels for the Oral Delivery of Salmon Calcitonin," Sixth Annual Chemical Engineering Graduate Student Symposium, Lexington, Kentucky, September 18, 1998, (P)*.
522. "Modelling of the Swelling Process and the Diffusion Front Position in Hydrophilic Matrices," Sixteen Meeting of ADRITELF, Pisa, Italy, October 9, 1998, (A)*.
523. "Advances in Drug and Protein Delivery," First International Pharmaceutical Students Federation Meeting, Coimbra, Portugal, November 3, 1998 (A), *Plenary Lecture*.
524. "A New Model Describing the Swelling and Drug Release Kinetics from HPMC Tablets," Annual American Association of Pharmaceutical Scientists Meeting, San Francisco, CA, November 13, 1998, (P)*.
525. "Some Properties of Novel Multifunctional pH-Sensitive and Bioadhesive Polymers," Annual American Association of Pharmaceutical Scientists Meeting, San Francisco, CA, November 13, 1998, (P)*.
526. "Biomaterials and Drug Delivery Systems," Annual AIChE Meeting, Miami Beach, FL, November 12, 1998, *Plenary Lecture*.
527. "Poly(ethylene glycol) Star Polymer Hydrogels," Annual AIChE Meeting, Miami Beach, FL, November 14, 1998, (A)*.

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528. "Structure and Morphology of Novel Poly(vinyl alcohol) Hydrogels Prepared by Freezing/Thawing Processes," Annual AIChE Meeting, Miami Beach, FL, November 14, 1998, (A)*.
529. "Molecular Level Investigation of Interpolymer Complexation in Copolymer Gels," Annual AIChE Meeting, Miami Beach, FL, November 14, 1998, (A)*.
530. "Experiments and Modelling of Ultraviolet Polymerizations," Annual AIChE Meeting, Miami Beach, FL, November 14, 1998, (A)*.
531. "Uncertainty and Robustness in Diabetic Patient Blood Glucose Control," Annual AIChE Meeting, Miami Beach, FL, November 14, 1998, (A)*.
532. "Preparation and Characterization of Poly(N-isopropyl acrylamide)/Poly(methacrylic acid) Interpenetrating Polymeric Networks," Annual AIChE Meeting, Miami Beach, FL, November 14, 1998, (A)*.
533. "pH-Sensitive Hydrogels with PEG-tethered Chains for Oral Delivery of Calcitonin," Annual MRS Meeting, Boston, MA, December 1, 1998, (A)*.
534. "Molecular Aspects of Muco- and Bioadhesion: Tethered Structures andSite-Specific Surfaces," Ninth International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 22, 1999, (P), *Invited Lecture*.
535. "Advances in Gel Science and Technology," US-Israel-Turkey NSF Meeting on Chemical Engineering, Haifa, Israel, March 10, 1999, (A), *Invited Lecture*.
536. "The Characterization of P(PEGMA-co-PEGDMA) Gels for Use in Coating the Tract of a Transjugular Intrahepatic Porto-systemic Shunt," Annual American Chemical Society Meeting, Anaheim, CA, March 24, 1999 (P)*.
537. "Structural and Morphological Characteristics of Carriers Based on Poly(acrylic acid)," Annual American Chemical Society Meeting, Anaheim, CA, March 24, 1999 (P)*.
538. "pH-Dependent Swelling of Nano-sized Poly(methacrylic acid-g-ethylene glycol) Gels," Annual American Chemical Society Meeting, Anaheim, CA, March 24, 1999 (P)*.
539. "A Thermodynamic Study of Polymer Chains Tethered on Gel Surfaces," Annual American Physical Society Meeting, Atlanta, GA, March 25, 1999 (A)*.
540. "Poly(N-isopropyl acrylamide)/Poly(methacrylic acid) Interpenetrating Polymeric Networks in Drug Delivery," Midwestern AAPS Meeting, Chicago, IL, May 17, 1999 (A)*.
541. "Targeted Oral Delivery of Insulin from Complexation Hydrogels," Annual Meeting of Society for Biomaterials, Providence, RI, April 30, 1999 (P)*, *Invited Lecture*.
542. "Intelligent Hydrogels and their Biotechnological and Separation Applications," Meeting of International Atomic Energy Agency, Takasaki, Japan, May 18, 1999 (P).
543. "Tailor-made Networks of Poly(ethylene glycol) for Controlled Drug Delivery," 26th International Symposium on Controlled Release of Bioactive Materials, Boston, MA, June 22, 1999, (P)*.
544. "P(AA-g-PEG) Copolymer Gels as Carriers for Delivery of Chemotherapeutic Agents," 26th International Symposium on Controlled Release of Bioactive Materials, Boston, MA, June 22, 1999, (P)*.
545. "A New Model Elucidating the Transport Mechanisms and Predicting the Release Kinetics from HPMC Matrices," 26th International Symposium on Controlled Release of Bioactive Materials, Boston, MA, June 22, 1999, (P)*.
546. "Protein Release from PVA Gels Prepared by Freezing and Thawing Techniques," 26th International Symposium on Controlled Release of Bioactive Materials, Boston, MA, June 22, 1999, (P)*.
547. "Kinetic Gelation Modeling of Polymer Networks Formed by a Living Radical Polymerization," Annual American Chemical Society Meeting, New Orleans, LA, August 23, 1999 (P)*.
548. "Interpenetrating Polymeric Networks with pH and Temperature Sensitivity," Annual American Chemical Society Meeting, New Orleans, LA, August 24, 1999 (P)*.
549. "Recent Advances and Molecular Observations on the Controlled Drug and Protein Delivery," Third Central European Symposium on Pharmaceutical Technology, Portoroz, Slovenia, September 23, 1999 (P), *Plenary Lecture*.
550. "Long and Short Chains Tethered on Gel Surfaces," Annual AIChE Meeting, Dallas, TX, October 31, 1999 (A)*.
551. "Kinetic Simulation and Analysis of PEG-containing Networks synthesized by Free Radical Polymerizations," Annual AIChE Meeting, Dallas, TX, November 1, 1999 (A)*.
552. "Robust H_∞ Control of Type I Diabetic Patient Blood Glucose," Annual AIChE Meeting, Dallas, TX, November 2, 1999 (A)*.

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553. "Analysis of Diffusional and Structural Characteristics of PVA Hydrogels Prepared by Freezing-Thawing Techniques," Annual American Association of Pharmaceutical Scientists Meeting, New Orleans, LA, November 16, 1999 (A).
554. "Poly(ethylene glycol) Tethered Chains and Their Roles in Gel Mucoadhesion," Annual American Association of Pharmaceutical Scientists Meeting, New Orleans, LA, November 16, 1999 (A).
555. "Molecular Structure and Diffusive Behavior of Poly(ethylene glycol)-Grafted Poly(acrylic acid) Hydrogels as Drug Carriers," Annual American Association of Pharmaceutical Scientists Meeting, New Orleans, LA, November 16, 1999 (A).
556. "Advances in Protein and Bioadhesive Delivery," US-Japan Drug Delivery Meeting, Maui, HI, December 14, 1999 (A).
557. "Development of Nano-sized pH-sensitive Complex Hydrogles for Oral Peptide Delivery," Annual Meeting of Society of Powder Technologies, Japan, Kobe, Japan, November 24, 1999.
558. "Gaseous and Solute Transport in Hydrogels," Symposium on Biomedical Polymers for the 21st Century, Boston, MA, March 17, 2000 (P), *Plenary Lecture*.
559. "Novel Patterned Films for Free-Radical Polymerization Techniques," Annual American Physical Society Meeting, Minneapolis, MN, March 21, 2000 (A)*.
560. "Kinetic Simulation of Networks Synthesized by Free Radical Polymerization," Annual American Physical Society Meeting, Minneapolis, MN, March 21, 2000 (A)*.
561. "Morphology and Dynamics of Interpenetrating Polymeric Networks with Combined pH and Temperature Sensitivity," Annual American Physical Society Meeting, Minneapolis, MN, March 21, 2000 (A)*.
562. "A New Mean-field Theory for Equilibrium Gel Swelling," Annual American Physical Society Meeting, Minneapolis, MN, March 21, 2000 (A)*.
563. "Tethered Polymer Chains Contribute to Gel-Gel Adhesion," Annual American Physical Society Meeting, Minneapolis, MN, March 21, 2000 (A)*.
564. "Fickian and non-Fickian Processes in Swellable Controlled Release Systems," Annual American Chemical Society Meeting, San Francisco, CA, March 26, 2000 (A), *Invited Lecture*.
565. "Cytotoxicity and Transport Enhancement of Proteins Through Cell Monolayers Using Novel pH-Sensitive Hydrogels," Third World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Berlin, Germany, April 6, 2000 (P)*.
566. "Calculation of the Required Size and Shape of HPMC Matrices to Achieve Desired Drug Release Profiles," Third World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Berlin, Germany, April 6, 2000 (P)*.
567. "Micropatterning and Molecular Imprinting for Medical Applications," Sixth European Symposium on Controlled Drug Delivery, Noordwijk aan Zee, Netherlands, April 12, 2000 (P), *Invited Lecture*.
568. "Tethered Polymers for Controlled Drug Delivery," Millennial World Congress of Pharmaceutical Sciences, San Francisco, CA, April 18, 2000, (A), *Invited Lecture*.
569. "Design of Advanced Biomaterials and Drug Delivery Carriers," Sixth World Congress for Biomaterials, Kamuela, Hawaii, May 19, 2000, (P), *Plenary Lecture*.
570. "Calcitonin Transport Through Poly(methacrylic acid)-PEG-Grafted Hydrogels Using a CaCo-2 Model," Sixth World Congress for Biomaterials, Kamuela, Hawaii, May 16, 2000 (P)*.
571. "Patterning and Molecular Imprinting with Polyfunctional Methacrylates," Sixth World Congress for Biomaterials, Kamuela, Hawaii, May 16, 2000 (P)*.
572. "Intelligent Biopolymers in Protein and Drug Delivery," Eleventh North American Membrane Society Meeting, Boulder, Colorado, May 26, 2000 (A), *Plenary Lecture*.
573. "Molecularly Imprinted Hydrogels with Polyfunctional Methacrylates," First International Workshop on Molecularly Imprinted Polymers, Cardiff, United Kingdom, July 5, 2000 (P)*.
574. "Non-covalent Molecular Imprinting of Glucose: Recognition in Aqueous Media," First International Workshop on Molecularly Imprinted Polymers, Cardiff, United Kingdom, July 5, 2000 (P)*.
575. "A New Mathematical Model to Predict Drug Release from Hydrophilic Matrices: The "Squential Layers" Model", 27th International Symposium on Controlled Release of Bioactive Materials, Paris, France, July 11, 2000, (P)*.
576. "Molecular Design of New Biomaterials for Controlled Release," 27th International Symposium on Controlled Release of Bioactive Materials, Paris, France, July 13, 2000, (P)*, *Invited Lecture*.

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577. “A New Dispersion Technique for Micro- and Nanoparticle Formation of Drug Delivery Carriers Based on Poly(acrylic acid)", 27th International Symposium on Controlled Release of Bioactive Materials, Paris, France, July 13, 2000, (P)*.
578. “A New Dispersion Technique for Micro- and Nanoparticle Formation of Drug Delivery Carriers Based on Poly(acrylic acid),” 40 th Minisymposium on Polymers in Medicine, Prague, July 19, 2000, (A)*.
579. "Glucose Responsive pH-Dependent Hydrogels," World Congress of Biomedical Engineering, Chicago, IL, July 25, 2000 (A)*.
580. "Novel pH-Sensitive Hydrogels for the Oral Delivery of Calcitonin: Caco-2 Cell Studies," World Congress of Biomedical Engineering, Chicago, IL, July 26, 2000 (A)*.
581. "UV Free Radical Polymerization for Micropatterning Poly(ethylene glycol)-containing Films," 45th SPIE Meeting, San Diego, CA, July 31, 2000 (P)*.
582. “Protein and Drug Delivery: Recent Successes and Future Challenges,” Whitaker Foundation Meeting, La Jolla, CA, August 13, 2000 (A), *plenary lecture*.
583. “Molecular Dynamics of pH-Sensitive Hydrogels Based on Poly(acrylic acid),” Annual ACS Meeting, Washington, DC, August 23, 2000 (P)*.
584. “Molecular Design of Mucoadhesive Drug Delivery Systems,” British Pharmaceutical Conference, Birmingham, United Kingdom, September 12, 2000 (A), *invited lecture*.
585. “Molecularly Imprinted Polyfunctional Methacrylates for Drug Delivery Applications,” Tenth International Pharmaceutical Technology Symposium, Instanbul, Turkey, September 12, 2000 (P)*.
586. “New Biomedical Gels Materials with Tethered Chains: Theory and Biological Interactions,” Third Joint China/USA Chemical Engineering Conference, Beijing, Chinca, September 27, 2000 (P)*.
587. “Poly(ethylene glycol)-containing Hydrogels as Insulin Delivery Carriers,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, October 31, 2000 (A)*.
588. “New Biomedical Gel Materials with Tethered Chains: Theory and Biological Interactions,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, October 31, 2000 (A)*.
589. “Poly(ethylene glycol)-containing Hydrogels as Insulin Delivery Carriers,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, October 31, 2000 (A)*.
590. “pH-Sensitive Drug Delivery Carriers Based on Modified Poly(acrylic acid),” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, October 31, 2000 (A)*.
591. “Recognition Mechanisms of Molecularly Imprinted Polymers: Smart Systems for Drug Delivery,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 1, 2000 (A)*.
592. “Non-covalent Molecular Imprinting of Glucose in Polar Protic Media,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 1, 2000 (A)*.
593. C. Donini, D.N. Robinson and N.A. Peppas, “Preparation and Characterization of pH-Sensitive Poly(methacrylic acid-g-Ethylene Glycol) Microspheres for Oral Insulin Delivery,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 1, 2000 (A)*.
594. “Drug Release Mechanisms from HPMC Matrices,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 1, 2000 (A)*.
595. “Novel pH-Sensitive Hydrogels for Oral Peptide Delivery: In Vitro Evaluation of their Cytocompatibility and Insulin-Transport Enhancing Effect in Caco-2 cell Monolayers,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 1, 2000 (A)*.
596. “ Development and Cytotoxicity of Poly(methacrylic acid-g-Poly(ethylene glycol)) Microparticles for Use as Drug Carriers in Oral Delivery,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 2, 2000 (A)*.
597. “Preparation of Thermosensitive Hydrogel Nanoparticles Containing Poly(ethylene glycol) for Microencapsulation of Peptides in the Wurster Coating Process,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 2, 2000 (A)*.
598. “Multilaminate PVA Hydrogel Systems as Protein Controlled Release Devices,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 2, 2000 (A)*.
599. “Drug Volume Fraction Profiles in HPMC Matrices by Image Analysis,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 2, 2000 (A)*.
600. “The Use of Self-Assembled Monolayers to Study Mucoadhesion,” Annual American Association of Pharmaceutical Scientists Meeting, Indianapolis, IN, November 2, 2000 (A)*.

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601. "Design of Advanced Biomaterials and Drug Delivery Carriers," Annual AIChE Meeting, Los Angeles, CA, November 13, 2000 (A), *invited lecture*.
602. "Future Directions of Drug and Protein Delivery," Annual AIChE Meeting, Los Angeles, CA, November 13, 2000 (A), *invited lecture*.
603. "Temperature-Sensitive Particulate Systems Containing Poly(ethylene glycol)," Annual AIChE Meeting, Los Angeles, CA, November 13, 2000 (A)*.
604. "Poly(methacrylic Acid-g-Ethylene Glycol) Microspheres for Protein Delivery Applications," Annual AIChE Meeting, Los Angeles, CA, November 14, 2000 (A)*.
605. "Poly(ethylene glycol)-Containing Hydrogels for Insulin Delivery Systems," Annual AIChE Meeting, Los Angeles, CA, November 14, 2000 (A)*.
606. "Patterned Poly(ethylene glycol)-Containing Films by UV Free-Radical Polymerization Techniques," Annual AIChE Meeting, Los Angeles, CA, November 15, 2000 (A)*.
607. "Molecularly Imprinted Gels Using Polymethacrylates and Poly(ethylene glycol)," Annual AIChE Meeting, Los Angeles, CA, November 16, 2000 (A)*.
608. "New Complexation-Sensitive Hydrogels for Oral Protein Delivery," Annual MRS Meeting, Boston, MA, November 27, 2000 (A), *invited lecture*.
609. "Direct Measurement of Interactions Between Tethered PEG Chains and Adsorbed Mucin Layers by Surface Force Apparatus," Annual MRS Meeting, Boston, MA, November 28, 2000 (A)*.
610. "Stimuli-sensitive Polymers," APGI/GRTV Meeting, "New Trends in Polymers for Oral and Parenteral Administration," Paris, France, March 12, 2001 (A), *Invited Lecture*.
611. "Protein/Carrier Interactions in Novel Protein Delivery Systems Examined by FTIR Spechoscopy," Second Mediterranean Meeting of the Controlled Release Society, Athens, Greece, April 28, 2001 (A)*.
612. "Teaching of Biomaterials Science and Engineering in a Modern Engineering Curriculum," Annual Meeting of the Society for Biomaterials, St. Paul, MN, April 26, 2001 (A), *invited lecture*.
613. "Compositional Dependence of Copolymerization Kinetics in an Intraocular Lens Formation," Annual Meeting of the Society for Biomaterials, St. Paul, MN, April 28, 2001 (P)*.
614. "Evaluation of Poly(ethylene glycol)-based Copolymers for Contact Lenses," Annual Meeting of the Society for Biomaterials, St. Paul, MN, April 28, 2001 (P).
615. "Study of the Network Structure of Swollen Cellulose Derivatives Used in Pharmaceutical Applications," 28th International Symposium on Controlled Release of Bioactive Materials, San Diego, CA, June 25, 2001 (P)*.
616. "New Glucose-Containing Poly(methacrylic acid-g-ethylene glycol) Hydrogels," Annual ACS Meeting, Chicago, IL, August 26, 2001 (P)*.
617. "Acrylic-Based Copolymers for Oral Insulin Delivery Systems," Annual ACS Meeting, Chicago, IL, August 26, 2001 (P)*.
618. "Macroscopic and Microscopic Investigations of HEMA-Based Molecularly Imprinted Networks," Annual ACS Meeting, Chicago, IL, August 27, 2001 (P)*.
619. "Biomimetic Materials for Drug Targeting and Drug Delivery," Annual ACS Meeting, Chicago, IL, August 28, 2001 (A)*, *invited lecture*.
620. "Length and Breadth Polyrotaxane Structures: A Concept in Three Dimensional Polymeric Systems for Biomedical Applications," Sixth International Symposium on Polymers for Advanced Technologies, Eilat, Israel, September 3, 2001 (P)*.
621. "Micropatterning and Microimprinting of Poly(ethylene glycol)-Containing Films," Sixth International Symposium on Polymers for Advanced Technologies, Eilat, Israel, September 5, 2001 (P), *plenary lecture*.
622. "Characterization of the Network Mesh Size of Swollen Cellulose Ethers Used for Controlled Release," Fourth Central European Symposium on Pharmaceutical Technology, Vienna, Austria, September 24, 2001 (P)*.
623. "Microfabrication of Biomedical Polymers for Sensor Applications," Second BioMEMS and Biomedical Nanotechnology World 2001, Columbus, OH, September 24, 2001 (A)*.
624. "Intelligent Biomaterials for Protein Delivery, Molecular Imprinting and Micropatterning," Annual Meeting of the National Academy of Engineering, Washington, D.C., October 8, 2001 (A), *invited lecture*.

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625. "The Sequential-Layer Model Quantifying Drug Release from Hydrophilic Matrix Tablets: Experimental Verification," Annual Meeting of American Association of Pharmaceutical Scientists, Denver, CO, October 24, 2001 (A)*.
626. "PEG-Containing Complexation Hydrogels Enhance Calcitonin Transport Across Caco-2 Cell Monolayers," Annual AIChE Meeting, Reno, NV, November 6, 2001 (A)*.
627. "Molecular Imprinting in PHEMA Copolymers," Annual AIChE Meeting, Reno, NV, November 6, 2001 (A)*.
628. "pH-Sensitive Hydrogels with Pendent Saccharides for Protein Delivery Applications," Annual AIChE Meeting, Reno, NV, November 7, 2001 (A)*.
629. "Use of Methacrylic Acid-Containing Hydrogels to Increase Protein Transport Across the Intestinal Epithelium," Annual Meeting of the American Physical Society, Indianapolis, IN, March 19, 2002 (A)*.
630. "Biomimetic Materials for Selective Recognition of Biologicals: Theoretical and Experimental Analysis," Annual Meeting of the American Physical Society, Indianapolis, IN, March 19, 2002 (A)*.
631. "Environmentally Sensitive Hydrogels Patterned on Silicon Microcantilevers," Annual Meeting of the American Physical Society, Indianapolis, IN, March 20, 2002 (A)*.
632. "Modeling of the Specific Binding of Biomolecules by Molecularly Imprinted Polymeric Gels," Annual Meeting of the American Physical Society, Indianapolis, IN, March 21, 2002 (A)*.
633. "Producing Networks for Recognition of Biomolecules: Biomimetic Materials for Drug Delivery and Targeting," Materials Research Society Annual Meeting, San Francisco, CA, April 2, 2002 (A)*.
634. Selective Recognition of Biologically Significant Molecules," Materials Research Society Annual Meeting, San Francisco, CA, April 5, 2002 (A)*.
635. "Use of Complexation Hydrogels for Oral Delivery of Cancer Theraputics," Materials Research Society Annual Meeting, San Francisco, CA, April 5, 2002 (A)*.
636. "Environmentally Sensitive Hydrogels Patterned on Silicon Microcantilevers," Materials Research Society Annual Meeting, San Francisco, CA, April 3, 2002 (A)*.
637. "Star Polymers for Molecular Recognition," Materials Research Society Annual Meeting, San Francisco, CA, April 4, 2002 (A)*.
638. "Requirements for Molecular Recognition by Imprinted Polymers," Materials Research Society Annual Meeting, San Francisco, CA, April 5, 2002 (A)*.
639. "Advances in Oral Protein Delivery," Fourth World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Florence, Italy, April 8, 2002 (A), *Plenary Lecture*.
640. "Characterization and Optimization of P(MAA-g-EG) Insulin-Loaded Nanospheres," Fourth World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Florence, Italy, April 9, 2002 (P)*.
641. "Novel Core-Shell Nanoparticles with Thermo- and pH-Responsive Swelling Properties for Oral Peptide Delivery," Fourth World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Florence, Italy, April 9, 2002 (P)*.
642. "Simulation of the Rupture of a Pulsatile Drug Delivery System," Fourth World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Florence, Italy, April 9, 2002 (P)*.
643. "Micro- and Nanospheres of Intelligent Biopolymers in Protein/Drug Delivery and Molecular Imprinting," Particles 2002, Orlanco, FL, April 22, 2002 (A), *Plenary Lecture*.
644. "Template-sensitive Polymers for Biomimetic Applications," Annual Meeting of the Society for Biomaterials, Tampa, FL, April 25, 2002 (A)*.
645. "Biomimetic Materials for Selective Recognition and Microsensing of Biologically Significant Molecules," Annual Meeting of the Society for Biomaterials, Tampa, FL, April 25, 2002 (A).
646. "25 Years of Oral Drug Delivery Research," 29th Annual Meeting of the Controlled Release Society, Seoul, Korea, July 22, 2002 (P), *Invited Lecture*.
647. "Intelligent Biomaterials in Protein Delivery, Molecular Imprinting and Micropatterning," 29th Annual Meeting of the Controlled Release Society, Seoul, Korea, July 23, 2002 (P), *Invited Lecture*.
648. "In vivo Studies of Oral Delivery Systems Based on Complexation Hydrogels," 29th Annual Meeting of the Controlled Release Society, Seoul, Korea, July 23, 2002 (P)*.
649. "Molecular Imprinting with Small Molecules: Effects on Polymerization and Imprinted Properties," Annual Meeting of American Chemical Society, Boston, MA, August 20, 2002 (P)*.
650. "Devices Based on Intelligent Biopolymers for Oral Protein Delivery," 11th International Pharmaceutical Technology Symposium, Istanbul, Turkey, September 9, 2002 (P), *Plenary Lecture*.

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651. "Recognition-based Hydrogel Networks as Intelligent Drug Delivery Systems," 11th International Pharmaceutical Technology Symposium, Istanbul, Turkey, September 9, 2002 (P).
652. "Histopathological Evaluation of Drug Loaded P(MAA-g-EG) Hydrogels," 11th International Pharmaceutical Technology Symposium, Istanbul, Turkey, September 9, 2002 (P).
653. "Ultrasensitive BioMEMS Sensor Based on Silicon Microcantilevers Patterned with Environmentally Responsive Hydrogels," Third Annual BioMEMS and Biomedical Nanotech Conference, Columbus, OH, September 8, 2002 (P).
654. "Biomimetic Networks for Selective Recognition of Biomolecules: Materials for Bionanotechnology," Third Annual BioMEMS and Biomedical Nanotech Conference, Columbus, OH, September 8, 2002 (P).
655. "Intelligent Biomaterials for Protein Delivery, Molecular Imprinting and Micropatterning," ACS Prospectives Meeting, Boston, MA, October 13, 2002 (A), *Plenary Lecture*.
656. "Molecular Design and Cellular Studies with Oral Insulin Delivery Systems," Annual Meeting of the Biomedical Engineering Society, Houston, TX, October 22, 2002 (A), *Invited Lecture*.
657. "Use of Complexation Hydrogels for Oral Delivery of Chemotherapeutic Agents," Annual Meeting of the Biomedical Engineering Society, Houston, TX, October 23, 2002 (A)*.
658. "A BioMEMs Sensor Platform Based on a Cantilever with a Precisely Patterned Environmentally Sensitive Hydrogel," Annual Meeting of the Biomedical Engineering Society, Houston, TX, October 23, 2002 (A)*.
659. "Computer Simulation of the Formation of Recognitive Polymer Networks," Annual AIChE Meeting, Indianapolis, IN, November 4, 2002 (A)*.
660. "Biomimetic Networks as Selective Recognition Elements for Detection of Biomolecules in Microsensor and Microarray Devices," Annual AIChE Meeting, Indianapolis, IN, November 4, 2002 (A)*.
661. "Protein Transport and Cell Interactions of Polymer Carriers with a Caco-2 Cell Line," Annual AIChE Meeting, Indianapolis, IN, November 5, 2002 (A).
662. "Swelling and Insulin Loading and Release from pH-sensitive hydrogels," Annual AIChE Meeting, Indianapolis, IN, November 5, 2002 (A).
663. "Poly(ethylene glycol)-tethered Structures as Improved Buccal and Oral Mucoadhesive Drug Delivery Systems," Annual AIChE Meeting, Indianapolis, IN, November 5, 2002 (A)*.
664. "Modified pH-Sensitive Copolymer Networks with Pendent Saccharides as Biomedical Materials," Annual AIChE Meeting, Indianapolis, IN, November 5, 2002 (A)*.
665. "Transport Mechanisms of Salmon Calcitonin and Other Model Molecules Using the Caco-2 Cell Model," Annual AIChE Meeting, Indianapolis, IN, November 5, 2002 (A)*.
666. "Environmentally Sensitive Hydrogels Patterned onto Silicon Microcantilevers as a Biomems Sensor Platform," Annual AIChE Meeting, Indianapolis, IN, November 6, 2002 (A)*.
667. "Development of Acylic-Based Copolymers for Oral Protein Delivery," Annual AIChE Meeting, Indianapolis, IN, November 6, 2002 (A).
668. "Biomolecular Specific Polymers for Sensing and Diagnostics," Annual AIChE Meeting, Indianapolis, IN, November 7, 2002 (A)*.
669. "Biological Recognition by Smart Hydrogels," Annual AIChE Meeting, Indianapolis, IN, November 7, 2002 (A)*.
670. "Glucose-Binding Polymeric Networks: Correlations Between Computational Simulations and Experiment," Annual AIChE Meeting, Indianapolis, IN, November 7, 2002 (A)*.
671. "Biomimetic Materials for Selective Recognition of Biomolecules: Recognitive Networks for Drug Delivery, Targeting, and Biosensors," Annual AIChE Meeting, Indianapolis, IN, November 7, 2002 (A)*.
672. "Novel Poly(ethylene glycol)-containing Hydrogels for Transmucosal Protein Delivery," Annual AIChE Meeting, Indianapolis, IN, November 7, 2002 (A)*.
673. "Use of Complexation Hydrogels for Oral Administration of Chemotherapeutic Agents," Annual AIChE Meeting, Indianapolis, IN, November 8, 2002 (A)*.
675. "Direct Measurements of Adhesion Between Mucin and Poly(ethylene glycol)," Annual AIChE Meeting, Indianapolis, IN, November 8, 2002 (A)*.
676. "The Role of Preparation Conditions on Particle Size and Redispersion Ability of P(MAA-g-EG) Nanospheres," Annual AAPS Meeting, Toronto, Canada, November 12, 2002 (A)*.

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677. "Simulation of Polymeric Network Formation with Atomic Level Interactions for the Study of Templated and Recognitive Materials," Annual Meeting of the American Physical Society, Austin, TX, March 3, 2003 (A)*.
678. "Biomprinted Polymer Scaffolds for Selective Recognition of RGD Peptides," Annual Meeting of the American Physical Society, Austin, TX, March 3, 2003 (A)*.
679. "Integration of Environmentally Responsive Hydrogels with Silicon Microcantilevers for Biosensor Applications," Annual Meeting of the American Physical Society, Austin, TX, March 4, 2003 (A)*.
680. "Micropatterning of Biomimetic Recognitive Hydrogels for Microsensing Applications", 20th Annual Houston Conference on Biomedical Engineering Research, Houston, TX, April 3, 2003.
681. Bioimprinted Polymer Scaffolds for Selective Recognition of RGD Peptides", 20th Annual Houston Conference on Biomedical Engineering Research, Houston, TX, April 3, 2003.
682. Improved Mucoadhesive Formulations for Buccal and Oral Drug Delivery", 20th Annual Houston Conference on Biomedical Engineering Research, Houston, TX, April 3, 2003.
683. Use of Complexation Hydrogels for Oral Administration of Chemotherapeutic Agents", 20th Annual Houston Conference on Biomedical Engineering Research, Houston, TX, April 3, 2003.
684. Synergestic Effect of Complexation Hydrogels and Permeation Enhancers on Model Intestinal Cell Monolayer: Implications to the Oral Delivery of Insulin", 20th Annual Houston Conference on Biomedical Engineering Research, Houston, TX, April 3, 2003.
685. "Biotechnology in a Chemical Engineering World", Council of Chemical Research, Austin, TX, April 8, 2003.
686. "Protein-Imprinted Polymeric Microparticles for Tissue Engineering Applications," Annual Meeting of the Society for Biomaterials, Reno, NV, May 2, 2003 (P)*.
687. "Insulin Transport Across Cell Monolayers in the Presence of Complexation Hydrogels," Annual Meeting of the Society for Biomaterials, Reno, NV, May 2, 2003 (P)*.
688. "Use of Complexation Hydrogels for Oral Administartion of Chemotherapeutic Agents", Annual Meeting of the Society for Biomaterials, Reno, NV, May 2, 2003 (P)*.
689. "New Biomaterials for Intelligent Biosensing, Recognitive Drug Delivery and Therapeutics", 37th Annual Meeting of the Academy of the Alpilles, St Remy, France, June 12, 2003 (P), *Invited Lecture*.
690. "Experimental Investigation of the Effect of Complexation Hydrogels on Insulin Transport Across Model Intestinal Cell Monolayers", Annual Meeting of the Japanese Drug Delivery Systems Society, Kyoto, Japan, June 20, 2003 (A)*.
691. "Development of Oral Insulin Delivery Systems and Evaluation as Pharmaceutical Dosage Forms in Diabetic Rats", Annual Meeting of the Japanese Drug Delivery Systems Society, Kyoto, Japan, June 20, 2003 (A)*.
692. "Comparison of Low and High Molecular weight HPMC Types: Drug and Polymer Release from Matrix Tablets", 30th International Symposium on Controlled Release of Bioactive Materials, Glasgow, Scotland, July 22, 2003 (P)*.
693. "Calculation of the Erosion and Swelling Front Positions in Swellable Controlled Release Tablets", 30th International Symposium on Controlled Release of Bioactive Materials, Glasgow, Scotland, July 22, 2003 (P)*.
694. "Oral Administration of P(MAA-g-EG) Particls to Rats: Histological Characterization", 30th International Symposium on Controlled Release of Bioactive Materials, Glasgow, Scotland, July 22, 2003 (P)*.
695. "Intelligent Mucoadhesive Nanospheres for Transmucosal Protein Delivery and Other Pharmaceutical Applications", 4th BioMEMS and NanoTech World Meeting, Washington, DC, August 25, 2003 (A), *Plenary Lecture.*
696. "Novel BioMEMS Sensor Platform: Fusion of Silicon Technologies with Intelligent Polymer Networks", 4th BioMEMS and NanoTech World Meeting, Washington, DC, August 25, 2003 (A)*.
697. "Use of Complexation Hydrogels for Oral Administration of Chemotherapeutic Agents", Annual BMES Meeting, Nashville, TN, October 4, 2003 (A)*.
698. "Biomimetoc Polymer Scaffolds for Selective Recognition of Cell Adhesion Proteins", Annual BMES Meeting, Nashville, TN, October 4, 2003 (A)*.
699. "Biologically Intelligent Complexation Hydrogels for the Oral Delivery of Therapeutic Proteins" Annual BMES Meeting, Nashville, TN, October 4, 2003 (A)*.
700. "Role of Complexation Hydrogels in Insulin Transport Across Model Intestinal Cell Monolayer", Annual BMES Meeting, Nashville, TN, October 4, 2003 (A)*.

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701. "Nanotechnology to Enhance Human Health", NIH-NSF Nanobiotechnology Workshop, Washington, DC, October 9, 2003 (P), *Plenary Lecture.*
702. "Elucidation of Water, Drug and Polymer Transport in Swellable Matrix tablets Unders Steric Restriction", Annual AAPS Meeting, Salt Lake City, UT, October 27, 2003 (A)*.
703. "Novel Poly(ethylene glycol) Containing Polymers as Mucoadhesive Drug Delivery Systems", Annual AAPS Meeting, Salt Lake City, UT, October 28, 2003 (A)*.
704. "Intelligent Polymer Networks as Sensing Elements: Enabling Technologies for Novel Biosensor Platforms" Annual AIChE Meeting, San Francisco, CA, November 17, 2003 (A)*.
705. "Templated Polymeric Networks for Molecular Recognition: Simulation and Experimental Correlations," Annual AIChE Meeting, San Francisco, CA, November 19, 2003 (A)*.
706. "Oral Delivery of Insulin Bioconjugates Using Complexation Hydrogels," Annual AIChE Meeting, San Francisco, CA, November 19, 2003 (A)*.
707. "Use of Complexation Hydrogels for Oral Administration of Chemotherapeutic Agents," Annual AIChE Meeting, San Francisco, CA, November 20, 2003 (A)*.
708. "Biomimetic Polymer Scaffolds for Selective Recognition of Blood Proteins In Tissue Engineering Applications," Annual AIChE Meeting, San Francisco, CA, November 21, 2003 (A)*.
709. "Novel Biomimetic Polymer Networks: Development and Application as Selective Recognition Elements for Biomolecules at the Micro/Nano-scale" Annual AIChE Meeting, San Francisco, CA, November 21, 2003 (A)*.
710. "Development and Application of Intelligent Polymer Networks as Recognition Elements for Novel Microdevices," Materials Research Society Annual Meeting, Boston, MA, December 1, 2003 (A)*.
711. "Molecular Simulations of Recognitive Polymer Networks Prepared by Biomimetic Configurational Imprinting as responsive Biomaterials," Materials Research Society Annual Meeting, Boston, MA, December 1, 2003 (A)*, *Invited Lecture*.
712. "Molecular Design and Cellular Response of Novel Intelligent Mucoadhesive Carriers for Oral Delivery of Proteins an Chemotherapeutic Agents," Materials Research Society Annual Meeting, Boston, MA, December 1, 2003 (A)* *Invited Lecture*.
713. "Molecular Imprinting of Novel Biodegradable Polymer Matrices for Drug Delivery Applications," US-Japan Drug Delivery Meeting, Maui, HI, December 17, 2003 (A)*.
714. "Oral Administration of Chemotherapeutic Agents from Complexation Hydrogels," US-Japan Drug Delivery Meeting, Maui, HI, December 17, 2003 (A)*.
715. "Development and Application of Intelligent Polymer Networks as Recognition Elements for Novel Biomedical Microdevices," US-Japan Drug Delivery Meeting, Maui, HI, December 17, 2003 (A)*.
716. "Advanced Oral Protein Delivery Systems: Modifying the Molecular Design to Create Biologically Intelligent Complexation Hydrogels," US-Japan Drug Delivery Meeting, Maui, HI, December 17, 2003 (A)*.
717. "Advances in Intelligent Biomaterials for Protein Delivery, Molecular Recognition and Micropatterning", Inaugural Meeting, Texas Academy of Science, Engineering and Medicine, San Antonio, TX, January 7, 2004, *Invited Lecture,* (A).
718. "Complexation Hydrogels for Oral Delivery of Insulin: Overcoming the Enzymatic Barriers", 21st Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 12, 2004 (A)*.
719. "A Novel Technique Using Degradable Components to Create configurationally Biomimetic Imprinted Polymers", 21st Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 12, 2004 (A)*.
720. "Biologically Intelligent Complexation Hydrogels for the Oral Delivery of Proteins", 21st Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 12, 2004 (A)*.
721. "Nanotechnology and Intelligent Therapeutics: Configurationally Biomimetic Imprinting and Protein Delivery", Southwest Regional Conference of the National Academy of Engineering, Houston, TX, March 25, 2004, *Invited Lecture,* (A).
722. "Voies de progrès en formulation: Quelles perspectives?", Gattefossé Meeting, Lyon, France, April 22, 2004. *Plenary Lecture,* (A).
723. "Transport Phenomena in Drug and Protein Delivery Processes and Therapeutics", NSF/NIH Workshop on Transport Processes in Biomedical Systems, Washington, DC, May 6, 2004, *Invited Lecture,* (A).

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724. "Drug Release Mechanisms in Swellable Matrix Tablets with Steric Restriction", European Conference on Drug Delivery and Pharmaceutical Technology, Seville, Spain, May 10, 2004, (P).
725. "Configurational Biomimesis as a Method for Preparation of Novel Biomaterials and Drug Delivery Carriers," Second World Congress on Pharmaceutical Sciences, Kyoto, Japan, May 31, 2004, *Invited Lecture*, (A).
726. "Elucidation of the Mechanisms for Increasing Oral Insulin Absorption in Delivery Systems Based on Complexation Hydrogels," Second World Congress on Pharmaceutical Sciences, Kyoto, Japan, June 1, 2004, (A)*.
727. "Development of Oral Delivery Systems for Peptide and Protein Drugs Based on Complexation Hydrogels," Second World Congress on Pharmaceutical Sciences, Kyoto, Japan, June 1, 2004, (A)*.
728. "Oral Insulin Delivery Systems Based on Complexation Hydrogels: Single and Multiple Administration Studies in Type 1 and 2 Diabetic Rats," Second World Congress on Pharmaceutical Sciences, Kyoto, Japan, June 1, 2004, (A)*.
729. "Application of Complexation Hydrogels to Oral Delivery Systems for Peptide and Protein Drugs", 31st International Symposium on Controlled Release of Bioactive Materials, Honolulu, Hawaii, June 14, 2004 (P)*.
730. "Characterization of Insulin Protection Properties of Complexation Hydrogels in Gastric and Intestinal Enzyme Fluids", 31st International Symposium on Controlled Release of Bioactive Materials, Honolulu, Hawaii, June 15, 2004 (P)*.
731. "Gastrointestinal Transit of Mucoadhesive Complexation Hydrogels in Rats", 31st International Symposium on Controlled Release of Bioactive Materials, Honolulu, Hawaii, June 15, 2004 (P)*.
732. "Successful Oral Insulin Carrier Systems Based on complexation Polymer Hydrogels: Single and Multiple Administration Studies in Type I and II Diabetic Rats", 31st International Symposium on Controlled Release of Bioactive Materials, Honolulu, Hawaii, June 16, 2004 (P)*.
733. "Cellular and Molecular Evaluation of Novel Carriers for Oral Chemotherapy", 31st International Symposium on Controlled Release of Bioactive Materials, Honolulu, Hawaii, June 16, 2004 (P)*.
734. "Bionanotechnology in Drug Delivery, Drug Design and Therapeutic Systems", 4th Asan-Harvard Joint International Symposium on Nanotechnology in Biology and Medicine, Seoul, Korea, June 16, 2004 (A), *Plenary lecture*.
735. "Intelligent Biomaterials in Microfabricated and Nanoscale Devices for Pharmaceutical Applications", 4th Asan-Harvard Joint International Symposium on Nanotechnology in Biology and Medicine, Seoul, Korea, June 16, 2004 (A), *Plenary lecture*.
736. "Bionanotechnology in Drug Delivery and Intelligent Therapeutic Systems", 20th Japanese Drug Delivery Systems Meeting, Tokyo, Japan, July 15, 2004 (P), *Plenary lecture.*
737. "Novel Biomimetic Polymer Networks with Tailored Recognition Properties: Functional Components in Diagnostic and Therapeutic Devices", 5th BioMEMS and NanoTech World Meeting, Washington, DC, August 17, 2004 (A).
738. "Advances in Intelligent Biomaterials for Protein Delivery, Biological Recognition and Responsive Systems", European Materials Research Society, Warsaw, Poland, September 6, 2004 (A), *Plenary lecture.*
739. "Novel Biomimetic Polymer Networks: Tailored Recognition Properties for Biomedical Applications", Annual Meeting Biomedical Engineering Society, Philadelphia, PA, October 15, 2004 (A)*.
740. "Molecular design ad Evaluation of Complexation Hydrogels as Advanced Oral Protein delivery Systems", Annual Meeting Biomedical Engineering Society, Philadelphia, PA, October 15, 2004 (A)*.
741. "Configurationally Biomimetic Imprinted Polymers Selective for Angiotensin II", Annual Meeting Biomedical Engineering Society, Philadelphia, PA, October 15, 2004 (A)*.
742. "Novel Molecularly Imprinted Hydrogels for the Recognition of Blood Proteins", Annual Meeting Biomedical Engineering Society, Philadelphia, PA, October 16, 2004 (A)*.
743. "Investigation of Degradable, Imprinted Microspheres for the Development of a Tissue Engineering Scaffold", Meeting on "Biomaterials in Regenerative Medicine", Philadelphia, PA, October 17, 2004 (P)*.
744. "Cellular and Molecular Evaluation of Oral Delivery Systems for Chemotherapeutic Agents", Annual AIChE Meeting, Austin, TX, November 8, 2004 (A)*.

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745. "Biomimetic, Molecularly Imprinted Hydrogels for Recognition and Capture of High Molecular Weight Proteins" Annual AIChE Meeting, Austin, TX, November 8, 2004 (A)*.
746. "Protein Recognition and Binding at Interfaces: Engineering Polymeric Materials to Bind Specific Molecules", Annual AIChE Meeting, Austin, TX, November 9, 2004 (A)*.
747. "Biomimetic Polymers in Drug Delivery and Sensing Applications: Effect of Network Molecular Structure on Recognition Properties, Annual AIChE Meeting, Austin, TX, November 9, 2004, (A)*.
748. "Incorporation of Degradable Components into a Configurationally Biomimetic Imprinted Polymer, Annual AIChE Meeting, Austin, TX, November 9, 2004, (A)*.
749. "Molecular Design of Advanced Oral Protein Delivery Systems Using Complexation Hydrogels", Annual AIChE Meeting, Austin, TX, November 9, 2004, (A)*.
750. "Thermo-responsive Polymer Nanoparticles for Stealth Drug Delivery and Molecular Recognition", Annual AIChE Meeting, Austin, TX, November 9, 2004, (A)*.
751. "Use of Complexation Hydrogels in Overcoming Enzymatic Barriers to Oral Insulin Delivery", Annual AIChE Meeting, Austin, TX, November 9, 2004, (A)*.
752. "Theory and Applications of Intelligent Biomaterials, Annual AIChE Meeting, Austin, TX, November 9, 2004, (A), *Invited lecture.*
753. "The Future of Intelligent Therapeutics", Annual AIChE Meeting, Austin, TX, November 10, 2004
754. "Complexation Hydrogels As Oral Delivery Vehicles For Insulin-Transferrin Conjugates", Annual AIChE Meeting, Austin, TX, November 11, 2004, (A)*.
755. "Kinetic Studies of Iniferter Photopolymerizations for Highly Crosslinked Polymer Networks", Annual AIChE Meeting, Austin, TX, November 11, 2004, (A)*.
756. "Modeling And Control Of The Behavior Of Glucose Sensing Devices", Annual AIChE Meeting, Austin, TX, November 12, 2004, (A)*.
757. "Transmucosal Drug Delivery Systems Using Mucoadhesive Brush-containing Networks", Annual AIChE Meeting, Austin, TX, November 12, 2004, (A)*.
758. "Influence of Electrolytes on the Dissolution Properties of Chlorpheniramine Maleate from Hot-Melt Extruded Tablets Containing Chitosan and an Anionic Polymer", Annual AAPS meeting, Baltimore, MD, November 12, 2004, (A)*.
759. "Design of pH and Buffer-species Independent Sustained Release Hot-Melt Extruded Tablets: Application of Inter- and Intra-Molecular Hydrogelation", Annual AAPS meeting, Baltimore, MD, November 12, 2004, (A)*.
760. "Novel Chronopharmacological Protein Delivery Systems Based on PEG-containing Hydrogels" Meeting on "Chronobiology and Chronotherapy", Austin, TX, November 12, 2004.
761. "Diseño y síntesis de hidrogeles acrílicos modificados para la liberación controlada de fármacos", Seventh Congress of the Spanish Society of Industrial and Galenic Pharmacy, Salamanca, Spain, February 7, 2005.
762. "Biomimetic Polymers in Sensing Applications and Drug Delivery", 22nd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 10, 2005 (A), *Invited lecture.*
763. "Integrating Stategies for Improved Oral Delivery of Therapeutic Proteins", 22nd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 10, 2005 (A)*.
764. "Utilization of the Adhesion Promoter Poly(ethylene glycol) in Mucoadesive Biomaterials", 22nd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 10, 2005 (A)*.
765. "Applications of Modeling and Control Toward the Development of Novel Therapies for Diabetes Mellitus", 22nd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 10, 2005 (A)*.
766. "Improvement of Novel Biomedical devices via Kinetic Studies of Iniferter Photopolymerization", 22nd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 11, 2005 (A)*.
767. "Temperature-Sensitive Stealth Nanoparticles as Intelligent Therapeutic Systems", 22nd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 11, 2005 (A)*.
768. "Biomimetic Systems and Nanotechnology in Intelligent Therapeutics", Annual Event of the American Institute of Medical and Biological Engineering, Washington, DC, February 17, 2005, (A), *Plenary Lecture.*

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769. "Intelligent Therapeutics and Nanoscale Delivery: Impact on Absorption and Transport", Third World Conference on Drug Absorption, Transport and Delivery, Barcelona, Spain, April 18, 2005 (A), *Plenary lecture.*
770. "Formulation Optimization for Oral Peptide and Protein Delivery", Third World Conference on Drug Absorption, Transport and Delivery, Barcelona, Spain, April 18, 2005 (A)*, *Plenary lecture.*
771. "Improved Absorption of Therapeuic Agents Through Acrylic-based Biohydrogels: Investigation of the in vitro Release Properties and Cytocompatibility", Third World Conference on Drug Absorption, Transport and Delivery, Barcelona, Spain, April 19, 2005 (A)*.
772. "In vitro Investigation of lectin Functionalized Complexation Hydrogels for Oral Protein Delivery", Third World Conference on Drug Absorption, Transport and Delivery, Barcelona, Spain, April 19, 2005 (A)*.
773. "Poly(methacrylic acid-g-ethylene glycol) Microparticles as Modulators of Tight Junction Morphology, Third World Conference on Drug Absorption, Transport and Delivery, Barcelona, Spain, April 19, 2005 (A)*.
774. "Biomimetic Imprinted Microparticles for the Recognition and Capture of Serum Proteins," Annual Meeting of the Society for Biomaterials, Memphis, TN, April 29, 2005 (P)*.
775. "Mucoadhesive Characteristics of Biomaterials Containing the Adhesion Promoter PEG," Annual Meeting of the Society for Biomaterials, Memphis, TN, April 29, 2005 (P)*.
776. "Molecular Design and Evaluation of Complexation Hydrogels as Advanced Oral protein Delivery Systems," Annual Meeting of the Society for Biomaterials, Memphis, TN, April 29, 2005 (P)*.
777. "Hydrogels as Biomaterials: Infinite Possibilities in Bionanotechnology, Drug Delivery, Biological Recognition and Tissue Engineering," Annual Meeting of the Society for Biomaterials, Memphis, TN, April 29, 2005 (P), *plenary lecture.*
778. "The Swelling Behavior of Hydrophilic Tablets as Revealed by High-Reoslution X-ray Computed Tomography" , Pharmaceutical Sciences Fair and Exhibition, Nice, France, June 14, 2005 (A)*
779. "Structural Analysis and Diffusional Behavior of Molecularly Imprinted Polymer Networks for Cholesterol Recognition", Pharmaceutical Sciences Fair and Exhibition, Nice, France, June 14, 2005 (A)*.
780. "Recognitive and Diagnostic Polymer Networks: Formation, Simulations and Thermodynamics", European Polymer Congress, Moscow, Russia, June 28, 2005 (P), *Plenary lecture*.
781. "The Swelling Behavior of Hydrophilic Tablets as Analyzed by High-Resolution X-Ray Computed Tomography", Symposium on Innovative Therapeutics, Louvain, Belgium, July 12, 2005 (A)*.
782. "Smart Drug Delivery and Bionanotechnology", 15th International Symposium on Microencapsulation, Parma, Italy, September 19, 2005, (P), *Plenary lecture*.
783. "Configurational Biomimetic Imprinting of Angiotensin II for Novel Drug Delivery Systems", 15th International Symposium on Microencapsulation, Parma, Italy, September 19, 2005, (P)*.
784. " Modeling the Effect of Scaffold Architecture on Diffusion of Oxygen in Tissue Engineering Constructs", Annual Meeting Biomedical Engineering Society, Baltimore, MD, September 30, 2005 (A)*.
785. "Calcium Dependent Epithelial Permeability Enhancement", Annual Meeting Biomedical Engineering Society, Baltimore, MD, September 30, 2005 (A)*.
786. "Molecular Imprinting of Pepetides for Novel Drug Delivery Systems", Annual Meeting Biomedical Engineering Society, Baltimore, MD, October 1, 2005 (A)*.
787. "Complexation Hydrogels for Biological Recognition and Intelligent Delivery", International Symposium on Polymer Gels, Sapporo, Japan, October 17, 2005 (A), *Plenary lecture*.
788. "Temperature Sensitive Nanoparticles as Intelligent Therapeutic Systems", International Symposium on Polymer Gels, Sapporo, Japan, October 18, 2005 (A)*.
789. "Synthesis and Characterization of pH Responsive Mucoadhesive Tethered Biomaterials", International Symposium on Polymer Gels, Sapporo, Japan, October 18, 2005 (A)*.
790. "Investigation of Lectin Functionalized Complexation Hydrogels for Oral Protein Delivery", Annual AAPS meeting, Nashville, TN, November 8, 2005, (A)*.
791. "Properties of Sustsained Release Floating Tablets Prepared by a Hot-Melt Extusion Process", Annual AAPS meeting, Nashville, TN, November 8, 2005, (A)*.
792. "Development of PEG-Containing pH-Responsive polymers for Oral Drug Delivery", Annual AAPS meeting, Nashville, TN, November 8, 2005, (A)*.

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793. "Properties of Mucoadhesive Oral Drug Delivery Systems for Spatial Localization of Levodopa", Annual AAPS meeting, Nashville, TN, November 8, 2005, (A)*.
794. "Molecularly Designed Mucoadhesive pH Responsive Tethered Biomaterials and their Use in Spatially Controlled Therapeutic Delivery", Annual AIChE Meeting, Cincinnati OH, October 30, 2005 (A)*.
795. "Mucoadhesive Oral Insulin Delivery Systems Using Lectin Functionalized Complexation Hydrogels", Annual AIChE Meeting, Cincinnati OH, October 31, 2005 (A)*.
796. "Novel Mucoadhesive Formuations Employing pH-Responsive Biomaterials", Annual AIChE Meeting, Cincinnati OH, October 31, 2005 (A)*.
797. "Molecularly Designed Mucoadhesive pH-Responsive tethered Biomaterials", Annual AIChE Meeting, Cincinnati OH, November 1, 2005 (A)*.
798. "Membrane Science and Intelligent Therapeutics", Annual AIChE Meeting, Cincinnati OH, November 1, 2005 (A), *Invited lecture*.
799. "Temperature-Sensitive Polymer-Gold Nanocomposites as Intelligent Therapeutic Systems", Annual AIChE Meeting, Cincinnati OH, November 3, 2005 (A)*.
800. "Intelligent Therapeutics and Bionanotechnology", US-Japan Drug Delivery Meeting, Maui, HI, December 19, 2005 (A), *Invited lecture*.
801. "Gold-Polymer Nanocomposites as Intelligent Therapeutic Systems", US-Japan Drug Delivery Meeting, Maui, HI, December 20, 2005 (A)*.
802. "Molecularly-Designed Mucoadhesive pH-Responsive Tethered Biomaterials", US-Japan Drug Delivery Meeting, Maui, HI, December 20, 2005 (A)*.
803. "Configurational Biomimetic Polymers for Novel Drug Delivery Systems", US-Japan Drug Delivery Meeting, Maui, HI, December 20, 2005 (A)*
804. "Metal-Polymer Nanocomposites as Externally Triggerred Intelligent Therapeutic Systems", 23rd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 9, 2006 (A)*.
805. "Temperature-Responsiv Interpenetrating Polymer Network Nanospheres as Intelligent Therapeutic Systems", 23rd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 9, 2006 (A)*.
806. "Application of Process Control Techniques Towards Type 1 Diabetes Mellitus", 23rd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 9, 2006 (A)*.
807. "Oral Insulin Delivery Using Lectin Functionalized Complexation Hydrogels", 23rd Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 9, 2006 (A)*.
808. "Lectin Functionalized Complexation Hydrogels for Oral Protein Delivery", 9th European Symposium on Controlled Drug Delivery, Noordwijk aan Zee, the Netherlands, April 6, 2006 (P)*.
809. "Selective Recognition of Angiotensin II for Novel Drug Delivery Systems", 9th European Symposium on Controlled Drug Delivery, Noordwijk aan Zee, the Netherlands, April 6, 2006 (P)*.
810. "Integration of Thermally Responsive Nanosphere Hydrogels with Gold Nanoparticles for Intelligent Therapeutic Applications" Annual Meeting of the Society for Biomaterials, Pittsburgh, PA, April 29, 2006 (P)*.
811. "Effect of Scaffold Architecture on Diffusion of Oxygen in Tissue Engineering Constructs" Annual Meeting of the Society for Biomaterials, Pittsburgh, PA, April 29, 2006 (P)*.
812. "Biomimetic Polymers in Intelligent Drug Delivery", 3rd World Congress on Biomimetics, Artificial Muscles and Nanobiotechnology, Lausanne, Switzerland, May 26, 2006 (A), *Invited lecture*.
813. "The Fascinating World of Bionanotechnology", ASEE Annual Conference, Chicago, IL, June 19, 2006 (A), *Plenary lecture.*
814. "Molecular Design and Cellular Studies of Oral Protein Delivery", 33rd International Symposium on Controlled Release of Bioactive Materials, Vienna, Austria, July 20, 2006 (P)*.
815. "Externally triggered Metal-Polymer Nanocomposites for Controlled Release Applications, 33rd International Symposium on Controlled Release of Bioactive Materials, Vienna, Austria, July 20, 2006 (P)*.
816. "Loading and Mobility of Spin-Labeled Insulin in Repsonsive Complexation Hydrogels", 33rd International Symposium on Controlled Release of Bioactive Materials, Vienna, Austria, July 20, 2006 (P)*.
817. "Oral Delivery of Proteins", 33rd International Symposium on Controlled Release of Bioactive Materials, Vienna, Austria, July 20, 2006 (P), *Plenary lecture*.

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818. "Polymeric Drug Delivery- Past, Present and Future", PolyPharma meeting, Halle, Germany, September 25, 2006, *Plenary lecture*.
819. "Loading and Mobility of Spin-Labeled Insulin in Responsive Complexation Hydrogels- An ESR Study", PolyPharma meeting, Halle, Germany, September 25, 2006 (P)*.
820. "Molecularly Imprinted Hydrogels for Recognition of Serum Proteins for Sustained Drug Delivery", Annual Meeting of the Biomedical Engineering Society, Chicago, IL, October 12, 2006 (A)*.
821. "Considering Mucus in the Enhancement of Paracytosis by P(MAA-g-EG) Drug Carriers", Annual Meeting of the Biomedical Engineering Society, Chicago, IL, October 12, 2006 (A)*.
822. "Molecular Imprinted Hydrogels as Intelligent Drug Delivery Systems", Annual Meeting of the Biomedical Engineering Society, Chicago, IL, October 12, 2006 (A)*.
823. "Influence of Sulfobutyl Ether Beta-Cyclodextrin on the Dissolution Properties of a Poorly Soluble drug from Extrudates Prepared by Hot-Melt Extrusion", Annual AAPS Meeting, San Antonio, TX, October 31, 2006 (A)*.
824. "Dynamics of Tethered Biomaterials and their Development into pH Responsive Mucoadhesive Oral Drug Delivery Systems", Annual AAPS Meeting, San Antonio, TX, October 31, 2006 (A)*.
825. "pH-Sensitive Complexation Hydrogels for the Oral Delivery of Proteins", Annual AAPS Meeting, San Antonio, TX, October 31, 2006 (A)*.
826. "Modeling of the Dynamics of Insulin Release from pH Responsive Cationic Hydrogel Nanospheres", Sixth Annual Diabetes Technology Meeting, Atlanta, November 3, 2006 (A)*.
827. "Metal-Polymer Nanocomposites for Therapeutic and Imaging Applications", Annual AIChE Meeting, San Francisco, CA, November 13, 2006 (P)*.
828. "Glucose-Responsive Systems for Insulin Delivery Based on Poly(Ethylene Glycol)-Containing, pH-Sensitive, Cationic Hydrogels", Annual AIChE Meeting, San Francisco, CA, November 13, 2006 (P)*.
829. "Dynamics of Novel Multifunctional, Intelligent Mucoadhesive Copolymers", Annual AIChE Meeting, San Francisco, CA, November 14, 2006 (P).
830. "In Vitro Investigation of Oral Insulin Delivery Systems Using Lectin Functionalized Complexation Hydrogels", Annual AIChE Meeting, San Francisco, CA, November 14, 2006 (P).
831. "Thermally Responsive Interpenetrating Polymer Network Nanoparticles", Annual AIChE Meeting, San Francisco, CA, November 14, 2006 (P)*.
832. "Drug Absorption in the Upper Small Intestine and Its Implications in the Design of Oral Protein Delivery Carriers", Annual AIChE Meeting, San Francisco, CA, November 15, 2006 (P).
833. "Penetrant Transport in Well-Characterized Glassy Polymers as Revealed by High-Resolution X-Ray Computed Tomography", Annual AIChE Meeting, San Francisco, CA, November 15, 2006 (P)*.
834. "Engineering of Novel Drug Delivery Devices Based on Convex/Concave Geometries and Dynamic Analysis Using X-Ray Tomography", Annual AIChE Meeting, San Francisco, CA, November 15, 2006 (P).
835. "Tethered pH Responsive Biomaterials for Mucoadhesive Oral Controlled Release Drug Delivery Systems", Annual AIChE Meeting, San Francisco, CA, November 15, 2006 (P)*.
836. "Selective Recognition of Angiotensin II", Annual AIChE Meeting, San Francisco, CA, November 15, 2006 (P).
837. "Characterizing Transport Enhancement by P(MAA-g-EG) Drug Carriers in the Presence of Mucus", Annual AIChE Meeting, San Francisco, CA, November 15, 2006 (P)*.
838. "Molecular Analysis of Interpolymer Complexing Hydrogels Based on Poly(Methacrylic Acid) and N-Vinyl Pyrrolidone as Carriers for Protein Delivery by Transmucosal Transport", Annual AIChE Meeting, San Francisco, CA, November 15, 2006 (P)*.
839. "Oral Delivery of Insulin Bioconjugates Using Intelligent Complexation Hydrogels", Annual AIChE Meeting, San Francisco, CA, November 15, 2006 (P)*.
840. "Bionanotechnology and Responsive, Biomimetic Drug Delivery Systems", Fifteenth Nisshin Engineering Particle Technology International Meeting "Nanotechnology in Life Sciences", Awajishima, Japan, December 11, 2006 (P), *Plenary lecture.*
841. "nanostructured Biomaterials and Surfaces for Recognition", Meeting on Biomaterials from 2D to 3D to Larger than Life, Maui, HI, December 15, 2007 (A). *Invited lecture*.
842. "Growth Hormone Release Using pH-Sensitive Complexation Hydrogels", 24th Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 9, 2007 (P)*.

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843. "Development an Characterization of Polycationic Nanogels for Targetted Intracellular Drug Delivery", 24th Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 9, 2007 (P)*.
844. "Comparing pH-Sensitive Carriers in Transporting Growth Homone", 24th Annual Houston Conference on Biomedical Engineering Research, Houston, TX, February 9, 2007 (P)*.
845. "Targeting with Molecularly Decorated Nanoparticles", Pharmaceutical World Congress, Amsterdam, The Netherlands, April 24, 2007 (A).
846. "Photoemulsion Polymerization of Polycationic Nanogels for Intracellular Drug Delivery", Pharmaceutical World Congress, Amsterdam, The Netherlands, April 24, 2007 (A)*.
847. "Nanotechnology and Intelligent Response: What Have They Done for Biomaterials Lately?" Annual Meeting of the Society for Biomaterials, Chicago, IL, April 20, 2007 (P).
848. "Growth Hormone Release from pH-Sensitive Complexation Hydrogels", Annual Meeting of the Society for Biomaterials, Chicago, IL, April 20, 2007 (P)*.
849. "Characterization of Hydrogel-Conductive Polymer Recognitive Interpenetrating Networks", Annual Meeting of the Society for Biomaterials, Chicago, IL, April 20, 2007 (P)*.
850. "Nanotechnology and Drug Delivery", BIO2007, Boston, MA, May 7, 2007.
851. "*Le plus ça change…* Nanotechnology and Bioengineering in an Evolving Chemical Engineering World", 9th Greek Scientific ChemicaL Engineering Conference, Athens, Greece, May 31, 2007 (P), *Plenary lecture*.
852. "Nanotechnology and Intelligent Systems in Drug Delivery", National Biotechnology Conference, AAPS, San Diego, CA, June 26, 2007 (A), *Plenary lecture*.
853. "Design of a Polymeric Insulin Infusion System for Blood Glucose Control", IEEE Control Systems Society and American Automatic Control Council Meeting, New York, NY, July 10, 2007 (P)*.
854. "Oral Delivery of Insulin Bioconjugates Using Intelligent Complexation Hydrogels", 14th International Symposium of Microncapsulation, Lexington, KY, September 11, 2007 (P)*.
855. D.A. Carr, W.A. Hunt and N.A. Peppas, "Evaluation of Therapeutic Protein Encapsulation and Release from pH-Sensitive Complexation Hydrogels", 14th International Symposium of Microncapsulation, Lexington, KY, September 11, 2007 (P)*.
856. "The Next Generation of Drug Delivery Technologies", Conference on the Impact of New technologies on the Future of Pharmacy Practice and Science, University of Central Lancashire, Preston, UK, September 13, 2007 (A), *Plenary Lecture.*
857. "Chemical Engineering in Bioengineering and Bionanotechnology", CHEMECA Meeting, Melbourne, Australia, September 25, 2007 (A), *Plenary Lecture.*
858. "Biomolecular Sensing with Polyaniline-Polymer Acid Complex", Annual Meeting Biomedical Engineering Society, Los Angeles, CA, September 28, 2007 (A)*.
859. "What Has Nanotechnology Done for Drug Delivery Lately?", Meeting of APGI and ADRITELF on Innovation in Drug Delivery, Naples, Italy, October 1, 2007 (P), *Plenary Lecture*.
860. "Complexation Hydrogels as Biomimetic Smart Materials," Materials and Complex Fluids Workshop, The University of Texas at Austin. Austin, TX. October 12, 2007 (A).
861. "Dynamics of Novel Multifunctional, Intelligent Mucoadhesive Copolymers". Annual AIChE Meeting, Salt Lake City, UT, November 5, 2007 (A)*.
862. "Polymerizations in the Service of Nanotechnology and Intelligent Biomaterials Science". Annual AIChE Meeting, Salt Lake City, UT, , November 5, 2007 (A), *Invited Lecture*.
863. "Computer Evaluation of Hydrogel-Based Systems for the Closed Loop Treatment of Type I Diabetes Mellitus", Annual AIChE Meeting, Salt Lake City, UT, November 5, 2007 (A)*..
864. "Polysaccharide-Tethered Hydrogels for Drug Delivery", Annual AIChE Meeting, Salt Lake City, UT, November 5, 2007 (A)*.
865. "Molecular Design and Dynamic Behavior of Interpolymer Complexing Hydrogels as Carriers for the Oral Delivery of Therapeutic Proteins" Annual AIChE Meeting, Salt Lake City, UT, November 6, 2007 (A)*.
866. "*In Situ* Dynamics of Penetrant Transport in Glassy Polymers", Annual AIChE Meeting, Salt Lake City, UT, November 6, 2007 (A)*.
867. "Le Plus ça Change…Nanotechnology and Bioengineering in an Evolving Chemical Engineering World". Annual AIChE Meeting, Salt Lake City, UT, November 7, 2007 (A), *Plenary Institute Lecture*.

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868. “Cationic Polymeric Systems for Glucose-Responsive Insulin Delivery”. Annual AIChE Meeting, Salt Lake City, UT, November 8, 2007 (A)*.
869. “Oral Delivery of Insulin-Transferrin Bioconjugates Using Intelligent Complexation Hydrogels”, Annual AIChE Meeting, Salt Lake City, UT, November 8, 2007 (A)*.
870. “Intelligent Biomaterials in Protein Delivery, Molecularly Reognitive Systems and Microdevices”, International Conference on Cellular and Molecular Engineering, Singapore, December 11, 2007 (A), *Plenary Lecture*.
871. “Complexation Hydrogels of Methacrylic Acid and N-Vinyl Pyrrolidone for the Oral Delivery of Therapeutic Proteins”, US-Japan Drug Delivery Meeting, Maui, HI, December 19, 2007 (A)*.
872. “Conductive Polymers for Recognitive Hydrogels”, US-Japan Drug Delivery Meeting, Maui, HI, December 19, 2007 (A)*.
873. “Oral Delivery of Insulin-Transferrin Bioconjugates Using Intelligent Complexation Hydrogels”, US-Japan Drug Delivery Meeting, Maui, HI, December 19, 2007 (A)*.
874. “Carbohydrate-Containing hydrogels for Oral Protein Delivery”, US-Japan Drug Delivery Meeting, Maui, HI, December 19, 2007 (A)*.
875. “Intelligent Glucose-Responsive Insulin Delivery via Cationic Hydrogel Systems, US-Japan Drug Delivery Meeting, Maui, HI, December 19, 2007 (A)*.
876. “Metal-Polymet Composites as Externally-Controlled Intelligent Therapeutic Systems”, US-Japan Drug Delivery Meeting, Maui, HI, December 19, 2007 (A)*.
877. “Towards the Development of Biodegradable Sensors from Smart Hydrogels”, US-Japan Drug Delivery Meeting, Maui, HI, December 19, 2007 (A)*.
878. "Hydrogel and Conductive Polymer Composite as a Sensing Device", 25th Annual Conference of the Houston Society for Engineering in Medicine and Biology, Houston, TX, February 8, 2008 (A)*.
879. "Material Characterization of pH-Sensitive Polycationic Nanocarriers for Intracellular Drug Delivery", 25th Annual Conference of the Houston Society for Engineering in Medicine and Biology, Houston, TX, February 8, 2008 (A)*.
880. "PEGylated Insulin Loading of Poly(Methacrylic Acid-G-Ethylene Glycol) Particles", 25th Annual Conference of the Houston Society for Engineering in Medicine and Biology, Houston, TX, February 8, 2008 (A)*.
881. "pH-Sensitive Polycationic Hydrogels for Intracellular Drug Delivery", 25th Annual Conference of the Houston Society for Engineering in Medicine and Biology, Houston, TX, February 8, 2008 (A)*.
882. "Recognitive Biomaterials for Neurotransmitters", 25th Annual Conference of the Houston Society for Engineering in Medicine and Biology, Houston, TX, February 8, 2008 (A)*.
883. “Bioengineering Advances to Improve the Quality of Life Throughout the World”, 17th Annual Event of the American Institute for Medical and Biological Engineering, Washington, DC, February 21, 2008, *Galletti Award Lecture*.
884. “Visualization and Analysis of the Dynamics of Methanol Transport in Poly(methyl methacrylate)”, American Physical Society Meeting, New Orleans, LA, March 14, 2008, (A)*.
885. “Protein Bioconjugate Delivery via Intelligent Complexation Systems”, Tenth European Controlled Release Meeting, Noordwijk, the Netherlands, April 3, 2008 (P), *Invited Lecture*.
886. “Oral Insulin Bioconjugate Delivery Using Intelligent Complexation Systems”, 6th World meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Barcelona, Spain, April 9, 2008, (A)*.
887. "New pH-sensitive Hydrogel for an Oral Delivery of Proteins with a High Isoelectric Point" 6th World meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Barcelona, Spain, April 9, 2008, (A)*.
888. “Oral Delivery of Insulin and Other Proteins”, 8th World Biomaterials Congress, Amsterdam, The Netehrlands, May 30, 2008 (P).
889. “Molecular Design of a Novel Complexation Hydrogel for the Oral Delivery of Therapeutic Proteins” 8th World Biomaterials Congress, Amsterdam, The Netherlands, May 30, 2008 (P)*.
890. “Oral Delivery of Insulin Bioconjugates Using Intelligent Complexation Hydrogels”, 8th World Biomaterials Congress, Amsterdam, The Netherlands, May 30, 2008 (P)*.
891. “Cationic Hydrogels for Intelligent Insulin Delivery”, 8th World Biomaterials Congress, Amsterdam, The Netherlands, May 29, 2008 (P)*.
892. “Analysis of Poly(Ethylene Glycol) Tethered Poly(Acrylic Acid) Networks for Mucoadhesive Applications”, ”, 8th World Biomaterials Congress, Amsterdam, The Netherlands, May 31, 2008 (P)*.

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893. "Metal-Polymer Nanocomposites as Externally Triggered Therapeutic Systems", ", 8th World Biomaterials Congress, Amsterdam, The Netherlands, May 29, 2008 (P)*.
894. "Fast- vs. Slow- Paclitaxel Eluting Degradable Stents and Their Impacts on Coronary Artery Smooth Muscle Cells Proliferation", ", 8th World Biomaterials Congress, Amsterdam, The Netherlands, May 31, 2008 (P)*.
895. "Design of Functional and Intelligent Polymeric Carriers for Improved Cellular Transport and Biorecognition", 6th International Conference of the Chemical Societies of the SE European Countries, September 13, 2008 (A), *Plenary Lecture.*
896. "The Role of Chemical Engineering in the Growth of Bioengineering and Nanotechnology", 11th Mediterranean Congress of Chemical Engineering, October 23, 2008 (P), *Plenary Lecture*.
897. "Conductive Polymer and Hydrogel Composites as Functional Biomaterials", Annual AIChE Meeting, Philadelphia, PA, November 16, 2008 (A)*.
898. "Investigating Dynamic Penetrant Transport In Glassy Polymers for High-Tech Applications", Annual AIChE Meeting, Philadelphia, PA, November 16, 2008 (A)*.
899. "Photopolymerized pH-Responsive Nanomatrices for Applications In Nanomedicine", Annual AIChE Meeting, Philadelphia, PA, November 16, 2008 (A)*.
900. "An Examination of Structural Parameters Affecting the Dynamics of Penetrant Transport In Glassy Polymers", Annual AIChE Meeting, Philadelphia, PA, November 17, 2008 (A)*.
901. "Past, Present and Future of Drug Delivery", Annual AIChE Meeting, Philadelphia, PA, November 17, 2008 (A)*.
902. "Biomolecular Sensing with Polyaniline-Poly(2-acrylamidomethylpropane sulfonic acid) Nanosystems", Annual AIChE Meeting, Philadelphia, PA, November 18, 2008 (A)*.
903. "Towards the Development of Biodegradable Sensors from Smart Hydrogels", Annual AIChE Meeting, Philadelphia, PA, November 21, 2008 (A)*.
904. "Diffusional Mechanisms in Glassy Polymers", Annual APS Meeting, Pittsburgh, PA, March 17, 2009 (A)*.
905. "The Development of an Oral Protein Delivery System Using PEGylated Proteins", Annual SFB Meeting, San Antonio, TX, April 24, 2009 (P)*.
906. "Hydrogels Modified with Carbohydrates for Oral Protein Delivery," Annual SFB Meeting, San Antonio, TX, April 24, 2009 (P)*.
907. "Temperature-Sensitive Polymer-Gold Nanocomposites for Externally Controlled Therapeutic Systems," Annual SFB Meeting, San Antonio, TX, April 24, 2009 (P)*.
908. "Protein Recognitive Hydrogel Systems for Biosensor/Biodiagnostic Applications", Annual SFB Meeting, San Antonio, TX, April 24, 2009 (P)*.
909. "Biodegradable, pH-Responsive Hydrogels as Sensing Microstructures", Annual SFB Meeting, San Antonio, TX, April 24, 2009 (P)*.
910. "Swelling Controlled Release 30 Years Later: Responsive Intelligence and Delivery Design", PharmSciFAir, Nice, France, June 10, 2009 (P), *Invited lecture*.
911. "Novel Microsensors From Biodegradable Smart Hydrogels", Annual AIChE Meeting, Nashville, TN, November 7, 2009 (A)*.
912. "Protein Recognitive Hydrogel Systems for Biosensor Applications", Annual AIChE Meeting, Nashville, TN, November 9, 2009 (A)*.
913. "Recent Advances in Hydrogels as Biomaterials", Annual AIChE Meeting, Nashville, TN, November 10, 2009 (A), *Invited Lecture*.
914. "Recognitive Networks in Advanced Responsive Systems", Annual AIChE Meeting, Nashville, TN, November 11, 2009 (A), *Invited Lecture*.
915. "Dynamics of Non-Fickian Penetrant Transport in Glassy Polymers", Annual AIChE Meeting, Nashville, TN, November 13, 2009 (A)*.
916. "Microcantilever Sensors Utilizing Biodegradable, pH-Responsive Hydrogel", Annual AIChE Meeting, Nashville, TN, November 13, 2009 (A)*.
917. "Investigating Dynamics Penetrant Transport in Glassy Polymers for High-Tech Applications", Annual AIChE Meeting, Nashville, TN, November 13, 2009 (A)*.
918. "Development of pH-Responsive Nanogels for Delivery of siRNA", Annual AIChE Meeting, Nashville, TN, November 13, 2009 (A)*.
919. "Synthesis and Caracterization of Polyaniline-Polymer Acid Complexes for Use in Biosensing Applications", Annual AIChE Meeting, Nashville, TN, November 13, 2009 (A)*.

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920. "Recognition and Delivery: The Next Generation of Medical Microdevices", US-Japan Drug Delivery Meeting, Maui, HI, December 18, 2009 (A)*, *Invited lecture*.
921. "Intelligent and Feedback-Controlled Nanoparticles for Intelligent Drug Delivery", First Global Congress on NanoEngineering for Medicine and Biology, ASME, Houston, TX, February 9, 2010 (A), *Plenary Lecture*.
922. "Nanoparticulate Metal-Polymer Systems for Externally-Controlled Delivery", First Global Congress on NanoEngineering for Medicine and Biology, ASME, Houston, TX, February 9, 2010 (A), *Plenary Lecture*.
923. ""Protein Recognitive Hydrogel Systems for Biosensor Applications", First Global Congress on NanoEngineering for Medicine and Biology, ASME, Houston, TX, February 9, 2010 (A), *Plenary Lecture*.
924. "The Evolution of Controlled Drug Delivery Devices and Systems: Pioneers and Imaginative Solutions", 7th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Valletta, Malta, March 8, 2010, *Maurice-Marie Janot Award Lecture*.
925. "The Future of Biomedical Engineering", Annual Meeting of the Southeastern Universities Research Association, Duke University, Durham, NC, March 10, 2010, *Distinguished Scientist Lecture*.
926. "Biomaterials in the Service of World Health and the Improvement of our Patients' Quality of Life", Society for Biomaterials meeting, Seattle, WA, April 22, 2010 (A), *Hall Award Lecture*.
927. "Nanoparticulate Gold-Polymer Systems for Externally-Controlled Delivery", Society for Biomaterials meeting, Seattle, WA, April 22, 2010 (A)*.
928. "Protein Recognitive Hydrogel Systems for Biosensor Applications", Society for Biomaterials meeting, Seattle, WA, April 22, 2010 (A)*.
929. "Health Care and Advanced Therapeutics", Meeting on Innovation in Health Care Delivery Systems, April 30, 2010 (A), *Invited Lecture*.
930. "Engineering Better Materials", Grand Challenges Summit of the National Academy of Engineering, University of Washington, Seattle, WA, May 3, 2010 (A), *Plenary Lecture*.
931. "Protein Recognitive Hydrogel Systems for Biosensor Applications", 20th World Congress on Biosensors, Glasgow, United Kingdom, May 27, 2010 (A)*.
932. "Controlled Release 50 Years Later: Responsive Intelligence and Delivery by Design", 37th Annual Meeting & Exposition of the Controlled Release Society, Portland, OR, July 14, 2010 (A), *Plenary Lecture*.
933. "Advanced Responsive and Feedback-Controlled Nanoparticles for Drug and Protein Delivery", 3rd International Meeting on Pharmacy & Pharmaceutical Sciences, Istanbul, Turkey, June 11, 2010 (A), *Plenary Lecture.*
934. "Chronotherapy of Hypertension: Past, Present and Future", 26th meeting of the International Society of Chronobiology, Vigo, Spain, July 12, 2010 (A)*.F
935. "Advances in Hydrogels as Intelligent Biomaterials", Annual BMES meeting, Austin, TX, October 7, 2010 (P), *Plenary Lecture, Acta Biomaterialia Lecture*.
936. "From Therapeutics and Drug Delivery to Advanced, Intelligent Biomedical Devices for Improvement of the Quality of Life of our Patients", Annual BMES meeting, Austin, TX, October 7, 2010 (P), *Plenary Lecture, BMES Distinguished Achievement Award Lecture.*
937. "Kinetic Swelling Responses of Iron Oxide/Hydrogel Nanocomposites", Annual BMES meeting, Austin, TX, October 7, 2010 (P)*.
938. "Optimizing Protein Recognitive Hydrogel Systems for Biosensor Applications", Annual BMES meeting, Austin, TX, October 7, 2010 (P)*.
939. "Polybasic 2-(Diethylaminoethyl) Methacrylate Nanogels and Their Application in Oral SiRNA Delivery", Annual BMES meeting, Austin, TX, October 7, 2010 (P)*.
940. "Metal-Polymer Composite Nanoparticle Systems for Externally Controlled Delivery", Annual BMES meeting, Austin, TX, October 7, 2010 (P)*.
941. "Development of PH-Responsive Nanoparticles for Targeted, Controlled Release of 5-Fluorouracil", Annual BMES meeting, Austin, TX, October 7, 2010 (P)*.
942. "Swelling and Insulin Release of Glucose-Responsive Microparticles and Nanogels", Annual BMES meeting, Austin, TX, October 7, 2010 (P)*.
943. "Carbohydrate Surface Modification for Oral Protein Delivery", Annual BMES meeting, Austin, TX, October 7, 2010 (P)*.

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944. "Investigating Case II and Anomalous Penetrant Transport in Glassy Polymers", Annual AIChE Meeting, Salt Lake City, UT, November 7, 2010 (A)*.
945. "Hydrogel-Based Protein Recognitive Systems for Diagnostic Applications", Annual AIChE Meeting, Salt Lake City, UT, November 8, 2010 (A)*.
946. "Case II and Anomalous Penetrant Transport in Glassy Polymers", Annual AIChE Meeting, Salt Lake City, UT, November 8, 2010 (A)*.
947. "Synthesis and in vitro Characterization of pH-Responsive Nanogels for Oral Delivery of siRNA", Annual AIChE Meeting, Salt Lake City, UT, November 10, 2010 (A)*.
948. "Seeking Art-ful Science in Biomaterials", Annual TERMIS Meeting, Orlando, FL, December 4, 2010 (A), *Invited Lecture*.
949. "Advances in Protein Delivery and Responsive Nanoscale Drug Delivery Systems", Congress of the Spanish Sciety of Industrial Pharmacy, Madrid, February 2, 2011 (P), *Plenary Lecture*.
950. "Development of pH-Responsive Biodegradable Hydrogels for the Controlled Release of Antitumor Drugs", Congress of the Spanish Sciety of Industrial Pharmacy, Madrid, February 2, 2011 (P)*.
951. "New Frontiers in Drug Delivery: Emerging Applications in Oral Administration", 15th International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February 15, 2011 (A), *Invited Lecture*.
952. "Tuning the Dynamics of Penetrant Transport in Glassy Polymers through Network Structure Modification," Annual American Physical Society Meeting, Dallas, TX, March 24, 2011 (A)*.
953. "Environmentally Responsive Polymeric Carrier Systems for Oral Delivery of Chemotherapeutics", SFB Biomaterials Day, College Station, TX, May 16, 2011 (A)*.
954. "Protein Conformational Studies for Molecularly Imprinted Polymers", SFB Biomaterials Day, College Station, TX, May 16, 2011 (A)*.
955. "Amphiphilic Interpenetrating Networks for Oral Anticancer Drug Delivery", SFB Biomaterials Day, College Station, TX, May 16, 2011 (A)*.
956. "Rapidly Degradable Dual-Responsive Nanoscale Hydrogels for siRNA Delivery", SFB Biomaterials Day, College Station, TX, May 16, 2011 (A)*.
957. "Advanced siRNA and Protein Delivery Through Smart Hydrogels", 7th International Symposium on Controlled Release Systems, Istanbul, Turkey, June 2, 2011 (A), *Plenary Lecture*.
958. "Evaluation of Polysaccharide-Modified Complexation Hydrogels for Oral Protein Delivery", Annual BMES meeting, Hartford, CT, October 13, 2011 (P).
959. "Temperature-Responsive Interpenetrating Polymer Network Nanogels and Nanocomposites", Annual BMES meeting, Hartford, CT, October 13, 2011 (P).
960. "Hydrophobic-Hydrophilic Interpenetrating Networks for Oral Chemotherapeutic Delivery" ", Annual BMES meeting, Hartford, CT, October 13, 2011 (P)*.
961. "Hydrophobic Nanoparticles Encapsulated in Hydrophilic Hydrogel for Oral Delivery of Chemotherapeutics", Annual BMES meeting, Hartford, CT, October 13, 2011 (P)*.
962. "An Injectable, Synthetic Immune Center for Cancer Vaccines: Efficient Delivery of Tumor-Antigens and Immune-Modulatory Nucleic Acids to Dendritic Cells", Annual BMES meeting, Hartford, CT, October 14, 2011 (P)*.
963. "Responsive Nanoscale Drug Delivery Systems", Biointerface meeting, Minneapolis, MN, October 26, 2011 (A), *Plenary Lecture*.
964. "An Injectable, Synthetic Immune-Priming Center for Efficient Delivery of Immunomodulatory Nucleic Acids and Protein/Peptide Antigens", US-Japan Drug Delivery Meeting, Maui, HI, December 18, 2011 (A)*.
965. "Oral Delivery of Interferon-alpha for Chemotehrapy", US-Japan Drug Delivery Meeting, Maui, HI, December 18, 2011 (A)*.
966. "Applications of Intelligent Nanotechnologies in Therapeutic Delivery, Miami 2012 Winter Symposium: Nanotechnology in Biomedicine, Miami, FL, February 29, 2012, *Plenary Lecture*.
967. "Advances in Hydrogels for Medical Applications", 6th International Symposium on Intelligent Drug Delivery, Seoul, South Korea, March 15, 2012 (A), *Plenary Lecture*.
968. "Advances in Intelligent and Recognitive Hydrogels for Treatment of Diabetes, Cancer and Multiple Sclerosis", International Symposium, Drugs, Nanomedicine and Biomaterials, Areces Foundation, Madrid, Spain, April 25, 2012 (A), *Plenary Lecture*.
969. "Intelligent Biomaterials for Medical Devices with Molecular Recognition Capabilities", 9th World Biomaterials Congress, Chengdu, China, June 2, 2012 (P), *Plenary Lecture*.

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970. "Efficient Delivery of siRNA with Dual-responsive Nanoscale Hydrogels", 9th World Biomaterials Congress, Chengdu, China, June 2, 2012 (P).
971. "Promoting Convergence in Biomaterials Engineering", Top-Level Forum: Biomaterials Science and Engineering, Present, Future and Development Stategy, Chengdu, China, June 2, 2012 (A).
972. "Intelligent Biomaterials to Control Recognition and Specificity in Naomedicine", NanoBioSeattle, Seattle, WA, July 23, 2012 (A), *Plenary Lecture*.
973. "Hydrogels as Biomaterials: A 40-year saga", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
974. "Responsive polycationic nanoparticles for co-delivery of siRNA and chemotherapeutical agents to overcome multidrug resistance in cancer therapy", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
975. "pH-Responsive Hydrogels for Oral Delivery of Therapeutic Proteins", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
976. "Comparing ARGET ATRP with traditional free radical polymerization for versatile polycationic hydrogel nanoparticles", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
977. "Two-part oral siRNA delivery system: polycationic hydrogel nanoparticles and alginate matrix", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
978. "Design of pH-Responsive Carriers for the Oral Delivery of High Molecular Weight Protein Therapeutics", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
979. "Complexation Hydrogels as Oral Delivery Vehicles of Therapeutic Antibodies", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
980. "Synthesis and Characterization of Composite Hydrogel Particles for Oral Delivery Small Interfering RNA", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
981. "Intelligent Polymeric Biomaterials for the Oral Delivery of Hydrophobic Therapeutic Agents for Cancer Treatment", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
982. "Externally-Triggered Thermally-Responsive Nanocomposites for Advanced Therapeutic Delivery", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
983. "Environmentally Responsive Polymeric Carrier Systems for Oral Delivery of Protein-Based Chemotherapeutic Agents", Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
984. "The Influence of Enhanced Core Hydrophobicity on Membrane Disruptive Properties of Poycationic Nanoscale Hydrogels Containing 2-(Diethylaminoethyl) Methacrylate, Biomaterials Days, Society for Biomaterials Regional Meeting, Houston, TX, July 27, 2012.
985. "Enhanced Membrane Disruption and siRNA Delivery through Responsive Nanoscale Hydrogels", Annual AAPS meeting, Chicago, IL, October 18, 2012.
986. "An injectable, immune priming center for cancer vaccines: Simultaneous, single-carrier delivery of tumor-antigens and immune-modulatory nucleic acids to dendritic cells", CPRIT Conference, October 25, 2012 (P).
987. "Nanohydrogels as delivery systems of antineoplastic drugs and siRNA to overcome multidrug drug resistance in cancer treatment" CPRIT Conference, October 25, 2012 (P).
988. "Two-part oral siRNA delivery systems for the treatment of colon cancer", CPRIT Conference, October 25, 2012 (P).
989. "Synthesis and Characterization of Composite Hydrogel Particles for Oral Delivery of siRNA," Annual BMES Meeting, Atlanta, GA, October 25, 2012 (P).
990. "Intelligent Nanoscale Hydrogels for the Oral Delivery of Chemotherapeutics", Annual BMES meeting, Atlanta, GA, October 27, 2012 (P).
991. "Composite Hydrogel Particles for Oral Small Interfering RNA Delivery", Annual BMES meeting, Atlanta, GA, October 26, 2012 (P).
992. "Complexation Hydrogels as Oral Delivery Vehicles of Therapeutic Antibodies," Annual BMES Meeting, Atlanta, GA, October 25, 2012 (P).
993. "Development of pH-Responsive Hydrogel Networks for the Oral Delivery of Human Growth Hormone", Annual BMES meeting, Atlanta, GA, October 26, 2012 (P).

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994. "Nanotechnology and Bioengineering in an Evolving Chemical Engineering World: The Next Generation of Recognitive, Intelligent Medical Microdevices", Topical Conference, Annual AIChE meeting, Pittsburgh, PA, October 29, 2012, (A) *Plenary Lecture*.
995. "pH-Responsive, Polycationic Nanoparticles Designed for Intracellular siRNA Delivery", Annual AIChE meeting, Pittsburgh, PA, October 30, 2012, (A)*.
996. "Nanoscale Anionic Hydrogel Prepared by Emulsion Polymerization for Oral Delivery of siRNA", Annual AIChE meeting, Pittsburgh, PA, October 30, 2012, (A)*.
997. "Surface Hydrolysis Mediated PEG Conjugation of Poly(N-isopropyl acrylamide-co-acrylamide) Nanospheres", Annual AIChE meeting, Pittsburgh, PA, October 30, 2012, (A)*.
998. "pH-Responsive Hydrogels for Oral Delivery of Therapeutic Proteins", Annual AIChE meeting, Pittsburgh, PA, November 1, 2012, (A)*.
999. "Grafted Polymeric Nanoscale Hydrogels for the Oral Delivery of Chemotherapeutics", Annual AIChE meeting, Pittsburgh, PA, November 1, 2012, (A)*.
1000. "Dynamics and Diffusional Behavior of Complexation Networks and gels with Applications to Drug Delivery and Molecular Recognition", 9th Society og Polymer Science Japan International Polymer Conference, Kobe, Japan, December 12, 2012, (A), *Plenary Lecture*.
1001. "Intelligent Hydrogels and the Future of Nanomedicine", NIPAM-80 meeting in honor of Allan Hoffman, December 16, 2012 (P), *Invited Lecture*.
1002. "Protein Transport Mechanisms and Protein/Polymer Dynamics in Transmucosal Delivery", Keynote Speaker, 4th International Conference on Biomolecular Engineering, Miami, FL January 13, 2013 (P), *Keynote Lecture*.
1003. "Development of a pH-Responsive Hydrogel Network for the Oral Delivery of Human Growth Hormone", Society for Biomaterials meeting, Boston, MA, April 10, 2013 (A)*.
1004. "Polycationic Hydrogel Nanoparticles for siRNA Delivery", Society for Biomaterials meeting, Boston, MA, April 12, 2013 (A)*.
1005. "Microencapsulated Polymeric Systems for the Oral Delivery of siRNA", Biomaterials Days, Society for Biomaterials Regional Meeting, Austin, TX, May 31, 2013*.
1006. "Startegies for the Enhanced Bioavailability of Orally-Delivered Growth Hormonw Utilizing pH-Responsive Polymeric Platforms", Biomaterials Days, Society for Biomaterials Regional Meeting, Austin, TX, May 31, 2013*.
1007. "Smart Hydrogel Nanocarriers for the Oral Delivery od Chemotherapeutics", Biomaterials Days, Society for Biomaterials Regional Meeting, Austin, TX, May 31, 2013*.
1008. "pH-Responsive polymer nanoparticles synthesized using ARGET ATRP for therapeutic siRNA delivery, Biomaterials Days, Society for Biomaterials Regional Meeting, Austin, TX, May 31, 2013*.
1009. "pH-Responsive Hydrogels for Improved Bioavailability of Therapeutic Proteins by Oral Administration, Biomaterials Days, Society for Biomaterials Regional Meeting, Austin, TX, May 31, 2013*.
1010. "Oral delivery of siRNA Using pH-Resonsive Hydrogel Nanoparticles", Biomaterials Days, Society for Biomaterials Regional Meeting, Austin, TX, May 31, 2013*.
1011. "Complexation Hydrogels as Oral Delivery Vehicles of Therapeutic Proteins: Evaluation of Protein Release and Bioactivity", Biomaterials Days, Society for Biomaterials Regional Meeting, Austin, TX, May 31, 2013*.
1012. "Novel Biocompatible Nanoparticles for Externally Triggered Drug Delivery", Biomaterials Days, Society for Biomaterials Regional Meeting, Austin, TX, May 31, 2013*.
1013. "Novel Intelligent and Recognitive Carriers for siRNA Delivery and Theranostics", 5th Asian Arden Conference, Nagoya, Japan, August 6, 2013, *Plenary Lecture* (P).
1014. "Novel Intelligent and Recognitive Carriers for siRNA Delivery and Theranostics," XXV Symposium of the European Symposium for Biomaterials, Madrid, Spain, September 8, 2013, *Plenary Lecture* (P).
1015. "Advanced Responsive and Feedback-Controlled Nanoparticles for Consumer and Cosmetic Applications," 19th International Symposium on Microencapsulation, Pamplona, Spain, September 10, 2013, *Plenary Lecture* (P).
1016. "Oral delivery of siRNA Using pH-Resonsive Hydrogel Nanoparticles", Annual BMES meeting, Seattle, WA, September 26, 2013 (P)*.
1017. "Delivery Vectors for Oral Protein Therapeutics: Characterization and Cellular Transport", Annual BMES meeting, Seattle, WA, September 26, 2013 (P)*.

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1018. “Synthesis and Characterization of pH-sensitive Hydrogel Carriers for Oral Vaccine Delivery”, Annual BMES meeting, Seattle, WA, September 27, 2013 (P)*.
1019. “Development and optimization of a pH-responsive hydrogel system for the oral delivery of high molecular weight protein therapeutics”, Annual BMES meeting, Seattle, WA, September 28, 2013 (P)*.
1020. “Design of surface imprinted nanoparticles for enhanced recognition of biomacromolecules”, Annual BMES meeting, Seattle, WA, September 28, 2013 (P)*.
1021. “Biodegradable microencapsulated nanogel system for the oral delivery of siRNA”, Annual Meeting Society of Women Engineers, Baltimore, MD, October 25, 2013, (P)*.
1022. “Oral Delivery of Therapeutic Proteins Exhibiting High Isoelectric Points in pH-Responsive Hydrogels,” 2013 Annual AIChE Meeting, San Francisco, CA, November 4, 2013, (P)*.
1023. “Responsive Nanoscale Hydrogels for the Oral Delivery of Chemotherapeutics,” 2013 Annual AIChE Meeting, San Francisco, CA, November 4, 2013, (P)*.
1024. “NSEF Forum Award Presentation: Intelligent and Recognitive Nanoscale Systems for a New Generation of Therapeutic Applications,” 2013 Annual AIChE Meeting, San Francisco, CA, November 4, 2013, (P), *Award Lecture*.
1025. “Microencapsulated Nanogel System for the Oral Delivery of siRNA,” 2013 AAPS Annual Meeting and Exposition, San Antonio, TX, November 11, 2013 (P)*.
1026. “Therapeutic siRNA Delivery Using pH-Responsive Polymer Nanoparticles,” 2013 AAPS Annual Meeting and Exposition, San Antonio, TX, November 12, 2013, (P)*.
1027. “Improved Release of Salmon Calcitonin from pH-Responsive Hydrogels,” 2013 AAPS Annual Meeting and Exposition, San Antonio, TX, November 12, 2013, (P)*.
1028. “Smart, Hydrogel Nanoparticles for the Oral Delivery of Hydrophobic Therapeutics,” 2013 AAPS Annual Meeting and Exposition, San Antonio, TX, November 12, 2013 (P)*.
1029. “Development and Characterization of Surface-modified pH-Responsive Hydrogels for Oral Delivery of Protein Therapeutics,” 2013 AAPS Annual Meeting and Exposition, San Antonio, TX, November 12, 2013 (P)*.
1030. “Advanced Biomaterials and Nanotechnology for Improved Health Care,” 2013 MRS Fall Meeting, Boston, MA, December 2, 2013, *Plenary Lecture*.
1031. "Development and characterization of a pH-responsive hydrogel system for the oral delivery of high molecular weight protein therapeutics", US-Japan Drug Delivery meeting, Lahaina, HI, December 15-19, 2013*.
1032. "Development of pH-responsive hydrogel carriers for targeted oral vaccine delivery", US-Japan Drug Delivery meeting, Lahaina, HI, December 15-19, 2013*.
1033. "Microencapsulated polymeric systems for the oral delivery of siRNA" , US-Japan Drug Delivery meeting, Lahaina, HI, December 15-19, 2013*.
1034. “Stimuli-Responsive Hydrogels for Oral Delivery of High Isoelectric Point-Exhibiting Therapeutic Proteins,” 2014 Annual ACS Meeting, Dallas, TX, March 18, 2014, (P)*.
1035. “Intelligent and Recognitive Networks and Hydrogels: From Theory to Biomedical Applications,” 2014 Annual ACS Meeting, Dallas, TX, March 18, 2014, *Award Address*. (P)*.
1036. “Surface-Modification of P(MAA-co-NVP) Microparticles for Oral Protein Delivery,” 2014 Annual ACS Meeting, Dallas, TX, March 18, 2014, (P)*.
1037. “Investigation of Core-Shell N-alkyl Substituted Acrylamides for Theranostic Delivery of Chemotherapeutics,” 2014 Annual ACS Meeting, Dallas, TX, March 19, 2014, (P)*.
1038. “Environmentally Responsive Theranostic Carrier Systems for Oral Delivery of Chemotherapeutic Agents,” 2014 Annual ACS Meeting, Dallas, TX, March 20, 2014, (P)*.
1039. “pH-Responsive Mannan-modified P(HEMA-co-MAA) Nano-hydrogel Carriers for Oral Vaccine Delivery, 9th PBP World Meeting, Lisbon, Portugal, April 10, 2014 (P)*.
1040. “Fabrication of Intelligent, Protein Recognitive Polymers on the Surface of Biodegradable Nanoparticles,” 2014 Annual SFB Meeting, Denver, CO, April 17, 2014, (P)*.
1041. “Surface Hydrolysis Mediated PEGylation for the Passivation of pNIPAM Nanogels,” 2014 Annual SFB Meeting, Denver, CO, April 17, 2014, (P)*.
1042. “Design of a Polyanhydride-Releasing Oral Microparticle Technology (PROMPT) for Oral Vaccine Delivery,” 2014 Annual SFB Meeting, Denver, CO, April 18, 2014, (P)*.
1043. “Evaluation of Surface-Modified P(MAA-co-NVP) Hydrogels for Oral Protein Delivery,” 2014 Annual SFB Meeting, Denver, CO, April 18, 2014, (P)*.

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1044. "Future Directions in Drug Delivery and Interlligent/ Responsive Materials", Recovery of Biological Products XVI Conference, Hohe Düne, Rostock, Germany, (A), July 30, 2014, *Plenary Lecture*.
1045. “Intelligent/Recognitive Nanoscale Systems for New Therapeutic Applications”, US-China Symposium on Nanobiology and Nanomedicine, Washington, DC (P), October 16, 2014, Keynote Lecture.
1046. “Polyanionic Nanoscale Hydrogels for the Oral Delivery of Chemotherapeutics”, Annual BMES meeting, San Antonio, TX, October 23, 2014 (P)*.
1047. “Macromolecularly Imprinted Polymers on the Surface of Nanoparticle Supports for Low-Cost Biosensors“, Annual BMES meeting, San Antonio, TX, October 22, 2014 (P)*.
1048. “Core/Shell Systems for Improved Control of the Externally Triggered Release of Chemotherapeutics”, Annual BMES meeting, San Antonio, TX, October 22, 2014 (P)*.
1049. “Passivation of pNIPAM Nanogels through Surface Hydrolysis Mediated PEGylation“, Annual BMES meeting, San Antonio, TX, October 23, 2014 (P)*.
1050. “Enzymatically Degradable Microgels for the Oral Delivery of siRNA”, Annual BMES meeting, San Antonio, TX, October 23, 2014 (P)*.
1051. “Optimization of pH-Responsive Hydrogels for Delivery of HMW Proteins”, Annual BMES meeting, San Antonio, TX, October 23, 2014 (P)*.
1052. “Development of pH-Responsive Hydrogel Carriers for Oral Vaccine Delivery”, Annual BMES meeting, San Antonio, TX, October 23, 2014 (P)*.
1053. “pH-Responsive P(IA-co-NVP) Hydrogels for the Oral Delivery of High Isoelectric Point Proteins” Annual BMES meeting, San Antonio, TX, October 23, 2014 (P)*.
1054. “Hydrogel Polymer Libraries for Developing Induced Pluripotent Stem Cell Derived Cardiac Patches“, Annual BMES meeting, San Antonio, TX, October 23, 2014 (P)*.
1055. “Polyanionic Nanoscale Hydrogels for the Oral Delivery of Chemotherapeutics”, Annual BMES meeting, San Antonio, TX, October 24, 2014 (P)*.
1056. “Macromolecularly Imprinted Polymers on the Surface of Nanoparticle Supports for Low-Cost Biosensors” Annual BMES meeting, San Antonio, TX, October 24, 2014 (P)*.
1057. “Core/Shell Systems for Improved Control of the Externally Triggered Release of Chemotherapeutics”, Annual BMES meeting, San Antonio, TX, October 24, 2014 (P)*.
1058. “Polyanionic Nanoscale Hydrogels for the Oral Delivery of Chemotherapeutics “, Annual BMES meeting, San Antonio, TX, October 23, 2014 (P)*.
1059. “Macromolecularly Imprinted Polymers on the Surface of Nanoparticle Supports for Low-Cost Biosensors” Annual BMES meeting, San Antonio, TX, October 23, 2014 (P)*.
1060. “Biomedical Engineering: Health Care’s Secret Weapon”, UT in a Day meeting, Houston, TX, November 13, 2014.
1061. “Characterization of pH-Sensitive Polymers for the Delivery of Hemophiliac Factors“, 2014 Annual AIChE Meeting, Atlanta, GA, November 19, 2014, (P)*.
1062. "pH-Sensitive P(IA-co-NVP) Hydrogels As Oral Delivery Vehicles for High Isoelectric Point-Exhibiting Therapeutic Proteins" 2014 Annual AIChE Meeting, Atlanta, GA, November 18, 2014, (P)*.
1063. “Core/Shell structures for the improved retention of hydrophobic chemotherapeutics”, 2014 Annual AIChE Meeting, Atlanta, GA, November 18, 2014, (P)*.
1064. “Hydrogel Polymer Libraries for Developing Induced Pluripotent Stem Cell Derived Cardiac Patches”, 2014 Annual AIChE Meeting, Atlanta, GA, November 19, 2014, (P)*.
1065. “The next Generation of Intelligent Hydrogels: Molecular Reognition, Cellular Interactions and Advanced Delivery Studies”, MaterialsToday Asia2014 meeting, Hong Kong, (A), December 9, 2014, *Plenary Lecture*.
1066. “Recognition of macromolecular biomarkers using core-shell imprinted nanoparticles”, BMES Cellular and Molecular Bioengineering Meeting, St. Thomas, US Virgin Islands, January 07, 2015 (A)*.
1067. “The Effect of Particle Swelling on Protein Adsorption and Recognition”, BMES Cellular and Molecular Bioengineering Meeting, St. Thomas, US Virgin Islands, January 07, 2015 (A)*.
1068. “Novel Biomaterial-Based Carriers for Oral Delivery of Hemophiliac Factor IX”, BMES Cellular and Molecular Bioengineering Meeting, St. Thomas, US Virgin Islands, January 07, 2015 (A)*.

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1069. "Improved Oral Delivery of High Isoelectric Point Therapeutic Proteins using P(IA-co-NVP) Hydrogels", BMES Cellular and Molecular Bioengineering Meeting, St. Thomas, US Virgin Islands, January 07, 2015 (A)*.
1070. "Innovation and Invention in the Pharmaceutical and Biomedical Industry: How to Improve Treatment and Quality of Life of our Patients" National Academy of Inventors meeting, Pasadena, CA, March 20, 2015 (A), *Plenary Lecture*.
1071. "Fundamentals and Applications of Biopolymers in Medical Applications and Drug Delivery", series of 12 lectures at Sichuan University, Checgdu, China, March 22-26, 2015.
1072. "Mathematical Modelling in Drug Delivery: How to Design New Systems Based on Modeling Analysis", Sichuan University, Chengdu, China, March 26, 2015.
1073. "Biomaterials: Past, Present and Future", Chinese Academy of Engineering, Beijing, China, March 27, 2015, *Invited Lecture*.
1074. "Cationic Block Copolymers for the Co-Delivery of siRNA and Chemotherapeutics", Materials Research Society meeting, San Francisco, CA, April 7, 2015 (P)*.
1075. "Molecularly imprinted polymer-based biosensors for detection of biomacromolecules", Materials Research Society meeting, San Francisco, CA, April 7, 2015 (P)*.
1076. "Core/Shell Systems for Improved Control of the Externally Triggered Release of Chemotherapeutics", Materials Research Society meeting, San Francisco, CA, April 7, 2015 (P)*.
1077. "Molecularly Imprinted Polymers on Surface-Modified Gold Nanoparticles for Biosensing Applications", 2015 Annual SFB Meeting, Charlotte, NC, April 16, 2015, (P)*.
1078. " PROMPT: Polyanhydride- Releasing Oral Microparticle Technology as an Oral Vaccine Strategy, ", 2015 Annual SFB Meeting, Charlotte, NC, April 16, 2015, (P)*.
1079. "pH-Responsive Carriers for the Oral Delivery of Hemophiliac Factor IX, 2015 Annual SFB Meeting, Charlotte, NC, April 17, 2015, (P)*.
1080. "pH Responsive Nanoparticles-in-Microparticles System for Oral Delivery of siRNA", 2015 Annual SFB Meeting, Charlotte, NC, April 16, 2015, (P)*.
1081. "Surface Hydrolysis for the Functionalization of pNIPAAm Nanogels", 2015 Annual SFB Meeting, Charlotte, NC, April 16, 2015, (P)*.
1082. "Synthesis and Characterization of Smart Molecularly Imprinted Polymers, Using Structural Analogue Templates, for the Capture and Detection of Biomolecules", Texas Biomaterials Day, Houston, TX, June 1, 2015.
1083. "Optimizing Microcarrier Loading for Oral Drug Delivery Systems", Texas Biomaterials Day, Houston, TX, June 1, 2015.
1084. "Surface Hydrolysis Mediated PEGylation of PNIPAAm Nanogels", Texas Biomaterials Day, Houston, TX, June 1, 2015.
1085. "Encapsulation of Polyanhydride Nanoadjuvants in Biodegradable Microgels for Oral Delivery", Texas Biomaterials Day, Houston, TX, June 1, 2015.
1086. "Synthesis and Characterization of Cationic Nanogels for Enhanced Cancer Therapy", Texas Biomaterials Day, Houston, TX, June 1, 2015.
1087. "Design and development of pH-responsive hydrogel systems for the oral delivery of therapeutic proteins", Texas Biomaterials Day, Houston, TX, June 1, 2015.
1088. "Intelligent, Recognitive Nanoscale Systems for New Therapeutic Applications", 10th Panhellenic Research Congress of Chemical Engineering, Patras, Greece , (A), June 4, 2015, *Plenary Lecture*.
1089. "Responsive polymer based nanobiosensors for diagnostic applications.", 2nd Polaris Conference, Guimaraes, Portugal, June 30, 2015, (P)*.
1090. "Molecularly Imprinted Polymers Capture Biomolecules According to Molecular Weight and Isoelectric Point", 2nd Polaris Conference, Guimaraes, June 30, 2015, (P)*.
1091. "Hydrogels in Drug Delivery". Controlled Rlease Society meeting , Edinburgh, Scotland, July 28, 2015, (A), *Plenary Lecturer.*
1092. "Thermodynamic Response and Structural Dynamics of Nanogels for Concurrent Delivery of Hydrophilic and Hydrophobic Chemotherapeutic Agents", Fouth Texas Soft Matter meeting, Houston, TX, August 21, 2015, (A)*.
1093. "Hydrogels as Biomaterials". European Society for Biomaterials meeting, Krakow, Poland, (A), September 1, 2015, *Award Lecture*.

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1094. “Synthesis and Characterization of Smart Molecularly Imprinted Polymers, Using Structural Analogue Templates, for the Capture and Detection of Biomolecules", Annual BMES Meeting, Tampa, FL, October 7, 2015, (P) *.
1095. “Optimizing Synthesized Nanoparticles for Applications in Drug Delivery”, Annual BMES Meeting, Tampa, FL, October 9, 2015, (P) *.
1096. “Detection of Protein Biomarkers Based On Fluorescence Quenching of Polymer-Coated Conjugated Polymer Nanoparticles”, Annual BMES Meeting, Tampa, FL, October 8, 2015, (P) *.
1097. “Stimuli-Responsive Polymer Shells on Surface-Modified Gold Nanomaterials for Biosensing Applications”, Annual BMES Meeting, Tampa, FL, October 8, 2015, (P) *.
1098. “Oral Delivery of siRNA Using Dual Stimuli-Responsive Microparticles”, Annual BMES Meeting, Tampa, FL, October 9, 2015, (P) *.
1099. “Encapsulation of Polyanhydride Nanoadjuvants in Biodegradable Microgels for Oral Delivery”, Annual BMES Meeting, Tampa, FL, October 9, 2015, (P) *.
1100. “Design & Development of pH-Responsive Hydrogels: An Oral Delivery Strategy for Protein Therapeutics”, Annual BMES Meeting, Tampa, FL, October 8, 2015, (P) *.
1101. “Design and Optimization of Smart Hydrogels for Protein Recognition", AIChE Southwest Regional Conference, Houston, TX, April 9, 2016*.
1102. “Avoiding the Needle: Novel Oral Delivery Systems of Hemophiliac Factor IX”, Annual Society of Women Engineers Meeting, Nashville, TN, October 21, 2015*.
1103. “Design and Development of pH-Responsive Hydrogels: An Oral Delivery Strategy for Protein Therapeutics”, Annual Society of Women Engineers Meeting, Nashville, TN, October 21, 2015*.
1104. “Intelligent Nanogels for the Concurrent Delivery of Hydrophilic and Hydrophobic Chemotherapeutic Agents”, Annual AIChE Meeting, Salt Lake City, UT. November 11, 2015, (A) *.
1105. “Tailoring Biomaterial Microcarriers for the Improved Delivery of Hemophiliac Factor IX”, Annual AIChE Meeting, Salt Lake City, UT. November 11, 2015, (A) *.
1106. “Cationic Nanogels for the Co-delivery of siRNA and Chemotherapeutics", Annual AIChE Meeting, Salt Lake City, UT. November 11, 2015, (A) *.
1107. “P-NIPMAMM Based Core/Shell Systems for Improved Retention of Hydrophobic Chemotherapeutics”, Annual AIChE Meeting, Salt Lake City, UT. November 12, 2015, (A) *.
1108. “The Challenge to Improve the Response of Biomaterials to the Physiological Environment”, Grand Challenges in Biomaterials for the 21st Century, Chengdu, China, November 27, 2015 (A), *Invited Lecturer*,
1109. “Biomaterials: Past, Present and Future”, 2015 Chinese Biomaterials Congress and the 3rd China-US Joint Forum on Innovation and Regulation of Biomaterials, Haiku, China, November 20, 2015, (A), *Invited Lecturer*.
1110. “The Challenge to Improve the Response of Biomaterials to the Physiological Environment”, US-China Entrepreneurship Symposium, Guangzhou, China, December 1, 2015, (A),
1111. “Advanced Intelligent Polymers” Annual Meeting of the Texas Academy TAMEST, Dallas, TX, January 12, 2016, (A*), Plenary Lecturer*.
1112. “Optimization of methacrylic acid-based pH-responsive hydrogels for the oral delivery of therapeutic proteins", Annual ACS Meeting, San Diego, CA, March 13, 2016, (A) *.
1113. “pH-Responsive Microcarriers for the Improved Oral Delivery of Hemophiliac Factor IX”, Annual ACS Meeting, San Diego, CA, March 13, 2016, (A) *.
1114. “Design and Development of a pH-Responsive Nanoscale Hydrogel Platform for Tumor-Targeted Drug Delivery”, World Biomaterials Congress, Montreal, Canada, May 19, 2016, , (A) *.
1115. “Molecularly Imprinted Polymers for Protein Capture, Sequestration, and Delivery”, World Biomaterials Congress, Montreal, Canada, May 21, 2016, , (A) *.
1116. “Development of protein biosensors using surface-imprinted silica-gold nanoshells”, World Biomaterials Congress, Montreal, Canada, May 19, 2016, , (A) *.
1117. “Hydrogel microencapsulation of polyanhydride nanoparticles for antibiotic treatment”, World Biomaterials Congress, Montreal, Canada, May 19, 2016, (A)*.
1118. “Polyanhydride-releasing oral microparticle technology (PROMPT) as a strategy for subunit vaccine administration”, World Biomaterials Congress, Montreal, Canada, May 19, 2016, (A)*.
1119. “Synthesis and Characterization of Tertiary Amine Methacrylate Nanogels for Co-delivery of Multiple Therapeutic Agents", World Biomaterials Congress, Montreal, Canada, May 20, 2016, (A)*.

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1120. “Development of a Dual-Responsive Hydrogel Platform for Tumor-Targeted Drug Delivery”, UT Austin-Portugal Collaboration Conference, Lisbon, Portugal, May 24, 2016, (A)*.
1121. “Intelligent Polymers for Tissue Engineering Applications", UT Austin-Portugal Collaboration Conference, Lisbon, Portugal, May 24, 2016, (A)*.
1122. “Recognitive Alginate Nanoparticles for Protein Therapeutics", UT Austin-Portugal Collaboration Conference, Lisbon, Portugal, May 24, 2016, (A)*.
1123. “Nanoscale Biomaterials”, NanoDay 2016" here at Bilkent UniversityMay 29, 2016, (A), Invited Lecturer.
1124. “*Development of pH-Responsive* Nanogels for Tumor-Targeted Drug Delivery”, Biomaterials Days, Society for Biomaterials Regional Meeting, San Antonio, TX, June 3, 2016, (A)*.
1125. “Influence of Copolymer Composition in Hydrogel-Mediated Chemotherapeutic Delivery”, Biomaterials Days, Society for Biomaterials Regional Meeting, San Antonio, TX, June 3, 2016, (A)*.
1126. “Design and Optimization of Smart Hydrogels for Protein Recognition”, Biomaterials Days, Society for Biomaterials Regional Meeting, San Antonio, TX, June 3, 2016, (A)*.
1127. “Toward Protein Recognition Within Oligopeptide-Containing Imprinted Hydrogels”, Biomaterials Days, Society for Biomaterials Regional Meeting, San Antonio, TX, June 3, 2016, (A)*.
1128. “Co-Delivery of Multiple Therapeutic Agents to Liver Cancer", Biomaterials Days, Society for Biomaterials Regional Meeting, San Antonio, TX, June 3, 2016, (A)*.
1129. “Molecularly and Cellularly Imprinted, Intelligent Scaffolds for Tissue Engineering”, International Symposium on Clinical and Translational Medicine 2016, Shanghai, China, September 24, 2016, (A), *Invited Lecturer*.
1130. “Intelligent Biomaterials to Control Recognition and Specificity, Research Forum on Frontiers in Materials, Sichuan University, Chengdu, China, September 26, 2016, (A), *Plenary Lecturer*.
1131. “Designing the Next Generation of Intelligent Biomaterials and Hydrogels: Molecular Recognition and Advanced Protein and Cell Delivery.“ Annual BMES Meeting, Minneapolis, MN, October 7, 2016, (P)*, *Pritzker Lecturer.*
1132. “Affinity-Mediated Retention and Delivery of High-Isoelectric Point Exhibiting Therapeutic Proteins from Molecularly Imprinted Microparticles", Annual BMES Meeting, Minneapolis, MN, October 7, 2016, (P)*.
1133. “Stimuli-Responsive Nanoscale Hydrogels for the Co-Delivery of Chemotherapeutic Agents”, Annual Society of Women Engineers Meeting, Philadelphia, PA, October 28, 2016, (A)*.
1134. “Design and Development of pH-Responsive Hydrogels: An Oral Delivery Strategy for Protein Therapeutics”, Annual Society of Women Engineers Meeting, Philadelphia, PA, October 28, 2016, (A)*.
1135. “Impact of Novel Intelligent and Recognitive Biomaterials in Medical Sciences”, 2016 World Life Science Conference, Beijing, China, November 3, 2016, (A), *Plenary Lecturer*.
1136. “Rational Design of Charged Nanogels for Differential Protein Capture", Annual AIChE Meeting, San Francisco, CA, November 16, 2016, (A)*.
1137. “Multiplexed Detection of Protein Biomarkers Using Recognitive Polymers in a Localized Surface Plasmon Resonance Sensor Array”, Annual AIChE Meeting, San Francisco, CA, November 17, 2016, (A)*.
1138. “Molecularly Imprinted Polymer-Peptide Hybrid Materials for Engineered Protein Recognition", Annual AIChE Meeting, San Francisco, CA, November 17, 2016, (A)*.
1139. “Polymer Nanoparticle Synthesis and Characterization for the Delivery of Osteoinductive Molecules", Annual AIChE Meeting, San Francisco, CA, November 17, 2016, (A)*.
1140. “Optimization of Cationic Nanogel Composition for Enhanced Co-Delivery of siRNA and Chemotherapeutics”, Annual AIChE Meeting, San Francisco, CA, November 14, 2016, (A)*.
1141. “A Self-Assembled pH-Responsive Multi-Component Platform for Oral Vaccination”, Annual AIChE Meeting, San Francisco, CA, November 16, 2016, (A)*.
1142. “Cell, Peptide and Protein Delivery Problems in Regenerative Engineering”, Annual AIChE Meeting, San Francisco, CA, November 16, 2016, (A)*.
1143. “Design, development, and optimization of pH-responsive hydrogels for the oral delivery of human growth hormone”, Annual AIChE Meeting, San Francisco, CA, November 17, 2016, (A)*.
1144. “Recognitive Methacrylated Alginate Nanoparticles for Protein Therapeutics", Annual AIChE Meeting, San Francisco, CA, November 14, 2016, (A)*.

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1145. Intelligent Hydrogel Systems for Recognitive and Responsive Delivery", Annual AIChE Meeting, San Francisco, CA, November 17, 2016, (A)*.
1146. "Stimuli-Responsive Nanoscale Hydrogels for the Co-Delivery of Chemotherapeutic Agents", Annual AIChE Meeting, San Francisco, CA, November 15, 2016, (A)*.
1147. "Development and Characterization of Stimuli-Responsive Hydrogel Microcarriers for Oral Protein Delivery", Annual SFB Meeting, Minneapolis, MN, April 6, 2017, (A)*.
1148. "Synthesis and Characterization of Polymer Nanogels for the Delivery of Therapeutic Small Molecule Analogs", Annual SFB Meeting, Minneapolis, MN, April 6, 2017, (A)*
1149. "Characterization of Protein Interactions with Molecularly Imprinted Hydrogels that Possess Engineered Affinity for High Isoelectric Point Biomarkers", Annual SFB Meeting, Minneapolis, MN, April 8, 2017, (A)*."
1150. "Influence of Molecular Architecture in the Design and Development of a pH-Responsive Nanoscale Hydrogel Platform for Tumor-Targeted Drug Delivery", 44th Annual Meeting & Exposition of the Controlled Release Society, Boston, MA, July 18, 2017, (A)*.
1151. "Design of pH Responsive Systems for the Oral Delivery of High pI, High Molecular Weight Protein Therapeutics", 44th Annual Meeting & Exposition of the Controlled Release Society, Boston, MA, July 18, 2017, (A)*.
1152. "Polymer Nanogels for the Delivery of Osteoinductive Small Molecule Analogs", 44th Annual Meeting & Exposition of the Controlled Release Society, Boston, MA, July 18, 2017, (A)*.
1153. "Hydrophobic Modifications of Cationic Nanogels for Enhanced Coloading of Cationic Chemotherapeutic Agents", 44th Annual Meeting & Exposition of the Controlled Release Society, Boston, MA, July 18, 2017, (A)*.

P = preprint available; A = abstract available; * = paper presented by collaborator.

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Invited Lectures at Universities and Companies

1. "Novel Heat Resistant Oligomeric Structures as Crosslinking Agents for Polystyrene," Bell Laboratories, Department of Chemistry and Plastics, Murray Hill, New Jersey, November 29, 1976.
2. "Approaches to the Development of Synthetic Biomedical Materials," Stevens Institute of Technology, Department of Chemistry and Chemical Engineering, Hoboken, New Jersey, November 30, 1976.
3. "Transport Properties of Flexible Packaging Materials," American Can Company, Neenah, Wisconsin, February, 1978.
4. "Crystallization of Polymer Networks and its Effect on their Mechanical and Transport Properties," Polymer Department, General Motors Technical Center, Warren, Michigan, October 12, 1978.
5. "Fundamental Studies of Molecular Structure of Polymer Networks in Relation to Applications in Biomedical Engineering," Iowa State University, Department of Chemical Engineering, Ames, Iowa, February 1, 1979.
6. "Non-Gaussian Macromolecular Network Models for the Investigation of the Structure of Bituminous Coals," University of Washington, Department of Chemical Engineering, Seattle, Washington, March 6, 1979.
7. "Hydrophilic Networks for Biomedical Applications," University of Washington, Bioengineering Center, Seattle, Washington, March 6, 1979.
8. "Crystallinity Effects on the Mechanical and Transport Properties of Polymer Films," Oregon State University, Department of Chemical Engineering, Corvallis, Oregon, March 8, 1979.
9. "Effect of Crystallinity on the Mechanical and Diffusion Properties of Polymer Films and Membranes," University of Alberta, Department of Chemical Engineering, Edmonton, Alberta, Canada, March 9, 1979.
10. "Design Possibilities for Portable Artificial Kidneys," University of Geneva, School of Medicine, Geneva, Switzerland, May 17, 1979.
11. "Fundamental Studies of Hydrophilic Polymeric Networks with Applications to Blood-Compatible Materials," University of Geneva, Departments of Chemistry and Pharmacy, Geneva, Switzerland, May 18, 1979.
12. "Crystallization of Hydrophilic Polymers," Federal Technical University of Lausanne, Departments of Chemical Engineering and Materials Science, Lausanne, Switzerland, May 21, 1979.
13. "Statistical Mechanics of Non-Gaussian Polymeric Networks," University of Naples, Department of Chemical Engineering, Naples, Italy, May 22, 1979.
14. "Diffusion through Model Polymeric Networks," University of Naples, Department of Chemical Engineering, Naples, Italy, May 23, 1979.
15. "Design Possibilities for Portable Artificial Kidneys," University of Athens, School of Medicine, Nephrology Section, Athens, Greece, May 30, 1979.
16. "Recent Research on the Mechanical Properties of and the Diffusion Through Hydrophilic Polymers," Greek Atomic Energy Commission, Democritos Nuclear Research Center, Athens, Greece, June 5, 1979.
17. "A Multi-phase Stefan Problem for Swelling of Glassy Polymers," Greek Atomic Energy Commission, Democritos Nuclear Research Center, Athens, Greece, June 5, 1979.
18. "Investigation of the Macromolecular Structure of Bituminous Coals with Applications to Coal Liquefaction," National Technical University of Athens, Department of Chemical Engineering, Athens, Greece, June 12, 1979.
19. "Transport Properties of Hydrophilic Polymers," University of Maine, Department of Chemical Engineering, Orono, Maine, August 15, 1979.
20. "Crystallinity Effects on the Mechanical and Transport Properties of Polymer Films," Rohm and Haas Company, Research Laboratories, Springhouse, Pennsylvania, November 8, 1979.
21. "Structure Effects on the Diffusion Through Rubbery and Glassy Polymers: Theory, Experiments and Applications," Michigan State University, Department of Chemical Engineering, East Lansing, Michigan, January 10, 1980.
22. "Investigation of the Crosslinked Macromolecular Nature of Bituminous Coals," Exxon Research Co., Corporate Research, Linden, New Jersey, May 9, 1980.

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23. "Structural Effects on the Diffusion through Rubbery and Glassy Polymers," DuPont de Nemours & Co., Engineering Experimental Station, Wilmington, Delaware, June 25, 1980.
24. "Prediction of Food Packaging Stability," American Can Co., Barrington Technical Center, Barrington, Illinois, July 8, 1980.
25. "Alcohol Diffusion in PVC," Democritos Nuclear Research Center, Athens, Greece, August 28, 1980.
26. "Effect of Polymer Structure on the Diffusion of Solutes through Membranes," Celanese Research Co., Summit, New Jersey, October 7, 1980.
27. "Theoretical and Experimental Studies of Solute Diffusion in Water-Swollen Polymers with Applications in Hemodialysis and Controlled Release Systems," University of Utah, Departments of Bioengineering and Pharmaceutics, Salt Lake City, Utah, February 10, 1981.
28. "Transport and Relaxation Phenomena in Polymer-Diluent Systems," Stanford University, Department of Chemical Engineering, Palo Alto, California, February 11, 1981.
29. "Solute Diffusion in Swollen Crosslinked Polymers," California Institute of Technology, Department of Chemical Engineering, Pasadena, California, February 12, 1981.
30. "Macromolecular Structures in Bituminous Coals," California Institute of Technology, Department of Chemical Engineering, Pasadena, California, February 13, 1981.
31. "Theoretical and Experimental Studies of Solute Diffusion in Water-Swollen Polymers," University of Michigan, Department of Chemical Engineering, Ann Arbor, Michigan, April 2, 1981.
32. "Controlled Release Technology," Rose-Hulman Institute and Terre-Haute AIChE Chapter, Terre-Haute, Indiana, November 17, 1981.
33. "Molecular Exclusion and Junction Fluctuations: Molecular Theories of Diffusion in Swollen Polymer Networks," University of California at San Diego, Department of Chemical Engineering, LaJolla, California, January 6, 1982.
34. "Macromolecular Structural Analysis of Coals: A New Tool for Investigation of Coal Structure and Coal Liquefaction," University of Houston, Department of Chemical Engineering, Houston, Texas, January 22, 1982.
35. "Molecular Diffusion in Swollen Polymeric Networks: Theories and Applications in Biomedical Separation and Solute Release," Virginia Polytechnic Institute, Department of Chemical Engineering, Blacksburg, Virginia, January 25, 1982.
36. "Recent Advances in Solute Diffusion Through Rubbery and Glassy Polymers," M.I.T., Department of Chemical Engineering, Cambridge, Massachusetts, March 11, 1982.
37. "Controlled Release Technology: Theory and Applications," University of Maine, Department of Chemical Engineering, Orono, Maine, March 12, 1982.
38. "How Polymer Theories Contribute to Our Understanding of Coal Utilization Processes," University of Illinois at Chicago Circle, Department of Energy Engineering, Chicago, Illinois, March 16, 1982.
39. "Recent Developments in EVAc-Based Controlled Release Systems," IMC Corporation, Terre Haute, Indiana, May 4, 1982.
40. "Swelling-Controlled Release Behavior," University of Geneva, Department of Pharmacy, Geneva, Switzerland, May 28, 1982.
41. "Biocompatible Polymers for Non-thrombogenic Applications," University of Lille, Faculty of Sciences, Lille, France, December 14, 1982.
42. "Anomalous Transport of Penetrants and Solutes in Polymers Undergoing Transitions," University of Bologna, Department of Chemical Engineering, Bologna, Italy, January 10, 1983.
43. "Diffusion in Polymer Networks," University of Naples, Department of Chemical Engineering, Naples, Italy, January 12, 1983.
44. "Engineering Aspects of Arteriosclerosis," University of Geneva, Department of Industrial Pharmacy, Geneva, Switzerland, January 14, 1983.
45. "Release of Bioactive Agents from Swellable Polymers: Theory and Experiments," Sandoz Ltd., Pharmaceutical Division, Basle, Switzerland, January 19, 1983.
46. "Transport of Bioactive Agents in the Nasal and Gastric Mucus," Zyma S.A., Nyon, Switzerland, January 26, 1983.
47. "Development, Characterization and Evaluation of New Membranes for Artificial Kidney Applications," Hospital Center of Vaud of the University of Lausanne, Department of Internal Medicine, Division of Nephrology and Hypertension, Lausanne, Switzerland, January 27, 1983.
48. "Contact Lenses as Biomaterials," University of Geneva, Faculty of Sciences, Geneva, Switzerland, February 4, 1983.

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49. "Recent Developments in Controlled-Release Drug Delivery Systems," University Hospital Center of Vaud of the University of Lausanne, Institute of Pharmacology, Lausanne, Switzerland, February 2, 1983.
50. "Diffusional Release from Polymers," Fournier S.A. and University of Dijon, Dijon, France, February 7, 1983.
51. "Recent Advances in Controlled-Release Systems," University of Geneva, Faculty of Sciences, Geneva, Switzerland, February 11, 1983.
52. "Recent Developments in Controlled-Release Drug Delivery Systems," University of Liege, Faculty of Medicine and Institute of Pharmacy, Liege, Belgium, February 14, 1983.
53. "Topological and Free Volume Analysis of Solute Diffusion in Hydrophilic Networks," Twente University of Technology, Department of Chemical Engineering, Enschede, The Netherlands, February 15, 1983.
54. "Topological and Free Volume Analysis of Solute Diffusion in Hydrophilic Networks," University of Leiden, Gorlaeus Laboratory, Department of Physical Chemistry, Leiden, The Netherlands, February 16, 1983.
55. "Energetics of Polymer Surfaces," University of Lausanne, Departments of Chemistry and Pharmacy, Lausanne, Switzerland, February 17, 1983.
56. "Physical Structure and Biocompatibility of Polymers," University of Paris (Paris-Sud), School of Science, Châtenay-Malabry, Paris, France, February 22, 1983.
57. "Some Recent Developments of Modeling and Physical Understanding of Transport of Solutes and Solvents in Glassy Polymers," University of California at Los Angeles, Department of Chemical Engineering, Los Angeles, California, March 18, 1983.
58. "Topological and Free Volume Analysis of Solute Diffusion in Polymeric Networks," University of California at Berkeley, Department of Chemical Engineering, Berkeley, California, April 11, 1983.
59. "Controlled Release of Bioactive Molecules *in vitro* and *in vivo,"* California Institute of Technology, Department of Chemical Engineering, Pasadena, California, April 21, 1983.
60. "Controlled Release of Bioactive Molecules," University of California at Davis, Department of Chemical Engineering, Davis, California, May 19, 1983.
61. "Drug Transport in Dynamically Swelling Hydrophilic Polymers," University of California at San Francisco, Department of Pharmaceutical Chemistry, San Francisco, California, May 27, 1983.
62. "Polymer Structure and Controlled Release of Biomolecules," a set of four seminars on "Diffusion of Solutes in Polymers," "Theories and Experiments of Solute Diffusion in Membranes," "Use of Swellable Polymers in Controlled Release" and "Biocompatibility of Polymers," Zyma Foundation, Nyon, Switzerland, November 24, 1983.
63. "Novel Hydrophilic Systems for Zero-Order Release of Drugs," Farmitalia Carlo Erba of Montedison, Milan, Italy, November 25, 1983.
64. "Swelling-and Relaxation-Controlled Release of Bioactive Agents from Polymers," Purdue University, School of Chemical Engineering, West Lafayette, Indiana, December 1, 1983.
65. "Free-Volume Theories of Solute Diffusion in Membranes," Indiana University-Purdue University at Indianapolis, Department of Chemistry, Indianapolis, Indiana, January 18, 1984.
66. "Swelling-Controlled Release of Bioactive Agents from Polymers," Purdue University, Department of Chemistry, West Lafayette, Indiana, January 25, 1984.
67. "Macromolecular Structure of Bituminous Coals," ACS Pittsburgh Section, Pittsburgh, Pennsylvania, February 16, 1984.
68. "Dynamic Swelling of Coal Particles as a Probe of their Macromolecular Structure," Pennsylvania State University, Department of Materials Science and Engineering, Fuel Science Program, University Park, Pennsylvania, March 8, 1984.
69. "Diffusion of Penetrants and Solutes in Swellable Polymers with Applications to Controlled Release Technology," University of Missouri-Rolla, Department of Chemical Engineering, Rolla, Missouri, April 11, 1984.
70. "Diffusion in Membranes," University of Vienna, Department of Physical Chemistry, Vienna, Austria, June 6, 1984.
71. "Polymers in Controlled Release," Schering Co., New York, New York, October 1, 1984.
72. "Swellable Polymers for Controlled Release of Biomolecules," Smith, Kline and Beckman, Philadelphia, Pennsylvania, December 11, 1984.

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73. "A New Experimental Method for the Determination of the Bioadhesive Bond Strength Between Polymers and Mucus," Menley and James Laboratories, King of Prussia. Pennsylvania, December 12, 1984.
74. "Gel Membrane Structure and Solute Diffusion," Department of Chemical Engineering, State University of New York, Buffalo, New York, January 8, 1985.
75. "Transport of Penetrants and Solutes Through Swellable Glassy Polymers," Department of Chemical Engineering, Washington University, St. Louis, Missouri, March 11, 1985.
76. "Development and Use of Polymer Time-Release Medications," Indianapolis AIChE Section, Indianapolis, Indiana, April 23, 1985.
77. "Characterization of Polymers for Sustained Release Dosage Forms," Upjohn Co., Kalamazoo, Michigan, June 7, 1985.
78. "Characterization Methods of Polymers for Controlled Release," University of Paris-Sud, Department of Pharmacy, Châtenay-Malabry, France, July 2, 1985.
79. "Hydrogels in Controlled Release: Structure of Hydrogels and Mathematical Modeling of Controlled Release Processes," Interx and University of Kansas, Department of Pharmaceutical Chemistry, Lawrence, Kansas, September 17, 1985.
80. "Multicomponent Diffusion in Glassy Polymers," University of Colorado, Department of Chemical Engineering, Boulder, Colorado, October 3, 1985.
81. "Anomalous Penetrant Transport in and Solute Release from Glassy Polymers," University of Wisconsin, Department of Chemical Engineering, Madison, Wisconsin, October 30, 1985.
82. "Bioadhesive Polymers," Hercon Co., S. Plainfield, New Jersey, January 13, 1986.
83. "Bioadhesive Controlled Release Systems," Eli Lilly & Co., Indianapolis, Indiana, February 4, 1986.
84. "Anomalous Transport in Glassy Polymers," University of Akron, Institute of Polymer Science, Akron, Ohio, April 3, 1986.
85. "Anomalous Transport in Glassy Polymers," Owens Corning, Conroe, Texas, May 12, 1986.
86. "Bioadhesion," Rhône-Poulenc Recherches, Saint-Fons, France, October 1, 1986.
87. "Diffusional Phenomena and Stresses Observed During Penetrant Transport and Solute Release in Hydrogels," Leiden University, Center for Biopharmaceutical Sciences, Leiden, Netherlands, October 9, 1986.
88. "Biocompatible Polymers," University of Paris-Sud, Department of Industrial Pharmacy, Châtenay-Malabry, France, October 16, 1986.
89. "Molecular Phenomena in Bioadhesion," Columbia University, Department of Chemical Engineering, New York City, New York, October 24, 1986.
90. "Unusual Applications of Biomaterials: Reconstruction of Vocal Cords, Cartilage and Genital Organs," University of Paris XI, Faculty of Sciences, Châtenay-Malabry, France, November 18, 1986.
91. "Modeling of Solute Diffusion in Polymers," Rhône-Poulenc Recherches, Saint-Fons, France, November 26, 1986.
92. "Solute Diffusion in Block Copolymer Membranes," Rhône-Poulenc Recherches, Saint-Fons, France, November 27, 1986.
93. "Bioadhesion," University of Trieste, Department of Pharmacy, Trieste, Italy, November 28, 1986.
94. "The Effect of Polymer Structure on Drug Delivery," University of Siena, Faculty of Chemistry, Siena, Italy, December 3, 1986.
95. "The Effect of Polymer Structure on Drug Delivery from Controlled-Release Systems," University of Milan, Faculty of Pharmacy, Milan, Italy, December 5, 1986.
96. "Novel Bioadhesive Controlled Release Systems for the Delivery of Febuverine and Metronidazole," Farmitalia Carlo Erba, Milan, Italy, December 5, 1986.
97. "Recent Studies on the Delivery of Peptides Using Swellable Polymers," University of Marmara, Faculty of Sciences, Istanbul, Turkey, December 22, 1986.
98. "Diffusion Studies of Testosterone Through Low Molecular Weight Gels for Transdermal Applications," Hercon Co., S. Plainfield, New Jersey, January 16, 1987.
99. "Bioadhesive Systems for Gastrointestinal and Nasal Applications," Smith, Kline and Beckman, Philadelphia, Pennsylvania, January 22, 1987.
100. "Interactions of Swellable Polymer Microparticles with Mucus," University of Texas, Department of Chemical Engineering, Austin, Texas, February 17, 1987.
101. "Liquid Diffusion in Glassy Polymers," Rice University, Department of Chemical Engineering, Houston, Texas, February 19, 1987.

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102. "A New Approach to Targeting of Genetically-Engineered Molecules: Use of Mucoadhesive Polymeric Microparticles as Carriers for Biomolecular Delivery," Duke University, Department of Biomedical Engineering, Durham, North Carolina, March 17, 1987.
103. "Bioadhesive Polymers," Cygnus Research Co., Redwood City, California, April 4, 1987.
104. "Polymer Microparticle/Mucus Interactions," North Carolina State University, Department of Chemical Engineering, Raleigh, North Carolina, April 6, 1987, *McCabe Lecture.*
105. "New Types of Gels for Biopharmaceutical Applications," Ciba-Geigy Corporation, Basic Pharmaceutics Division, Ardsley, New York, April 14, 1987.
106. "Tablet Disintegration Mechanisms," University of Pavia, Department of Pharmacy, Pavia, Italy, July 3, 1987.
107. "Structure, Swelling and Transport Properties of Methacrylate-Based Networks," University of Cincinnati, Department of Chemical and Nuclear Engineering, Cincinnati, Ohio, October 29, 1987.
108. "Controlled Release Within and Beyond Pharmaceutical Research," University of Pavia, Department of Pharmacy, Pavia, Italy, November 24, 1987, Inaugural *Lecture*.
109. "Bioadhesive Controlled Release Systems," University of Parma, Department of Pharmacy, Parma, Italy, November 25, 1987.
110. "Controlled Release Applications of Hydrophilic Polymers," University of Arizona, Department of Chemical Engineering, Tucson, Arizona, December 8, 1987.
111. "Controlled Release of Perfumes and Other Cosmetic Products," University of Paris XI, Department of Pharmacy, Châtenay-Malabry, France, December 14, 1987.
112. "Environmentally-sensitive Hydrogels," Purdue University, Department of Industrial and Physical Pharmacy, West Lafayette, Indiana, January 19, 1988.
113. "Interactions of Polymers with Mucus: Analysis of Bioadhesive Problems," Johns Hopkins University, Department of Chemical Engineering, Baltimore, Maryland, April 11, 1988.
114. "Swelling-controlled Release Systems," American Cyanamid Company, Lederle Laboratories, Pearl River, New York, April 15, 1988.
115. "Controlled Release from Swellable and Environmentally-Sensitive Polymers," University of Minnesota, College of Pharmacy, Minneapolis, Minnesota, April 21, 1988, *Minnetonka Lecture.*
116. "Polymers as Carriers for Controlled Release Applications," Tecnofarmaci, Milan, Italy, May 6, 1988.
117. "Swelling and Dissolution of Polymers," University of Modena, School of Pharmacy, Modena, Italy, May 13, 1988.
118. "Bioadhesion," University of Pisa, Faculty of Sciences, Pisa, Italy, May 16, 1988.
119. "Swelling and Dissolution of Tablets for Zero-order Controlled Release Systems," University of Geneva, School of Pharmacy, Geneva, Switzerland, May 20, 1988.
120. "Swelling and Dissolution of Polymers," University of Turin, School of Pharmacy, Turin, Italy, May 23, 1988.
121. "Polymer Considerations in the Design of Peptide Delivery Systems," University of Parma, School of Pharmacy, Parma, Italy, May 26, 1988.
122. "Swelling and Collapse of Gels," University of Houston, Department of Chemical Engineering, Houston, Texas, September 23, 1988.
123. "Hydrogels Sensitive to pH, Ionic Strength and Temperature Changes," Northwestern University, Department of Chemical Engineering, Chicago, Illinois, November 10, 1988.
124. "Polymers and Transdermal Systems," Cygnus Research Company, Redwood City, California, November 17, 1988.
125. "pH-Sensitive Hydrogels," University of Washington, Department of Chemical Engineering, Seattle, Washington, March 6, 1989.
126. "Crosslinking in Multimethacrylate Reactions," University of South Florida, Department of Chemical Engineering, Tampa, Florida, March 17, 1989.
127. "Temperature- and pH-Sensitive Hydrogels," University of Pennsylvania, Department of Chemical Engineering, Philadelphia, Pennsylvania, March 20, 1989.
128. "Ionic Hydrogels," Dow Chemical USA, Midland, Michigan, May 5, 1989.
129. "Polymers as Carriers for Controlled Release," Procter & Gamble, Cincinnati, Ohio, October 3, 1989.
130. "Novel Release Systems for the Delivery of Perfumes and Essential Oils Used in Flavorings," Procter & Gamble, Cincinnati, Ohio, October 3, 1989.
131. "Temperature and pH-Sensitive Hydrogels in Biomedical and Pharmaceutical Applications," University of Michigan, Department of Pharmacy, Ann Arbor, Michigan, October 11, 1989.

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132. "The Effect of the Chemical and Physical Polymer Structure on the Release of Bioactive Agents," Ethyl Corporation, Baton Rouge, Louisiana, February 8, 1990.
133. "Swelling Characteristics and Mechanical Properties of Highly Swollen Hydrogels," Kimberly-Clark, Neenah, Wisconsin, February 15, 1990, *Distinguished Lecturer*.
134. "Programmed Insulin Delivery Using Thermosensitive Hydrogels," University of Parma, Department of Pharmaceutical Sciences, Parma, Italy, March 6, 1990.
135. "Ionic Permeability of Polymer Films," C.R. Bard Co., Tewksbury, Massachusetts, April 18, 1990.
136. "Diffusion of Oxygen in Hydrogels," Vistakon, Inc., Jacksonville, Florida, June 20, 1990.
137. "Mechanical Properties of Hydrogels," Vistakon, Inc., Jacksonville, Florida, June 20, 1990.
138. "Drug Release from Hydrogels that Respond to pH and Temperature," University of Geneva, School of Pharmacy, Geneva, Switzerland, September 24, 1990.
139. "Polymers for Articular Cartilage Replacement," Rose-Hulman Institute of Technology, Terre-Haute, Indiana, October 8, 1990.
140. "Structure-Property Relationships in Poly(ethylene oxide-g-methacrylic acid) Hydrogels," Bausch and Lomb Co., Contact Lens Division, Rochester, New York, March 26, 1991.
141. "Recent Advances in Environmentally Sensitive Polymers," Virginia Polytechnic Institute, Department of Chemical Engineering, Blacksburg, Virginia, April 9, 1991.
142. "Characterization of Polymeric Hydrogels," Johnson & Johnson Co., New Brunswick, New Jersey, April 23, 1991.
143. "Diffusional Phenomena and Processes in Polymers in Relation to Consumer Products Development," Kimberly-Clark, Roswell, Georgia, May 17, 1991, *Horizons Lecturer*.
144. "Biodegradable Absorbent Polymers," Dow Chemical Co., Midland, Michigan, August 6, 1991.
145. "Peptide and Protein Delivery from Novel Poly(vinyl alcohol) and Poly(N-vinyl pyrrolidone) Carriers," University of Toronto, Department of Pharmacy, Toronto, Ontario, Canada, October 15, 1991.
146. "Physiologically-sensitive Hydrogels for Biomedical and Drug Delivery Applications," University of Toronto, Department of Chemical Engineering, Toronto, Ontario, Canada, October 16, 1991, Distinguished *Lecturer*.
147. "Bioadhesion of Polymer Gels with Mucin and Mucus: Interdiffusion, Wetting Phenomena and Experimental Verification," Center for Biomaterials, Ontario Center for Materials Research, Toronto, Ontario, Canada, October 16, 1991.
148. "Fast UV Curing Kinetics of Multimethacrylates and their Applications to the Field of Information Storage Systems," McMaster University, Department of Chemical Engineering, Hamilton, Ontario, Canada, October 17, 1991.
149. "Kinetics and Properties of Crosslinked Polymers from Multifunctional Methacrylates," Princeton University, Department of Chemical Engineering, Princeton, New Jersey, November 6, 1991.
150. "Mathematical Modeling of Controlled Release Systems," University of Geneva, Department of Pharmacy, Geneva, Switzerland, April 29, 1992.
151. "Bioadhesive Polymers," University of Santiago, Department of Pharmacy, Santiago de Compostella, Spain, November 12, 1992.
152. "Polymer Gels in Medicine and Biology," Texas A&M University, Department of Chemical Engineering, College Station, Texas, January 29, 1993.
153. "Controlled Release with Ionic Polymers," Landec Corporation, Redwood City, California, May 5, 1993.
154. "Recent Advances in Bioadhesive," Nichiban Co., Tokyo, Japan, April 27, 1993.
155. "Hydrogels in Drug Delivery," Advanced Polymer Systems, Menlo Park, California, July 1, 1993.
156. "Physiologically Sensitive Controlled Release Systems," Seoul National University, Department of Pharmacy, Seoul, Korea, August 30, 1993.
157. "Modeling of Multifunctional UV Polymerizations of Multimethacrylates," Seoul National University, Department of Chemical Engineering, Seoul, Korea, August 30, 1993.
158. "Bioadhesive Controlled Release Systems," Korean Institute of Science and Technology, Department of Polymer Science, Seoul, Korea, August 31, 1993.
159. "Poly(vinyl alcohol) Hydrogels," Kyoto University, Department of Biomedical Engineering, Kyoto, Japan, September 1, 1993.
160. "Temperature Sensitive Networks," Osaka University, Department of Chemistry, Osaka, Japan, September 2, 1993.

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161. "Bioadhesive Polymers," Massachusetts Institute of Technology, Department of Chemical Engineering, Cambridge, Massachusetts, October 1, 1993.
162. "Classification of Release Systems," University of Parma, Faculty of Pharmacy, Parma, Italy, October 22, 1993.
163. "Fundamental of Diffusion," University of Parma, Faculty of Pharmacy, Parma, Italy, October 22, 1993.
164. "Polymer Structure and Controlled Release," University of Parma, Faculty of Pharmacy, Parma, Italy, October 25, 1993.
165. "Diffusion Controlled Systems (Matrix Devices)," University of Parma, Faculty of Pharmacy, Parma, Italy, October 25, 1993.
166. "Reservoir and Osmotic Systems," University of Parma, Faculty of Pharmacy, Parma, Italy, October 26, 1993.
167. "Swelling-Controlled Release Systems," University of Parma, Faculty of Pharmacy, Parma, Italy, October 26, 1993.
168. "Pulsatile Delivery and pH-Sensitive Systems," University of Parma, Faculty of Pharmacy, Parma, Italy, October 26, 1993.
169. "Bioadhesive Systems," University of Parma, Faculty of Pharmacy, Parma, Italy, October 26, 1993.
170. "Microencapsulation," University of Parma, Faculty of Pharmacy, Parma, Italy, October 27, 1993.
171. "Polymers for Drug Targeting Systems," University of Parma, Faculty of Pharmacy, Parma, Italy, October 27, 1993.
172. "Swelling Controlled Release Systems," Hoshi University, Faculty of Pharmacy, Shinagawa, Tokyo, Japan, January 17, 1994.
173. "Bioresponsive Drug Delivery Systems," Hoshi University, Faculty of Pharmacy, Shinagawa, Tokyo, Japan, January 25, 1994.
174. "Recent Advances in Swelling Controlled DDS for Release of Drugs and Proteins," Kyoto University, Faculty of Pharmaceutical Sciences, Sakyo, Kyoto, Japan, January 26, 1994.
175. "Bioresponsive Drug Delivery Systems," Takeda Chemical Industries, Yodogawa, Osaka, Japan, January 27, 1994.
176. "Contemporary Issues in Hydrogel Development," Kyoto University, Research Center for Biomedical Engineering, Sakyo, Kyoto, Japan, January 28, 1994.
177. "Novel Applications of Star Polymers in Drug Delivery," Sanagawa Academy of Science and Technology, Kawasaki, Japan, February 2, 1994.
178. "Bioresponsive Drug Delivery Systems," Tokyo Institute of Technology, Department of Biomolecular Engineering, Midori, Tokohama, Japan, February 2, 1994.
179. "Diffusion in Polymers," Nichiban Co., Hidaka, Japan, February 3, 1994.
180. "Novel Applications of Star Polymers in Drug Delivery," Hoshi University, Faculty of Pharmacy, Shinagawa, Tokyo, Japan, February 4, 1994.
181. "Contemporary Issues in Hydrogels Research," Tokyo Women's Medical College, Shinjuku, Tokyo, Japan, February 7, 1994.
182. "Cationic Hydrogels as pH-Sensitive Materials," Hoshi University, Faculty of Pharmacy, Shinagawa, Tokyo, Japan, February 8, 1994.
183. "Bioadhesives," Teijin Ltd., Chiyoda, Tokyo, Japan, February 10, 1994.
184. "Bioadhesive Polymers," Hebrew University, Faculty of Medicine, Jerusalem, Israel, March 20, 1994.
185. "Polymer Dissolution," Ben-Gurion University, Chemical Engineering Department, Beer-sheva, Israel, March 28, 1994.
186. "Probing the Nature of the Mucoadhesive Behavior of PEG and PAA-Containing Hydrogels via ATR-FTIR Spectroscopy, Near Field FTIR Spectroscopy and the Falling Liquid Film Technique," Cygnus Therapeutic Systems, Redwood City, California, September 15, 1994.
187. "Trends, New Technologies and Smart Polymers in Controlled Release," Colorcon, Princeton, NJ, October 12, 1994.
188. "Issues in Contemporary Hydrogels Research for Medical Applications", University of Wisconsin, Department of Chemical Engineering, Madison, Wisconsin, December 1, 1994.
189. "Chain Interpenetration and Fracture in Gel/Gel and Gel/Mucin Adhesion," Michigan State University, Department of Chemical Engineering, East Lansing, Michigan, February 16, 1995.
190. "Bioadhesive Poly(vinyl alcohol) as a Carrier for Controlled Release of Proteins and Factors for Wound Healing," Sankyo Company, Research Institute, Tokyo, Japan, March 7, 1995.

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191. "Smart Materials in Medicine Applications," Ventritex Co., Sunnyvale, California, April 5, 1995.
192. "Contemporary Hydrogels Research," Kagoshima University, Department of Applied Chemistry and Chemical Engineering, Kagoshima, Japan, April 17, 1995.
193. "Hydrogels: Synthesis, Properties and Biomedical Applications," ConvaTec, Princeton, New Jersey, June 15, 1995.
194. "Diffusion and Drying Phenomena in Hydrogels: Influence of Gels' Structure and Hydrophilicity," Cygnus, Redwood City, California, August 31, 1995.
195. "Multifunctional Methacrylates as Biomaterials in Ocular Applications," Alcon Labs, Ft. Worth, Texas, January 23, 1996.
196. "Molecular Dynamics in Polymer Networks with Applications in Biomedical and Drug Delivery Systems," University of Michigan, Department of Chemical Engineering, Ann Arbor, Michigan, January 25, 1995.
197. "Hydrogels in Pharmaceutical Applications," B.F. Goodrich, Brecksville, Ohio, February 1, 1996.
198. "Mechanistic Aspects of Polymer Dissolution," University of Kentucky, Department of Chemical Engineering, Lexington, Kentucky, February 7, 1996.
199. "Mechanistic Aspects of Polymer Dissolution," City University of New York, Department of Chemical Engineering, New York, New York, March 18, 1996.
200. "Poly(vinyl alcohol)-Based Release Systems," ALZA Corporation, Palo Alto, California, April 30, 1996.
201. "Intelligent Biomaterials: Scientific Curiosity or Panacea?" Ohio State University, Department of Chemical Engineering, Columbus, OH, May 2, 1996.
202. "Diffusion in Polymers," University of Naples, Department of Materials Science, Naples, Italy, May 15, 1996.
203. "Use of Hydrogels in Drug Delivery," University of Naples, Department of Pharmaceutical Chemistry, Naples, Italy, May 21, 1996.
204. "Swelling-Controlled Release Systems," University of Rome, Department of Pharmaceutical Chemistry, Rome, Italy, May 24, 1996.
205. "Crystal-Dissolution-Controlled Poly(Vinyl Alcohol)-Based Release Systems," University of Pavia, Department of Pharmaceutical Sciences, Pavia, Italy, November 26, 1996.
206. "Recent Advances in Drug Delivery," Vectorpharma Co., Trieste, Italy, November 28, 1996.
207. "Solute and Water Transport in Polymeric, Swelling-Controlled Release Systems," Cygnus, Redwood City, California, February 6, 1997.
208. "Protein Delivery Using Novel Hydrogel Systems," B.F. Goodrich Co., Brecksville, Ohio, March 19, 1997.
209. "Kinetics and Properties of Crosslinked Polymers from Multifunctional Methacrylates," New Mexico State University, Department of Chemical Engineering, Las Cruces, NM, April 11, 1997.
210. "Protein Release from Hydrogels," B.F. Goodrich, Brecksville, Ohio, June 23, 1997.
211. "Poly(vinyl alcohol)-based Gels by Freezing/Thawing Processes," Hokkaido University, Division of Biological Sciences, Sapporo, Japan, July 10, 1997.
212. "Carriers from PEG Star Polymers for Drug Delivery and Molecular Imprinting," University of Parma, Department of Pharmacy, Parma, Italy, May 19, 1998.
213. "Protein Delivery with Poly(ethylene glycol) Systems," University of Ferrara, Faculty of Pharmacy, Ferrara, Italy, May 21, 1998.
214. "Glassy/rubbery Transitions in Food Products and Importance in Flavor Release," Kellogg, Battle Creek, MI, September 23, 1998.
215. "Intelligent Biomaterials and Advanced Methods of Drug Delivery," University of Ghent, Belgium, *Honorary Doctorate Lecture*, March 19, 1999.
216. "Drug Delivery from PVA Networks," University of Parma, Department of Pharmacy, Parma, Italy, May 5, 1999.
217. "Dynamics of Chain Interpenetration of PEG-Tethered Hydrogels," Washington University, Department of Chemical Engineering, St. Louis, Missouri, September 7, 1999.
218. "Interpolymer Complexes, Star Polymers and Ionic Hydrogels in Protein and Drug Delivery," Carnegie Mellon University, Department of Chemical Engineering, September 14, 1999.
219. "Intelligent Biomaterials and Advanced Methods of Drug Delivery," University of Parma, Italy, *Honorary Doctorate Lecture*, October 13, 1999.

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220. "Interpolymer Complexes, Star Polymers and Ionic Hydrogels in Protein and Drug Delivery," University of Akron, Department of Chemical Engineering, October 21, 1999.
221. "Molecular Chemical Engineering: The Contributions of Chemical Engineers to Biomaterials and Pharmaceutical Engineering," University of Pittsburgh, Department of Chemical Engineering, *Bayer Lecture*, February 24, 2000.
222. "Poly(ethylene glycol)-based Hydrogels for Protein Delivery and Molecular Imprinting," University of Pittsburgh, Department of Chemical Engineering, *Bayer Lecture*, February 25, 2000.
223. "Intelligent Biomaterials and Advanced Methods of Drug Delivery," University of Athens, Greece, *Honorary Lecture*, March 9, 2000.
224. "Poly(ethylene glycol)-based Hydrogels for Protein Delivery and Molecular Imprinting," Aventis Research and Technologies, Frankfurt, Germany, March 15, 2000.
225. "Advances in Mucoadhesive Delivery," Aventis Research and Technologies, Frankfurt, Germany, March 15, 2000.
226. "Novel Oral Protein Delivery Systems: Design, Formulation, Cellular and in vivo Studies," Free University of Berlin, Department of Pharmacy, Berlin, Germany, January 19, 2001.
227. "Oral Protein Delivery Systems Based on Complexation Hydrogels," University of Santiago de Compostela, Department of Pharmacy and Pharmaceutical Technology, Santiago de Compostela, Spain, March 7, 2001.
228. "Mucoadhesive Drug Delivery Systems," University of Santiago de Compostela, Department of Pharmacy and Pharmaceutical Technology, Santiago de Compostela, Spain, March 8, 2001.
229. "Polymer-cell Interactions in Relation to the Development of Oral Delivery Systems," University of Santiago de Compostela, Department of Pharmacy and Pharmaceutical Technology, Santiago de Compostela, Spain, March 8, 2001.
230. "UV Free Radical Polymerizations for Micropatterning and Molecular Imprinting of Poly(ethylene glycol)-containing Films," National Science Foundation, Institute of Science and Technology of Polymers, Madrid, Spain, March 15, 2001.
231. "Advances in Oral Delivery of Proteins Using Smart Polymer Carriers," University of Seville, Department of Chemistry, Seville, Spain, March 16, 2001.
232. "Mucoadhesive Systems in Drug Delivery," University of Barcelona, Department of Pharmacy and Pharmaceutical Technology, Barcelona, Spain, March 23, 2001.
233. "Novel Complexation Hydrogels for Oral Protein Delivery," University of Marburg, Departments of Chemistry and Pharmacy, Marburg, Germany, May 14, 2001.
234. "Molecular Imprinting and Micropatterning in Pharmaceutical and Biomedical Applications," Institute of Pharmacy, Free University of Berlin, May 23, 2001.
235. "Intelligent Biomaterials for Protein Delivery, Molecular Imprinting and Micropatterning", Department of Chemical and Biochemical Engineering, Rutgers University, March 28, 2002, *Named Lecture*.
235. "Intelligent Biomaterials for Protein Delivery, Molecular Imprinting and Recognition," University of Texas, Departments of Chemical and Biomedical Engineering, May 9, 2002.
236. "Intelligent Biomaterials for Protein Delivery, Molecular Imprinting and Micropatterning," Texas A&M University, Department of Chemical Engineering, May 16, 2002.
237. "Mucoadhesion and Bioadhesion: Mechanisms, Experimental Techniques and Development of New Systems," Schering A.G., Berlin, Germany, October 7, 2002.
238. "Intelligent Systems for Transmucosal Delivery of Insulin, Calcitonin and Other Proteins," Eurand, Milan, Italy, November 25, 2002.
239. "Intelligent Biomaterials for Configurational Biomimesis: New Devices for Molecular Recognition," Eurand, Milan, Italy, November 25, 2002.
240. "Solvent-Activated Controlled Release Systems: Swelling Systems and the Use of Hydrogels in Controlled Release," Eurand, Trieste, Italy, November 26, 2002.
241. "Mucoadhesion and Bioadhesion: Mechanisms, Experimental Techniques and Development of New Systems," Eurand, Trieste, Italy, November 26, 2002.
242. "Devices Based on Intelligent Biopolymers for Oral Protein Delivery," Eurand, Trieste, Italy, November 26, 2002.
243. "Advances in Protein Delivery, Molecular Recognition and Micropatterning", Iowa State University, Department of Chemical Engineering, Ames, IA, April 10, 2003, *Named Lecture*.

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244. "Intelligent Biomaterials for Protein Delivery, Molecular Recognition and Imprinting", University of Oklahoma, Department of Chemical Engineering, Norman, OK, April 17, 2003, *Named Lecture.*
245. "Mucoadhesive Polymers", Amano Enzymes, Elgin, IL, August 6, 2003.
246. "Advances in Intelligent Biomaterials; Protein Delivery, Configurational Biomimetic Systems and Bionanotechnology", Johnson & Johnson, Somerville, NJ, August 7, 2003.
247. "Advanced Sensor-Based Control", Becton Dickinson, Chapel Hill, NC, December 18, 2003.
248. "The Future of Biomaterials", EI duPont de Nemours, Wilmington, DE, January 9, 2004.
249. "Advances in Intelligent Biomaterials for Protein Delivery, Molecular Recognition and Micropatterning", EI duPont de Nemours, Wilmington, DE, January 9, 2004.
250. "Advances in Intelligent Biomaterials for Protein Delivery, Molecular Recognition and Micropatterning", Rice University, Department of Biomedical Engineering, Houston, TX, February 5, 2004.
251. "Intelligent Polymer Networks in Protein Delivery and Molecular Recognition", MIT, Program in Polymer Science and Technology, Cambridge, MA, March 17, 2004.
252. "New Hydrogel Systems for Smart Delivery of Drugs and Proteins", University of Tokyo, Department of Materials Science, Tokyo, Japan, July 16, 2004.
253. "Cellular and Molecular Evaluation of Oral Delivery Systems for Chemotherapeutic Agents", Hoshi University, Tokyo, Japan, July 17, 2004.
254. "The Future of Nanotechnology with Special Emphasis on Biomedical Applications", Technical University of Lodz, Poland, September 9, 2004.
255. "Intelligent Biomaterials in Protein Delivery, Micropatterning and Molecular Recognition", Technical University of Lodz, Poland, September 9, 2004.
256. "Materials and Methods of Bio- and Mucoadhesion", Technical University of Lodz, Poland, September 9, 2004.
257. "Bionanotechnology and Molecular Recognition," Texas A&M University, Department of Chemical Engineering, College Station, Texas, December 17, 2004.
258. "Polymers for Medical Applications: The Future of Biomaterials", Nanyang Technological University, Department of Materials Science and Engineering, Singapore, January 11, 2005.
259. "Advances in Intelligent Biomaterials for Protein Delivery, Molecular Recognition and Bionanotechnology", Nanyang Technological University, Singapore, January 12, 2005.
260. "Fast UV-Polymerization Kinetics and Reaction Engineering: Kinetics and Network Structure in Relation to Microfabrication", Nanyang Technological University, Department of Chemical Engineering, Singapore, January 13, 2005.
261. "Oral Delivery Systems for Chemotherapeutic Agents and Protein", Nanyang Technological University, Department of Materials Science and Engineering, Singapore, January 14, 2005.
262. "Advances in Intelligent Biomaterials for Protein Delivery, Molecular Recognition and Bionanotechnology", University of Texas at San Antonio, College of Engineering, San Antonio, TX, January 24, 2005.
263. "Advances in Intelligent Biomaterials for Protein Delivery, Molecular Recognition and Bionanotechnology", University of Texas at Austin, IGERT Program, Austin, TX, February 4, 2005.
264. "Intelligent Protein and Drug delivery Systems", University of Barcelona, College of Pharmacy, Barcelona, Spain, March 30, 2006.
265. "Intelligent Acrylic and Methacrylic Biohydrogels for Protein Delivery, Molecular Imprinting and Micropatterning", Arkema, King of Prussia, PA, June 8, 2006.
266. "Biomimetic Polymers in Responsive and Intelligent Drug Delivery," University of Kentucky, Department of Chemical Engineering, Lexington, Kentucky, October 20, 2006, *Ashland Lecture*.
267. "The Next Generation of Drug Delivery Technologies", School of Pharmacy, University of Central Lancashire, Preston, UK, September 13, 2007, *Named Lecture.*
268. "Nanotechnology and Inteligent Response: Their Impact in Biomaterials and Drug Delivery", Nanyang Technological University, Department of Materials Science and Engineering, Singapore, December 12, 2007.
269. "Advances in Biomaterials for Intelligent Biomedical and Pharmaceutical Systems", University of Puerto Rico at Mayagüez, Mayagüez, PR, March 6, 2008, *Merck Lecture*.
270. "Molecular Recognition using Intelligent Biomaterials", University of Massachusetts, Amherst, MA, May 6, 2008, *Rohm & Haas Lecture*.

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271. “Recognition and Delivery: Thermodynamics and Kinetic Phenomena in the Design of Medical Microdevices”, Naval Research Laboratory, Cente for Bio/Molecular Science & Engineering, Washington, DC, March 24, 2009, *Distinguished Lecture*
272. “Recognition and Delivery: The Next Generation of Medical Microdevices”, MIT, Department of Chemical Engineering, Cambridge, MA, April 3, 2009, *Alan Michaels Lecture*.
273. “Recognition and Delivery: The Next Generation of Medical Microdevices”, Duke University, Department of Chemical and Biological Engineering, Rolla, MO, April 15, 2009, *Missouri Academy Lecture*.
274. “Addressing Educational Problems in an Evolving, Global and Challenging Engineering World”, Duke University, Department of Chemical and Biological Engineering, Rolla, MO, April 15, 2009, *Missouri Academy Lecture*.
275. “Intelligent Biomaterials for Protein Delivery, Molecular Imprinting and Micropatterning”, Duke University, Department of Biomedical Engineering, Durham, NC, April 23, 2009, *Kewaunee Lecture*.
276. “Responsive Biomaterials and Feedback-Controlled Medical Devices for Protein Delivery, Molecular Imprinting and Microfabricated Systems”, Department of Biomedical Engineering, University of California at Davis, Davis, CA, February 4, 2010, *Distinguished Lecturer*.
277. "Molecular and Cellular Aspects of Transmucosal Protein Delivery", Collège de France, Paris, France, March 15, 2010, *Distinguished Lecturer*.
278. “Responsive and Feedback-Controlled Materials for Protein Delivery, Molecular Imprinting and Microfabricated Systems, Imperial College, Department of Chemical Engineering, London, England, May 12, 2010, *Distinguished Lecturer*.
279. “Biomaterials and Drug Delivery Systems”, MIT, Department of Chemical Engineering, Cambridge, MA, May 14, 2010, *Merrill Symposium*.
280. “Intelligent Biomaterials for Protein Delivery, Molecular Imprinting and Recognitive Devices”, Northwestern Univesrity, Department of Chemical Engineering, Evanston, IL, February 10, 2011, *Eugene W. Skinner and Eugene P. Lautenschlager Memorial Lecture.*
281. “Intelligent Biomaterials for the Next Generation of Responsive Drug and Protein Delivery Systems”, Auburn University, February 23, 2011, *Bashore Distinguished Lecture*.
282. “Mass Transfer in Drug Delivery and Cellular Biological Media”, University of Houston, Houston, TX, March 4, 2011, *Alkiviades Payatakes Lecture*.
283. “Intelligent Biomaterials for Protein Delivery, Molecular Imprinting and Recognitive Devices”, University of Delaware, Department of Chemical Engineering, Newark, DE, April 29, 2011, *Kurt Wohl Memorial Lecture*.
284. "Nanotechnology and Bioengineering in an Evolving Chemical Engineering World: The Next Generation of Recognitive, Intelligent Medical Microdevices", ETH Zurich, Chemical Engineering Department, Zurich, Switzerland, September 26, 2011.
285. Centennial Lecture, Purdue University, School of Chemical Engineering, October 7, 2011.
286. "Intelligent Biomaterials for Protein Delivery, Molecular Imprinting and Recognitive Medical Devices" University of North Carolina , Eshelman School of Pharmacy and Department of Biomedical Engineering, Chapel Hill, NC, November 14, 2011, *UNC/Eisai Distinguished Lecture in Drug Delivery*.
287. “Novel Methods of siRNA Delivery”, Eisai Co, Durham, NC, November 15, 2011.
288. “Intelligent Biomaterials for Responsive Delivery of Therapeutic Agents”, Department of Chemical and Biomolecular Engineering, University of California, Berkeley, CA, April 2, 2012, *The Berkeley Lectures*.
289. “Nanotechnology and Bioengineering in an Evolving Chemical Engineering World: The Next Generation of Recognitive Micro- and Nanodevices”, Department of Chemical and Biomolecular Engineering, University of California, Berkeley, CA, April 4, 2012, *The Berkeley Lectures*.
290. “Intelligent Biomaterials for Responsive Delivery of Therapeutic Agents”, RTI International, Research Triangle, NC, June 26, 2012.
291. “Nanotechnology and Bioengineering in an Evolving Chemical Engineering World: The Next Generation of Recognitive Micro- and Nanodevices”, RTI International, Research Triangle, NC, June 26, 2012.
292. “Micro- and Nanotechnology in Drug Delivery”, Corporate Research & Engineering - Materials Science, Kimberly-Clark Corp, Neenah, WI, August 2, 2012, *Extrapolations Lecture*.
293. “Hydrogels”, National Academy of Engineering, October 2012, *Founders Award Lecture*.

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294. "Advances in Intelligent and Recognitive Hydrogels for Treatment of Diabetes, Cancer and Multiple Sclerosis", College of Pharmacy, University of Ljubljana, Ljubljiana, Slovenia, December 5, 2012, *Distinguished Lecture*.
295. "New Frontiers in the Pharmaceutical and Medical Sciences: Improving Health Care through New Medical Devices and Treatments", University-wide Lecture, University of Ljubljana, Ljubljiana, Slovenia, December 5, 2012, *Honorary Doctoral Lecture*.
296. "Intelligent Protein Delivery Systems", Dainippon Sumitomo Pharma, Osaka, Japan, December 11, 2012, *Distinguished Lecture*.
297. "Intelligent Polymer Systems for the Delivery of Proteins, siRNA and Chemotherapeutics", Department of Pharmacy, Kobe Gakuin University, Kobe, Japan, December 13, 2012.
298. "New Frontiers in the Pharmaceutical and Medical Sciences: Advanced Intelligent Hydrogels for Treatment of Diabetes, Cancer and Multiple Sclerosis", College of Engineering, Michigan Tech, Houghton, MI, March 7, 2013, *Distinguished Lecture*.
299. "Intelligent and Diagnostic Therapeutic Systems: Advanced Biomaterials and Improved Health Care ", University of Buffalo, Department of Chemical Engineering, Buffalo, NY, April 23, 2013, *Ruckenstein Lecture*.
300. "New Frontiers in the Pharmaceutical and Medical Sciences: Advanced Intelligent Hydrogels for Protein Delivery", University of Illinois at Urbana, Department of Chemical and Biomolecular Engineering, Urbana, IL, April 25, 2013, *Parr Lecture*.
301. "Fundamentals and Applications of Controlled Release and Drug Delivery", Faculty of Pharmacy, University of Belgrade, Belgrade, Serbia, May 23, 2013, *University Lecture*.
302. "Advances in Intelligent Hydrogels for Recognitive and Protein Delivery Systems", Institute of Bioengineering, School of Life Sciences & School of Engineering, Ecole Polytechnique Federale de Lausanne, Lausanne, Switzerland, July 4, 2013.
303. "Hydrogels, Intelligence and Therapeutic Systems: Is there a Future?", Department of Bioengineering, University of Washington, Seattle, WA, October 13, 2013, *Hoffman Lecture.*
304. "Molecular Imprinting and Recognitive Medical Devices", School of Engineering, University of Minho, Braga, Portugal, January 23, 2014.
305. "Hydrogels for Recognitive and Protein Delivery Systems", Bioengineering Department, University of California San Diego, CA, February 3, 2014, *Skalak Lecture*.
306. "Advances in Intelligent Hydrogels for Recognitive and Protein Delivery Systems", Department of Chemical and Biochemical Engineering, University of Iowa, Iowa City, IA, March 6, 2014, *Kammermeyer Lecture.*
307. "Intelligent and Recognitive Nanoscale Systems for New Therapeutic Applications", Louisiana Tech University, Ruston, LA, September 22, 2014, *Frontiers in Biomedical Research Lecture.*
308. "Biomedical Engineering Responding to Personal Needs", Louisiana Tech University, Ruston, LA, September 23, 2014 *Frontiers Lecture*.
309. "Responsive and Intelligent Biopolymers for Recognitive Systems, Biosensing and Proten Delivery", Department of Chemical Engineering, Columbia University, New York, NY, October 28, 2014, *Gaden Memorial Lecture*.
310. "Intelligent Delivery of Therapeutic Agents: A Tribute to Didi Sangalli and an Ever Changing Field", Department of Pharmaceutical Sciences, University of Milan, Milan, November 5, 2014, *Sangalli Lecture.*
311. "Intellligent/Recognitive Nanoscale Systems for New Therapeutic Applications", Dipartimento di Chimica, Materiali ed Ingegneria Chimica :Giulio Natta", Politecnico di Milano, Milan, Italy, November 7, 2014, *Giulio Natta Lecture.*
312. "Advances in Intelligent Biomaterials and Recognitive Systems, Biosensors and Protein Delivery Systems", Strategic Research Theme, Biomedical Engineering and Nanotechnology, University of Hong Kong, December 12, 2014.
313. "Advances in siRNA and Protein Delivery Through Smart Polymers", Department of Chemical and Biomolecular Engineering, University of Notre Dame, Notre Dame, IN, March 31, 2015, *Reilly Lecture 1.*
314. "Nanotechnology and Bioengineering in an Evolving Chemical Engineering World", Department of Chemical and Biomolecular Engineering, University of Notre Dame, Notre Dame, IN, March 31, 2015, *Reilly Lecture 2.*

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315. "Thermodynamics of Intelligent Hydrogels for Recognitive and Protein Delivery Systems", Department of Chemical and Biochemical Engineering, Rutgers University, New Brunswick, NJ, April 21. 2015, *J&J Distinguished Lecture*.

316. "Multiresponsive Nanogels for the Delivery of Small Interfering RNA and Advanced Protein Therapeutic Agents", Department of Chemical Engineering, Purdue University, West Lafayette, IN, April 28, 2015, *50th Kelly Lecture 1*.

317. "Intelligent Polymer Hydrogels: From Obscure Molecular Structures to Useful Multifunctional Systems", Department of Chemical Engineering, Purdue University, West Lafayette, IN, April 29, 2015, *50th Kelly Lecture 2.*

318. "Advances in siRNA and Protein Delivery Through Smart Polymers", Chemical Engineering Department, City College of New York, CUNY, New York, NY, May 11, 2015, *Stanley Katz Lecture.*

319. "Smart Biomaterials for Diagnosis of Diseases and Improvement of the Quality of Life of Patients", Simson Querrey Institute for BioNanotechnology, Northwestern University, Evanston, IL, June 1, 2015, *Inaugural Lecture*.'

320. "Advances in Polymer Networls and Biomaterials", University of Patras, Patras, Greece, June 5, 2015, *Invited Doctoral Lecture*.

321. "Intelligent Nanoscale Biopolymers for Recognitive and Responsive Delivery of Drugs, Peptides and Proteins" Chinese Academy of Engineering, Beijing, China, March 28, 2015, *Distinguished Lecturer*.

322. "Intelligent Nanoscale Biopolymers for Recognitive and Responsive Delivery of Drugs, Peptides and Proteins ", Illinois Institute of Technology, Chicago, Illinois, *Pritzker Lecturer*, February 17, 2016.

323. "Advances in Protein and siRNA Delivery Through Smart Polymers" , Department of Chemical Engineering, Ohio State University, Columbus, OH, April 1, 2016, *Lowrie Lecturer* 1 "A Historical

324. "Perspective of Nanotechnology and Bioengineering in an Evolving Chemical Engineering World, " Department of Chemical Engineering, Ohio State University, Columbus, OH April 2, 2016, *Lowrie Lecturer* 2.

325. "Intelligent Nanoscale Biopolymers for Recognitive and Responsive Delivery of Drugs, Peptides and Proteins", University of California Davis, Davis, CA, College of Engineering, April 21, 2016, *Distinguished Lecturer*.

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Research Grants

1. Research Corporation - Cottrell Research Grant
   "Migration of Low Molecular Weight Components from Plasticized Polymeric Systems"
   $10,000
   9/1/77 - 2/29/80
2. Rohm and Haas Company
   Unrestricted Funds
   $2,500
   6/1/77 - 5/31/78
   "Migration of Plasticizers through Polymers"
   $2,500
   6/1/79 - 12/31/79
   "ESCA Studies"
   $2,500
   6/1/82-12/31/82
3. Purdue Energy Engineering Center
   "Fundamental Studies of Macromolecular Networks in Coal"
   $6,500
   11/1/77 - 6/30/78
4. Dow Corning Corporation
   "Vapor Pressure Osmometer"
   $5,000
   8/1/78 - 12/31/78
5. Medicornea Eastern
   "Development and Evaluation of Polymeric Materials for Contact Lens Applications"
   $34,853,
   7/1/78 - 6/30/79
6. N.S.F. - Division of Engineering - Engineering Equipment
   Grant Request (with J.M. Caruthers)
   "Investigation of Rheological Properties of Polymers Utilizing a Rotary Rheometer"
   $74,040 (cost-shared)
   9/1/78 - 8/31/79
7. Ford Motor Company
   "Dynamic Viscoelastometer"
   $15,000
   1/1/79 - 8/31/79
8. Eli Lilly Foundation
   "Development of a Blood Treatment Cell for Use as an Artificial Kidney"
   (with S.R. Ash, R. Barile, D. Kessler, J. Thornhill, B. Hillberry)
   $347,844
   7/1/78 - 6/30/79
   $384,923,
   7/1/79 - 6/30/80
   $229,888
   7/1/80 - 6/30/81
9. Department of Energy - Pittsburgh Energy Technology Center
   "Investigation of the Crosslinked Polymeric Nature of Bituminous Coals"
   $99,998,
   9/1/78 - 8/31/80,
10. Purdue University, Schools of Engineering,
    "Polymer Equipment" (with J.M. Caruthers)
    $56,000
    1/1/79 until expended
11. Purdue Research Foundation - David Ross Grant
    "Swelling and Diffusional Behavior of Plasticized Glassy Polymers"

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$9,120
9/1/79 - 8/31/81

12. Olin Corporation Charitable Trust,
"Diffusion through Polymer Membranes with Applications to Industrial Separations"
$1,500,
6/18/79 - 8/24/79
$1,700
6/15/80 - 8/25/80
$1,700
1/15/81 - 8/25/81
$1,800
1/15/82 - 8/25/82

13. National Science Foundation - Instructional Scientific Equipment Proposal
"Development of a Polymer Science Laboratory Course" (with J.M. Caruthers)
$46,540 (cost-shared)
9/1/79 - 8/31/80

14. Medicornea Eastern
"Evaluation of Polymeric Materials for Contact Lens Applications"
$3,500
12/1/79 - 8/31/80

15. North Atlantic Treaty Organization - Scientific Affairs Division
"Fundamental Investigation of the Structure, Physical and Diffusive Properties of Charged and Non-Charged Polystyrene Gels and Membranes"
$11,070
1/1/80 - 12/31/82

16. Department of Energy - Pittsburgh Energy Technology Center
"Molecular Characterization of Bituminous Coals during Coal Extraction and Solubilization: Coal Crosslinks, Entanglements and Molecular Weight Distributions"
$187,643
9/1/80 - 8/31/83

17. Continental Oil Company
"Molecular Weight Distribution of Degraded Coal Products"
$57,000
3/8/80 - 6/30/81
$46,000
7/1/81 - 8/31/83
$5,000
3/1/83 - 12/31/83

18. Exxon Research Foundation
"Coal as a Polymer"
$10,000
11/1/80 - 10/31/81
$10,000
11/1/81 - 10/30/82
$10,000
11/1/82 - 10/31/83

19. National Science Foundation - Thermodynamics and Mass Transfer Program
"Mechanisms of Solute Diffusion in Swellable Hydrophilic Polymer Systems"
$90,000
9/1/82 - 8/31/84

20. Chevron Education Foundation
"Biointerfacial Phenomena"
$2,500
6/1/83 - 9/1/83

21. Department of Energy - Pittsburgh Energy Technology Center
"Anomalous Solvent Transport in Macromolecular Coal Networks"

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199,440
9/1/83-8/31/86

22. Dow Corning Corporation
"Fundamental Studies of Solute Diffusion in Membranes of PVA, PHEMA and their Silicon-Containing Monomers"
$26,000
12/1/83 - 11/30/85

23. National Science Foundation - Separation Processes Program
"Ultrafiltration and Hyperfiltration Membranes from Heat-Treated Hydrophilic Polymers"
$204,157
9/1/84 - 8/31/87

24. National Science Foundation - Western Europe Cooperative Science Program
"Release of Macromolecular Drugs from Swelling-Controlled Polymeric Systems"
$12,670
9/1/84 - 8/31/85

25. Electric Power Research Institute
"Computerized Data Base on Dielectric Materials" (with C.Y. Ho and H.H.Li)
$350,000
7/1/85-12/31/86

26. David Ross Grant
"Bioadhesive Interactions of Polymers with Mucus"
$19,800
7/1/85-6/30/88

27. Rohm & Haas Company
Polymer Laboratory
$30,000
3/1/86-until expended

28. Plastics Institute of America
"A Predictive Model for Diffusion in Polymers"
$2,500
7/1/86 - 6/30/87

29. National Science Foundation - Engineering Equipment Grant Request
"Acquisition of a Mercury Intrusion Porosimeter" (with D.N. Winslow and C.W. Lovell)
$47,500
9/1/86-8/31/87

30. North Atlantic Treaty Organization - Scientific Affairs Division,
"Fundamental Studies of Solute Diffusion in Swellable Polymers"
$12,930
1/1/87-12/31/89

31. National Science Foundation - Process & Reaction Engineering
"Suspension Polymerization of Hydrophilic Monomers"
$160,002
4/1/87-3/31/90

32. National Science Foundation - Engineering Equipment Grant Program
"Acquisition of an Interferometer/Polariscope"
$31,508
6/1/87-5/31/88

33. National Science Foundation - Process and Reaction Engineering
"Poly(alkyl methacrylates) in Microlithography, Audio and Video Technology"
$7,988
8/15/87 - 8/14/88

34. Trask Fund
"Polymerization of Miltifunctional Methacrylates to Produce Polymers for Replication of Laser Videodiscs"
$14,810
4/15/87 - 4/14/88

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35. Department of Energy - Pittsburgh Energy Technology Center
"Macromolecular Coal Structure as Revealed by Novel Diffusion Tests"
$196,862
9/15/87 - 9/14/90

36. National Science Foundation - Separation and Purification Processes
"Block Copolymer Membranes with Hydrophilic/Hydrophobic Domains"
$127,098
9/1/87 - 8/31/89

37. National Science Foundation - Separation and Purification Processes
"Release of Volatile Compounds Using Block Copolymers"
$5,418
11/15/87 - 11/14/88

38. Rhône Poulenc
"Polymer Membranes"
$10,000
12/1/88 - 2/28/90

39. National Institutes of Health
"pH-Sensitive Hydrogels for Drug Release"
$232,536
12/1/89 - 11/30/92

40. National Science Foundation - Instrumentation and Laboratory Improvement
"New Directions in ChE Undergraduate Laboratory Experience"
(with G.V. Reklaitis, R.P. Andres, W.N. Delgass)
$254,740
1/1/90 - 12/31/90

41. National Science Foundation - Scientific Equipment Proposal
"In Situ Infrared Analysis of Reaction and Transport in Advanced Materials"
(with E.I. Franses, J.M. Caruthers, W.N. Delgass, C.G. Takoudis)
$200,000
5/1/90 - 10/31/91

42. Dow Chemical Company
"Biodegradable Superabsorbent Polymers"
$48,180
8/1/90 - 7/31/91

43. National Institutes of Health
"Mucoadhesive Polymers for Nasal and Buccal Drug Delivery"
$382,650
5/1/91 - 4/30/94

44. David Ross
"Dynamic and Equilibrium Behavior of Ionic Hydrogels of P(EG-g-MAA)"
$18,000
3/1/91 - 2/28/93

45. National Science Foundation - Western Europe Cooperative Science Program
"Swellable Controlled Release Polymeric Systems With or Without Dissolution"
$10,790
5/1/91 - 4/30/92

46. Trask Fund
"Novel Bioadhesive Controlled Release Polymeric Systems"
$11,850
5/1/91 - 4/30/92

47. Department of Education
"Program for Graduate Assistance in Chemical Engineering Areas of National Need"
(with G.V. Reklaitis, J.M. Caruthers, D. Ramkrishna and W.N. Delgass)
$336,269
6/1/91 - 5/30/94

48. National Science Foundation - Scientific Equipment Proposal

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"An Advanced Thermal Analysis System for Macromolecular Coal Studies"
$168,140
8/1/91 - 12/31/92

49. National Science Foundation - Undergraduate Curriculum Development
"Development of a Unique Modular Materials Education Package" (with G.V. Reklaitis, W.N. Delgass, J.M. Caruthers and J.M. Wiest)
$70,000
7/1/91 - 6/30/92

50. Dow Chemical Company
"Biodegradable Superabsorbent Polymers Based on Poly(vinyl Alcohols)"
$49,888
11/1/91 - 10/31/92

51. National Science Foundation - Interfacial Transport
"Thermal Analysis Studies of Polymerization Reaction Dynamics"
$7,825
12/1/91 - 11/30/92

52. National Science Foundation
"An REU Site in Chemical Engineering" (with J. Wiest, W.N. Delgass, J.M. Caruthers)
$50,000
7/1/92 - 6/30/93

53. National Science Foundation - Interfactial Transport
"Polymer Dissolution"
$196,313
9/15/92 - 9/14/95

54. National Science Foundation - Undergraduate Materials Education Initiative - (with J.M. Caruthers, D.R. Gaskell, K.J. Bowman and K.P. Trumble)
"An Innovative Undergraduate Materials Curriculum"
$350,000
10/1/92 - 9/30/95

55. National Science Foundation
"An REU Site for New Directions in Chemical Engineering" (with J. Wiest, E.I. Franses, W.N. Delgass, H.L. Lackritz)
$150,000
7/1/93 - 6/30/96

56. PRF Research Grant
"Kinetics of Multimethacylate Polymerizations and Structure Analysis of Networks Thereof"
$19,800
3/1/93-2/28/95

57. National Science Foundation
"Multifunctional Polymerization Kinetics and Network Structure Thereof"
$187,923
8/15/93-8/14/96

58. Showalter Foundation
"Biomedical Engineering"
$120,000
11/15/93-11/14/95

59. National Science Foundation
"Polymer Dissolution"
$5,000
3/1/94-2/28/95

60. National Science Foundation
"Multifunctional Polymerizations"
$9,496
2/1/94-1/31/95

61. National Science Foundation (with G.V. Reklaitis, W.N. Delgass, R.P. Andres, J.M. Caruthers)
"Renovation of Advanced Materials Laboratory"

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$337,500
3/1/94-11/30/95

62. Showalter Foundation (with F.J. Doyle III)
"Insulin Response and Delivery Using Controlled Drug Delivery Devices for the Treatment of Diabetes Mellitus"
$50,000
7/1/94-6/30/95

63. North Atlantic Treaty Organization
"Investigation of Water and Solute Diffusion in Hydrophilic Polymers"
$10,927
9/1/94-8/31/97

64. National Institutes of Health
"pH-Sensitive Complex Hydrogels and IPNs for Drug Release"
$690,735
9/1/95-8/31/99

65. National Science Foundation
"Polymer Dissolution"
$6,250
9/1/95-8/30/96

66. Showalter Foundation
"Biomedical Engineering"
$120,000
11/15/95-10/14/96

67. Nagai Foundation
"Nasal Powder Forms: Materials, Technology and Therapeutic Applications"
$700,000
7/1/96-6/30/97

68. Showalter Foundation
"Novel Mucoadhesive Biopolymers for the Targeted Delivery of Peptides and Other Drugs to Tissues"
$50,000
7/1/96-6/30/97

69. Whitaker Foundation
"A New Gradate Program in Biomedical Engineering" (with G. Wodicka)
$50,000
12/1/96 - 8/31/97

70. Showalter Foundation
"Biomedical Engineering"
$60,000
7/1/97 - 6/30/98

71. Showalter Foundation
"Blood Thrombosis Prevention Using Fibrinolytic Enzyme-Immobilized Star Polymers"
$50,000
8/1/97 - 7/31/98

72. Showalter Foundation (with S. Badylak)
"Development of a New Composite Biodegradable Material"
$50,000
8/1/97 - 7/31/98

73. United States-Israel Binational Science Foundation
"Length and Breadth" and Interlooping Hydrogel Systems" (with A. Domb)
$36,000
7/1/97 - 6/31/98

74. Alcon
"Copolymerizations"
$10,000
7/1/97 - 9/30/97

75. National Institutes of Health

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"PEG-Promoted Mucoadhesive Drug Delivery Systems"
$406,625
8/1/97 - 7/31/00

76. National Science Foundation
"Polymer/Mucin Adhesion for Targeted Therapy"
$360,000
9/1/97 - 8/30/00

77. Whitaker Foundation (with G. Wodicka et al.)
“A Collaborative Program in Biomedical Engineering”
$991,000
12/1/97 - 11/30/00

78. Alcon
“Copolymerizations”
$19,000
1/1/98-4/30/98

79. National Institutes of Health
“pH-Sensitive Complex Hydrogels for Protein Drug Release”
$1,435,717
7/1/99–6/31/03

80. National Science Foundation
“Training Program on Therapeutic and Diagnostic Devices”
$2,695,000
8/1/99-7/31/04

81. Alcon
“Copolymerization”
$22,200
4/1/00-3/31/01

82. National Institutes of Health (with S. Badylak and K. Park)
“Origin of Cells that Repopulate ECM Scaffolds”
$1,649,497
7/1/00-6/30/04

83. Argonne National Laboratories
“Molecular Imprinting”
$60,000
5/1/03-3/1/04

84. National Science Foundation (with R. Richards-Kortum)
“Cellular and Molecular Imaging for Diagnostics and Therapeutics”
$3,871,200
10/01/03-9/30/08

85. National Science Foundation
“Configurational Biomimetic Imprinting Methods for Advanced Drug Delivery”
$190,000
11/1/03-10/31/05

86. National Institutes of Health
“pH-Sensitive Complex Hydrogels for Protein Drug Release”
$1,890,000
3/1/05–2/28/09

87. National Science Foundation (with D. Lloyd and R. Bonnecaze)
“Structure Control in Membrane Formation”
$150,016
9/1/06-8/31/08

88. Emergent Technologies
“Novel Nanodevices for Biomolecular Sensing”
$60,000
10/1/06-8/31/07

89. Portuguese Science and Technology Fdn

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"International Collaboratory for Emerging Technologies-CoLab"
$1,635,834
3/2/07 – 12/31/20

90. Emergent Technologies
"Novel Nanodevices for Biomolecular Sensing"
$20,000
5/1/09-4/30/10

91. National Cancer Institute
"Center of Transport Oncophysics" (with M. Ferarri, R Paqualini, R. Richards-Kortum and others)
$11,600,000
11/1/09-10/30/14

92. Bill and Belinda Gates Foundation
"Targeted Oral Vaccines to Induce Cellular & Mucosal Immunity"
$100,000
10/1/09-10/1/10

93. National Science Foundation
"siRNA Delivery"
09/01/10-08/31/12

94. National Institutes of Health
"pH-Sensitive Complex Hydrogels for Protein Drug Release"
$1,698,733
3/5/11–2/28/15

95. National Institutes of Health
"Thermosensitive Hydrogels"
$275,000
12/1/11- 11/30/13

96. Texas 4000
"Optimization of Environmentally Responsive Nanocarriers for the Oral Delivery of Chemotherapeutic Agents for the Treatment of Cancer"
$25,000
9/1/14–8/31/15

97. International Collaboration for Emerging Technologies
"Development of Scaffolds for Regenerative Medicine by Molecular Imprinting"
$100,000
9/1/14 – 12/31/17

98. UT-Portugal Program, Portuguese Science and Technology Foundation (with R. Reis, M. Gomes)
"Intelligent scaffolds for molecular recognition of advanced applications in regenerative medicine"
$200,000
4/1/15-3/31/17

99. UT-Portugal Program, Portuguese Science and Technology Foundation (with H. Florindo, R. Gaspar)
"Multidisciplinary strategy for the development of a new multiple nanosystem for modulation of immunologic response"
$200,000
4/1/15-3/31/17

100. National Institutes of Health
"Sensor arrays based on molecularly imprinted polymers for diagnosis of Sjogren's syndrome:"
$1,550,000
12/1/16 – 11/31/21

Graduate Students and Researchers Supervised

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Yen Bao, Ph.D.
Donald Barar, M.S., M.B.A., Georgia Pacific Resins, Inc., Elk Grove, CA
Barbara Barr (Howell), M.S., BP-Amoco Fabrics & Fibers, Atlanta, GA

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Jennifer Lopez, M.S., Eli Lilly and Co., Kansas City, MO
Anthony Lowman, Vice Provost, Temple University, Philadelphia, PA
Lucy Lucht (Hair), Ph.D., Lawrence Livermore Laboratories, Livermore, CA
Steven Lustig, M.S., Ph.D., E.I. duPont de Nemours, Wilmington, DE
Surya Mallapragada, Ph.D. , Head and Distinguished Professor, Iowa State University, Ames, IA
Steve Marek, Ph.D., Lecturer, University of Texas, Austin, TX
David Meadows, M.S., Ph.D., Alcon Laboratories, Inc., Ft. Worth, TX
Anthony Mikos, M.S., Ph.D., Chaired Professor, Rice University, Houston, TX
Donald Miller, Ph.D., Pfizer, Philadelphia, PA
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Humphrey Moynihan, M.S., Ph.D., Westvaco, Covington, VA
Scott Napp, M.S., Ph.D., Atlas Copco Rotoflow, Inc., Gardena, CA
Balaji Narasimhan, Ph.D., Professor and Associate Dean, Iowa State University, Ames, IA
Jorge Olivares, M.S., Eli Lilly & Co., San Juan, Puerto Rico.
Ebru Oral, Ph.D., Assistant Professor, Harvard Medical School, Cambridge, MA
Don Owens, Ph.D., Sabic, Evansville, IN
Javier Pacheco-Gomez, M.S., Eli Lilly, Lafayette, IN
Bob Parker, Ph.D. , Associate Professor, University of Pittsburgh, Pittsburgh, PA
Jonathan Peters,
Kairali Podual, Ph.D., BioArray Solutions, Piscataway, NJ
Amey Puranik,
Catherine Reinhart (Stutts), M.S., at home, Corning, NY
Philip Ritger, M.S., Horizon Medical, Santa Ana, CA
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8. Richard W. Korsmeyer: "Drug Diffusion in Swellable Polymer Systems," M.S. Thesis, 1980.
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36. Hai-Shung Andy Tsou, "Water Transport into Epoxy Resins and Composites," Ph.D. Thesis, 1987, ***Ph.D. Thesis No 13***.
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37. M. Lisa Brannon, "Structural Characteristics and Swelling Behavior of pH-Sensitive Hydrogels," Ph.D. Thesis, 1988, ***Ph.D. Thesis No 15***.
38. Ronald S. Harland, "Synthesis, Characterization and Transport Studies of Hydrophilic/Hydrophobic Block and Graft Copolymer Membranes," Ph.D. Thesis, 1988, ***Ph.D. Thesis No 16***.
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41. John Klier, "Self-Associating Networks of Poly(methacrylic Acid-g-Ethylene Glycol)," Ph.D. Thesis, 1989, ***Ph.D. Thesis No 18***.
42. Jennifer Sahlin, "Characterization of Penetrant Transport into Epoxy Resins," M.S. Thesis, 1989.
43. Steven Lustig, "A Continuum Thermodynamics Theory for Transport in Polymer/Fluid Systems," Ph.D. Thesis, 1989, ***Ph.D. Thesis No 19***.
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47. Myung Cheon Lee, "Investigation of the Diffusion and Mechanical Behavior of Epoxy Composites Upon Water Sorption," Ph.D. Thesis, 1991, ***Ph.D. Thesis No 22***.
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Current Theses Supervision

Ph.D. Theses:

Angela Wagner
Expected graduation August 2019
John Clegg, Molecularly Imprinted Polymers for the Detaction and Capture of Extracellular Structures
Expected graduation August 2019
Marissa Wechsler
Expected graduation August 2020
Matthew Miller
Expected graduation August 2021.
Heidi Oldenkamp
Expected graduation August 2022.
Andrew Murphy
Expected graduation August 2022.
Aaliyah Shoeinde

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Expected graduation August 2022.

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