IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LIMITED, Plaintiff, v. ABRAXIS BIOSCIENCE, INC., Defendant.	)	Case No. 06-438-GMS **REDACTED – PUBLIC VERSION**

APPENDIX OF EXHIBITS TO DEFENDANT ABRAXIS BIOSCIENCE, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR JUDGMENT AS A MATTER OF LAW OF NONINFRINGEMENT, INVALIDITY, INEQUITABLE CONDUCT, AND ITS MOTION FOR NEW TRIAL AND DEFENDANT ABRAXIS BIOSCIENCE, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO AMEND THE JUDGMENT AND ENTER FINDINGS THAT ELAN ENGAGED IN INEQUITABLE CONDUCT IN PROCURING THE '363 AND '025 PATENTS

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Dated: August 18, 2008

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Exhibit No.	Description	Date	Page Nos.
JX088	Sterling Memo from Department of Vascular and Biochemical Pharmacology re Final Study Report for Study Report No. 1137	03/02/1993	A 2207-2256
PX717	Laboratory Notebook 5489 (Nancy Peltier)		A 2257-2272
DX472	CV – Jerry L. Atwood, Ph.D. (Exhibit A to Atwood Opening Expert Report)		A 2273-2346
DX474	CV – Mansoor M. Amiji, R.Ph., Ph.D. (Exhibit A to Amiji Opening Expert Report)		A 2347-2393
	Excerpts from Plaintiff Elan Pharma International Limited's Sixth Amended Answers and Objections to Defendant Abraxis's Second Set of Interrogatories (Nos. 2-9)	10/29/2007	A 2394-2399
	Excerpts from Plaintiff Elan Pharma International Limited's First Amended Objections and Answers to Defendant Abraxis's Third Set of Interrogatories (Nos. 10-13)	10/29/2007	A 2400-2404
	Excerpts of Trial Transcripts	06/02-11/2008	A 2405-2420

CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on August 20, 2008, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on August 20, 2008**,** I caused a true and correct copy of the foregoing document to be served by e-mail on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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REDACTED IN THEIR ENTIRETY

CURRICULUM VITAE

Jerry L. Atwood

Personal

Date of Birth: July 27, 1942
Place of Birth: Springfield, Missouri
Married: Tracey Machen, 1984

Education

B.S., Southwest Missouri State, Chemistry and Mathematics, 1964
Ph.D., University of Illinois, 1968

Professional Experience

Assistant Professor, University of Alabama, 1968-1972
Associate Professor, University of Alabama, 1972-1978
Professor, University of Alabama, 1978-1987
Visiting Professor, Imperial College, 1977
University Research Professor, University of Alabama, 1987 - 1994
Professor and Chairman, University of Missouri-Columbia, 1994-
Curators' Professor, University of Missouri-Columbia, 1999-

Professional Activities

Co-Editor, *New Journal of Chemistry* (2005-)
Editor, *Journal of Supramolecular Chemistry* (2000-2004)
Editor, *Supramolecular Chemistry* (1992-2000)
Associate Editor, *Chemical Communications* (1996-2006)
Consulting Editor, *Journal of Chemical Crystallography* (1999-)
Editor, *Journal of Chemical Crystallography* (1985-1998)
Regional Editor, *Journal of Coordination Chemistry*, A & B (1985-1993)
Editor, *Journal of Inclusion Phenomena* (1983-1991)
Editorial Advisory Board, *Crystal Growth & Design* (2000-)
International Advisory Editorial Board, *New Journal of Chemistry* (2003-)
Editorial Board, *Supramolecular Chemistry* (2000-)
Editorial Board, *Journal of Coordination Chemistry* (1993-)
Editorial Board, *Journal of Organometallic Chemistry* (1986-2000)
Editorial Board, *Crystal Engineering* (1998-)
Co-Editor, *Inclusion Compounds* (five volumes)
Co-Editor, *Comprehensive Supramolecular Chemistry* (ten volumes)
Co-Editor, *Encyclopedia of Supramolecular Chemistry* (two volumes)
Member, American Chemical Society
Member, American Institute of Chemical Engineers
Member, Royal Society of Chemistry
Member, American Crystallographic Association
Institute of Scientific Information, Highly Cited Researchers, isihighlycited.com

Publications Summary

Publications in Refereed Journals	632
Patents	11

Case No. 06-438-GMS
DX-472

Honors and Awards:

1986	Burnum Award for Teaching and Research, U of Alabama
1987	University Research Professor, U of Alabama
1989	von Humboldt Senior Scientist Award, Germany
1992	Japanese Society for the Promotion of Science Award
1996	Outstanding Alumni Award, SMSU
1999	Curators' Professor, University of Missouri (MU)
2000	President's Award for Research and Creative Activity, MU
2000	Izatt-Christensen International Macrocyclic Chemistry Award
2000	Polish Academy of Science, Elected Foreign Member
2002	Alumni-Faculty Award, MU
2005	Royal Society of Chemistry, Elected Fellow
2005	Honorary Medal of the Institute of Physical Chemistry, Polish Academy of Sciences
2005	Midwest Chemist Award, American Chemical Society

PUBLICATIONS

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2. J. L. Atwood and G. D. Stucky, "Dative Nitrogen-to-Metal π-bonding in Bis(dimethylamino)beryllium," *Chem. Comm.*, 1169 (1967).

3. J. L. Atwood and G. D. Stucky, "$Mg[Al(OCH_3)_2(CH_3)_2]_2{\cdot}C_4H_8O_2$ A Novel Coordination Compound of a Metal Alkoxide and a Donor Molecule," *J. Organometal. Chem.*, **13**, 53 (1968).

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5. J. L. Atwood and G. D. Stucky, "The Stereochemistry of Polynuclear Compounds of the Main Group Elements. XI. The Structure of Bis(dimethylamino)beryllium and Its Reaction with Trimethylaluminum," *J. Amer. Chem. Soc.*, **91**, 4426 (1969).

6. J. L. Atwood and G. D. Stucky, "The Stereochemistry of Polynuclear Compounds of the Main Group Elements. XII. The Synthesis and Structure of the Ethyleniminodimethylaluminum Trimer," *J. Amer. Chem. Soc.*, **92**, 285 (1970).

7. J. L. Atwood, P. A. Milton, and S. K. Seale, "Thermal Decomposition of Anionic Organoaluminum Thiocyanates," *J. Organometal. Chem.*, **28**, C29 (1971).

8. C. D. Whitt and J. L. Atwood, "The Structure of Dimethylbis(quinuclidine)-beryllium," *J. Organometal. Chem.*, **32**, 17 (1971).

9. C. D. Whitt, L. M. Parker, and J. L. Atwood, "The Crystal Structure of Trimethyl(quinuclidine)aluminum," *J. Organometal. Chem.*, **32**, 291 (1971).

10. P. G. Laubereau, L. Ganguly, J. H. Burns, B. M. Benjamin, J. Selbin, and
J. L. Atwood, "Triindenylthoriumchloride and Triindenyluraniumchloride," *Inorg. Chem.*, **10**, 2274 (1971).

11. J. L. Atwood and P. A. Milton, "Thermolysis of Tetramethylammonium Iodotrimethylaluminate," *J. Organometal. Chem.*, **36**, C1 (1972).

12. K. D. Smith and J. L. Atwood, "The Nature of the Scandium-Carbon Bond. The Crystal and Molecular Structure of $[(C_5H_5)_2ScCl]_2$," *J. C. S. Chem. Comm.*, 593 (1972).

13. J. L. Atwood and W. R. Newberry, III, "Solid State Structure and Solution Behavior of Compounds of the Type $M[Al_2(CH_3)_6X]$," *J. Organometal. Chem.*, **42**, C77 (1972).

14. R. A. Abramovitch, G. Grins, R. B. Rogers, J. L. Atwood, M. D. Williams, and S. Crider, "A Novel β-Alkylation of Pyridine and Quinoline 1-Oxides," *J. Org. Chem.*, **37**, 3383 (1972).

15. M. L. Simms, J. L. Atwood, and D. A. Zatko, "The Crystal Structure of Ethylenebis(biguanide)silver(III) Perchlorate," *J. C. S. Chem. Comm.*, 46 (1973).

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18. J. L. Atwood, J. H. Burns, and P. G. Laubereau, "The Crystal Structure of Triindenylsamarium," *J. Amer. Chem. Soc.*, **95**, 1830 (1973).

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20. J. L. Atwood, M. L. Simms, and D. A. Zatko, "Bis(2,2'-bipyridine)silver(II) Nitrate Monohydrate, $Ag(N_2C_{10}H_8)_2{\cdot}(NO_3)_2{\cdot}H_2O$," *Cryst. Struct. Comm.*, **2**, 279 (1973).

21. J. L. Atwood and P. A. Milton, "The Crystal Structure of Iododimethyl-(trimethylamine)aluminum," *J. Organometal. Chem.*, **52**, 275 (1973).

22. J. L. Atwood and D. C. Hrncir, "Thermal Decomposition of Anionic Organoaluminum Compounds. IV. The Formation of Alkali Metal

Tetramethylaluminates and the Crystal Structure of Rb[Al(CH_3)$_4$]," *J. Organometal. Chem.*, **61**, 43 (1973).

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24. J. L. Atwood, C. F. Hains, M. Tsutsui, and A. E. Gebala, "X-ray Crystallographic Characterization of the Uranium-Carbon Sigma bond in Tricyclopentadienyl- phenylethynyluranium (IV)," *J. C. S. Chem. Comm.*, 452 (1973).

25. J. L. Atwood and K. D. Smith, "Crystal Structure of Di-μ-chloro-bis[di-η-cyclo- pentadienylscandium(III)] Dimer," *J. C. S. Dalton Trans.*, 2487 (1973).

26. M. Tsutsui, N. Ely, A. E. Gebala, and J. L. Atwood, "Sigma-Bonded Organometallic Derivatives of the Lanthanides and Actinides," *Ann. N. Y. Acad. Sci.*, **239**, 160 (1973).

27. S. K. Seale and J. L. Atwood, "Cationic Influence in Anionic Organoaluminum Chemistry Synthesis and Structure of Dimethylthallium Isothiocyana- totrimethylaluminate," *J. Organometal. Chem.*, **64**, 57 (1974).

28. J. L. Atwood and W. R. Newberry, III, "The Interaction of Aromatic Hydrocarbons with Organometallic Compounds of the Main Group Elements III. The Crystal Structure of K[$Al_2(CH_3)_6F$]·C_6H_6," *J. Organometal. Chem.*, **66**, 15 (1974).

29. J. L. Atwood and W. R. Newberry, III, "The Interaction of Aromatic Hydrocarbons with Organometallic Compounds of the Main Group Elements. II. Solution Behavior and Crystal Structure of K[$Al_2(CH_3)_6N_3$]," *J. Organometal. Chem.*, **65**, 145 (1974).

30. J. L. Atwood and K. D. Smith, "Synthesis and Structure of Bis(indenyl)magnesium," *J. Amer. Chem. Soc.*, **96**, 994 (1974).

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32. S. K. Seale and J. L. Atwood, "Thermal Decomposition of Anionic Organoaluminum Compounds. V. The Preparation and Crystal Structure of

the (Isopropylidenamino)dimethylaluminum Dimer," *J. Organometal. Chem.*, **73**, 27 (1974).

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41. J. L. Atwood, K. E. Stone, H. G. Alt, D. C. Hrncir, and M. D. Rausch, "Crystal and Molecular Structure of Titanocene Dicarbonyl, $(\eta^5\text{-}C_5H_5)_2Ti(CO)_2$," *J. Organometal. Chem.*, **95**, C4 (1975).

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Structure and Mössbauer Spectrum of [2]-Ferrocenophanethiazine 1,1-Dioxide," *Inorg. Chem.*, **14**, 3085 (1975).

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45. J. L. Atwood, W. E. Hunter, H. Alt, and M. D. Rausch, "The Molecular Structure of 1,1-Bis(η^5-cyclopentadienyl)2,3,4,5-tetraphenyltitanole and its Hafnium Analogue," *J. Amer. Chem. Soc.*, **98**, 2454 (1976).

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47. I. Bernal, J. L. Atwood, F. Calderazzo, and D. Vitali, "Structural Studies on Organodisulfides as Ligands. I. The Crystal and Molecular Structure of $[Re_2Br_2(CO)_6S_2(C_6H_5)_2]$, a Compound Containing Both Disulfide and Bromide Bridges and Capable of Reversible Coordination of an Intact Disulfide Ligand," *Gazz. Chim. Italiana*, **106**, 971 (1976).

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54. M. M. Goodman, J. L. Atwood, R. T. Carlin, W. E. Hunter, and W. W. Paudler, "Tetrazolo[1.5-b]-1,2,4-Triazines: Syntheses and Structure Determination," *J. Org. Chem.*, **41**, 2860 (1976).

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56. R. L. Mahaffey, J. L. Atwood, M. B. Humphrey, and W. W. Paudler, "N-(p-Bromphenyl)[2.2](2,5)pyrrolophane: Synthesis and Self-Condensation," *J. Org. Chem.*, **41**, 2963 (1976).

57. J. L. Atwood and A. L. Shoemaker, "Synthesis and Crystal Structure of the Novel Ferrocenylalane $[(\eta^5\text{-}C_5H_5)Fe(\eta^5\text{-}C_5H_3)Al_2Me_3Cl]_2$," *J. C. S. Chem. Comm.*, 536 (1976).

58. J. L. Atwood, W. E. Hunter, B. A. Lampert, and R. H. Garner, "The Crystal and Molecular Structure of 1-Hydroxy-2,3-dicarbomethoxy-1,3-cycloheptadiene," *J. Cryst. Mol. Struct.*, **6**, 291 (1976).

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61. I. Bernal, J. L. Atwood, F. Calderazzo, and D. Vitali, "Structural Studies on Organodisulfides as Metal Ligands. II. The Crystal and Molecular Structure of $[Re_2Br_2(CO)_6]S_2(CH_3)_2$, a Compound Containing an Intact Dimethyldisulfide Bridge Across the Two Metals," *Israel J. Chem.*, **15**, 153 (1976/77).

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Structure of Tetramethylammonium Acetatotrimethylaluminate," *J. Organometal. Chem.*, **127**, 403 (1977).

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Mavani, and D. Vitali, "The Crystal and Molecular Structure of μ-Dibromo-μ-tetraphen- yldiphosaphanebis[tricarbonylrhenium(I)]," *J. C. S. Dalton Trans.*, 1189 (1978).

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filed April 19, 2004.

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EDUCATION AND TRAINING

September, 1984 - June, 1988: Undergraduate Student in the College of Pharmacy and Allied Health Professions, Northeastern University, Boston, Massachusetts.

September, 1986 - May, 1988: Undergraduate Honors Student Research Project Entitled *"Preparation and Characterization of Doxorubicin-Dextran Conjugates"*

June, 1988: B.S. in Pharmacy (*magna cum laude*).

August, 1988 - July, 1992: Graduate Student in the Department of Industrial and Physical Pharmacy, School of Pharmacy, Purdue University, West Lafayette, Indiana.

August, 1988 - June, 1989: Teaching Assistant in the Department of Industrial and Physical Pharmacy.

July, 1989 - June, 1992: Research Assistant in the Department of Industrial and Physical Pharmacy.

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July, 1989 - June, 1992: Doctoral Dissertation Research Entitled *"Surface Modification of Biomaterials with Water-Soluble Polymers: A Steric Repulsion Approach"* - Major Advisor: Professor Kinam Park.

July, 1992: Ph.D. in Pharmaceutics/Biomaterial Science.

PROFESSIONAL AND ACADEMIC POSITIONS

August, 1992 - December, 1992: Senior Research Scientist, Columbia Research Laboratories, Madison, WI. (Due to financial concerns, the company closed its Research and Development unit in December of 1992).

January, 1993 - June, 1999: Assistant Professor, Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University, Boston, Massachusetts.

July, 1999 - April, 2006: Associate Professor (with tenure), Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University, Boston, Massachusetts.

June, 2000 - December, 2000: Visiting Research Scholar. Department of Chemical Engineering, Massachusetts Institute of Technology, Cambridge, Massachusetts. (Sabbatical leave appointment in Professor Robert Langer's laboratory).

May, 2006 - Present: Full Professor, Department of Pharmaceutical Sciences, School of Pharmacy, Northeastern University, Boston, Massachusetts.

ADMINISTRATIVE POSITIONS

July, 1995 – Present: Pharmaceutics Section Leader, Department of Pharmaceutical Sciences, School of Pharmacy at Northeastern University, Boston, Massachusetts.

September, 2002 – June, 2004: Education and Outreach Coordinator, Molecular Biotechnology Initiative at Northeastern University, Boston, Massachusetts.

July 2003 – Present: Co-Director, Nanomedicine Education and Research Consortium (NERC) at Northeastern University, Boston, Massachusetts.

July, 2005 – Present: Associate Department Chairman, Department of Pharmaceutical Sciences, School of Pharmacy at Northeastern University, Boston, Massachusetts.

RESEARCH INTERESTS

The primary focus of research in my laboratory is on the development of biocompatible materials from natural and synthetic polymers, target-specific drug and gene delivery systems for cancer and infectious diseases, and nanotechnology applications for medical diagnosis, imaging, and therapy. Specific projects that we are currently pursuing include:

- Synthesis of novel polymeric materials for medical and pharmaceutical applications.

- Surface modification of cationic polymers by the complexation-interpenetration method to develop biocompatible materials.
- Preparation and characterization of polymeric membranes and microcapsules with controlled permeability properties for medical and pharmaceutical applications.
- Target-specific drug delivery systems for gastro-intestinal tract infections.
- Delivery of DNA to mucosal surfaces for gene therapy and vaccination.
- Bioadhesive microspheres formulations of protein and peptide drugs for sustained intranasal delivery.
- Localized delivery of cytotoxic and antiangiogenic drugs for solid tumors in novel biodegradable polymeric nanoparticles.
- Intracellular delivery systems for drugs and genes using target-specific, long-circulating, biodegradable polymeric nanoparticles.
- Multifunctional therapeutic strategies to overcome multidrug resistance in tumors.
- Novel oil-in-water nanoemulsion formulations for drug delivery through the gastrointestinal tract and across the blood-brain barrier.
- Intranasal administration of liposomes and nanoemulsions to enhance brain delivery of proteins and genes.
- Functionalized metal nanoparticles - including gold and iron-gold alloys and core-shell nanostructures - for biosensing, imaging, and targeted therapeutic applications.

PUBLICATIONS

Books:

Amiji, M.M. and Sandmann, B.J. (Eds.). *Applied Physical Pharmacy.* McGraw-Hill Medical Publishing Division. New York, NY. 2002.

Amiji, M.M. (Ed.) *Polymeric Gene Delivery: Principles and Applications.* CRC Press, LLC (a subsidiary of Taylor and Francis). Boca Raton, FL. 2004.

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van Vlerken, L.E., Little, S., Duan, Z., Seiden, M., Langer, R., and **Amiji, M.** Modulation of multidrug resistance in cancer with polymer blend nanoparticles. *Proceedings of the First National Cancer Institute's Alliance in Nanotechnology Meeting.* San Diego, CA October 24-26, pp 30 (2006).

Migliore, M., Vyas, T.K., Campbell, R.C., **Amiji, M.M.,** and Waszczak, B.L. Brain delivery of proteins by the intranasal route of administration using cationic liposomes. *Proceedings of the Society of Neuroscience Meeting, Atlanta,* GA (2006).

Devalapally, H.K., Shenoy, D.B., Little, S., Langer, R., and **Amiji, M.M.** Tumor-targeted delivery of hydrophobic drugs in pH-sensitive poly(ethylene oxide)-modified poly(beta-amino ester) nanoparticles. *The AAPS Journal,* **8:** S2, (2006).

Desai, A., Vyas, T.K., and **Amiji, M.M.** Development and characterization of nanoemulsion formulations containing multimodal therapeutics for brain tumor. *The AAPS Journal,* **8:** S2, (2006).

Shah, L.K., Gamsiz, E.D., Carrier, R.L., and **Amiji. M.M.** Biodegradable polymeric nanoparticles for intracellular saquinavir delivery in HIV/AIDS. *The AAPS Journal,* **8:** S2, (2006).

Bhavsar, M.D. and **Amiji, M.M.** Oral plasmid DNA administration and transfection using nanoparticles-in-microsphere formulations. *The AAPS Journal,* **8:** S2, (2006).

van Vlerken, L.E., Little, S., Duan, Z., Seiden, M., Langer, R., and **Amiji, M.** Modulation of multidrug resistance in cancer with polymer blend nanoparticles. *The AAPS Journal,* **8:** S2, (2006).

Kommareddy, S. and **Amiji, M.M.** Tumor-targeted sFlt-1 gene delivery using long-circulating thiolated gelatin nanoparticles. *The AAPS Journal,* **8:** S2, (2006).

Vyas, T.K. and **Amiji, M.M.** Improved oral delivery of saquinavir in nanoemulsion formulations for HIV/AIDS. *The AAPS Journal,* **8:** S2, (2006).

Amiji, M.M. Nanotechnology for targeted drug and gene delivery. *Nanomedicine,* **2(4):** 299-300 (2006).

Amiji, M.M. Nanotechnology in cancer diagnosis, imaging, and therapy. *Proceedings of the American College of Veterinary Pathologists 57th Annual Meeting and the American Society for Veterinary Clinical Pathology 41st Annual Meeting,* pp 4-7 *(2006).*

INTRAMURAL AND EXTRAMURAL RESEARCH FUNDING

Funded Grant Applications:

Source: National Institutes of Health, Biomedical Research Support Grant
Title: Prevention of Protein Adsorption on Poly(Ethylene Oxide)-Modified Surfaces
Amount: $2,000 (total).
Duration: June, 1993 - May, 1994
Role: Principal Investigator

Source: Northeastern University, 1995 Research and Scholarship Development Fund
Title: Development of Blood-Compatible Hemodialysis Membranes from Chitosan
Amount: $10,000 (total)
Duration: July, 1995 - December, 1996 (with 6-months no-cost extension)
Role: Principal Investigator

Source: Bristol-Myers Squibb Pharmaceutical Research Institute, Kenilworth, NJ.
Title: Development of Novel Thermogelling System for Localized Delivery of Taxol®
Amout: $8,000 (total)
Duration: July, 1996 - June, 1997
Role: Principal Investigator.

Source: Roche Laboratories, Inc., Nutley, NJ.
Title: HPLC Assay Development for Mycophenolic Acid and Mycophenolic Acid Glucuronide
Amount: $10,000 (total)

Duration: July 1996 - December, 1996
Role: Co-Principal Investigator (PI: Prof. Rafaat Seifeldin, Department of Pharmacy Practice, Northeastern University)

Source: Northeastern University, Honors Program Research Funds
Title: Undergraduate Honors Students Research Initiatives
Amount: $5,000.
Duration: July 1997 - June 1999.
Role: Principal Investigator.

Source: Pharmaceutical Research and Manufacturers of America Foundation, Undergraduate Pharmaceutics Research Fellowship. (On behalf of Ms. Phung-Kim Lai, B.S. student in the class of 1999).
Title: Novel Thermogelling Paclitaxel Formulation for Intra-Tumoral Delivery
Amount: $5,000 (total)
Duration: January, 1999 - December, 1999
Role: Principal Investigator.

Source: Northeastern University, 1999 Research and Scholarship Development Fund
Title: Stomach-Specific Antibiotic Delivery for *H. pylori* Infection
Amount: $10,000 (total)
Duration: July, 1999 - June, 2000
Role: Principal Investigator

Source: EOS Pharmaceuticals Corporation, Woburn, MA (through National Institutes of Health, Small Business Innovation Research Program, Phase I Grant)
Title: Stomach-Specific Anti-*H. pylori* Therapy
Amount: $50,000 (total, ~ 45% of the total SBIR funding)
Duration: July, 2000 – June, 2001
Role: Principal Investigator

Source: American Association of Pharmaceutical Scientists and American Foundation for Pharmaceutical Education, 2000-2001 "Gateway" Research Scholar Program. (On behalf of Mr. Chi-Sing Nip, Pharm.D. student, Class of 2001)
Title: Perm-selective Membranes from Chitosan for Extracorporeal Removal of ? -2-Microglobulin
Amount: $5,000 (total)
Duration: July, 2000 – June, 2001
Role: Principal Investigator

Source: Braintree Laboratories, Inc., Braintree, MA
Title: Analysis of Phosphate Binding to Cationic Polymers
Amount: $31,000 (total)
Duration: December, 2000 – June, 2001
Role: Principal Investigator

Source: Pharmaceutical Research and Manufacturers of America Foundation, Undergraduate Pharmaceutics Research Fellowship. (On behalf of Ms. Erica J. Waugh, Pharm.D. student in the class of 2002)

Title: Novel Biodegradable Long-Circulating Nanoparticles for Tumor-Selective Drug Delivery
Amount: $5,000 (total)
Duration: January, 2001 – December, 2001
Role: Principal Investigator

Source: Braintree Laboratories, Inc., Braintree, MA
Title: Chitosan-Iron Complexes as Polymeric Phosphate Binders
Amount: $15,000 (total)
Duration: January, 2002 – June, 2002
Role: Principal Investigator

Source: Northeastern University, Undergraduate Research Fund. (On behalf of Ms. Nikita Mody, Pharm.D. student in the class of 2004)
Title: Tumor-Selective Gene Delivery Systems
Amount: $3,000 (total)
Duration: January, 2002 – June, 2002
Role: Principal Investigator

Source: Northeastern University, 2002 Research and Scholarship Development Fund
Title: Immobilized Enzyme System for Detection and Detoxification of Chemical Warfare Agents
Amount: $5,006 (total)
Duration: July, 2002 - June, 2003
Role: Principal Investigator

Source: Alfred P. Sloan Foundation, New York, NY
Title: Multi-Track Professional Masters Degree Program in Biotechnology
Amount: $75,000 (total)
Duration: July, 2002 – June 2004 (with one year no-cost extension)
Role: Co-Investigator (PI: Prof. William Detrich, Department of Biology, Northeastern University).

Source: Boston Scientific Corporation. Watertown, MA
Title: Drug Interactions with Poly(Vinyl Alcohol) Embolic Microspheres: Part I
Amount: $33,256 (total)
Duration: February, 2003 – December, 2003
Role: Principal Investigator

Source: National Cancer Institute, National Institutes of Health (R01-CA95522-01A2, Priority Score 241, 18.1th Percentile)
Title: Long-Circulating Tumor-Selective DNA Delivery Systems
Amount: $744,100 (total)
Duration: July, 2003 – June, 2007* (with one-year no-cost extension)
Role: Principal Investigator

Source: National Science Foundation, Major Research Instrumentation Grant (MRI-0320638)
Title: Acquisition of Scanning Electron Microscope for Nanoscience and Biotechnology
Amount: $477,846 (total)

Duration: July, 2003 – June, 2004
Role: Co-Investigator (PI: Prof. Donald Heiman, Department of Physics, Northeastern University)

Source: Roger Williams Medical Center, Providence, RI. Subcontract of the Department of Defense Grant DAMD17-03-0716
Title: Drug Encapsulation in Poly(Epsilon-Caprolactone) Nanoparticles
Amount: $20,119 (total)
Duration: October, 2003 – September, 2005 (with one year no-cost extension)
Role: Principal Investigator

Source: Boston Scientific Corporation. Watertown, MA
Title: Drug Interactions with Poly(Vinyl Alcohol) Embolic Microspheres: Part II
Amount: $44,865 (total)
Duration: February, 2004 – December, 2004
Role: Principal Investigator

Source: American Foundation for Pharmaceutical Education, Undergraduate Gateway Research Scholarship. (On Behalf of Ms. Stephanie Whalen, Pharm.D. Class of 2006)
Title: Novel Gold Nanoparticle Sensor for Non-invasive Glucose Measurements
Amount: $5,000 (total)
Duration: June, 2004 – December, 2004
Role: Principal Investigator

Source: Boston Scientific Corporation, Natick, MA
Title: Preparation and Characterization of Drug-Loaded SIBS Copolymer Microsphere Formulations
Amount: $100,019 (total)
Duration: October, 2004 – December, 2005 (with no-cost extension)
Role: Principal Investigator

Source: American Foundation for Pharmaceutical Education, Undergraduate Gateway Research Scholarship. (On Behalf of Mr. Zeu Hong Tzeng, PharmD Class of 2007)
Title: Thiolated Gelatin Nanoparticles for Intracellular siRNA Delivery
Amount: $5,000 (total)
Duration: July, 2005 – June, 2006
Role: Principal Investigator

Source: Novavax, Inc., Malvern, PA.
Title: Nanocarrier Formulation Optimization Studies
Amount: $60,543 (total)
Duration: May, 2005 – December, 2005
Role: Principal Investigator

Source: Northeastern University, 2005 Research and Scholarship Fund
Title: Functionalized Gold Nanoparticles as Novel Mitochondria-Targeted Vectors
Amount: $15,000 (total)
Duration: July, 2005 – June, 2006

Role: Co-Investigator (PI: Prof. Volkmar Weissig, Department of Pharmaceutical Sciences, Northeastern University)

Source: Transport Pharmaceuticals, Inc., Framingham, MA
Title: Evaluation of Formulation Properties Used in Iontophoretic Drug Delivery Device
Amount: $58,875 (total)
Duration: August, 2005 – July, 2006
Role: Principal Investigator

Source: National Cancer Institute/National Science Foundation, Interdisciplinary Graduate Education and Training (IGERT) Grant
Title: IGERT-Nanomedical Science and Technology
Amount: $3,320,168 (total)
Duration: October, 2005 – September, 2010
Role: Co-Investigator (PI: Prof. Srinivas Sridhar, The Nanomedicine Education and Research Consortium, Northeastern University)

Source: National Institutes of Health. NCI Nanotechnology for Cancer Alliance's RFA "Cancer Nanotechnology Platform Partnership Grant" program (1R01-CA119617-01, Priority Score 190)
Title: Nanotherapeutic Strategy for Multidrug Resistant Tumors
Amount: $1,529,399 (total)
Duration: October, 2005 – September, 2009
Role: Principle Investigator

Source: Boston Scientific Corporation. Malborough, MA
Title: Drug Interactions with Poly(Vinyl Alcohol) Embolic Microspheres: Part III
Amount: $125,208 (total)
Duration: March, 2006 – February, 2007
Role: Principal Investigator

Source: National Cancer Institute, Nanotechnology Characterization Laboratory
Title: Multifunctional Nanoemulsions for Brain Tumor Imaging and Therapy
Amount: Undisclosed (complete preclinical characterization studies)
Duration: May, 2006 – December, 2007
Role: Principal Investigator

Source: Transport Pharmaceuticals, Inc., Framingham, MA
Title: Evaluation of Formulation Properties Used in Iontophoretic Drug Delivery Device: Part II
Amount: $72,952 (total)
Duration: August, 2006 – July, 2007
Role: Principal Investigator

Pending Grant Applications:

Source: National Science Foundation, Major Research Instrumentation Grant (MRI-0320638)
Title: MRI: Acquisition of Transmission Electron Microscope for Research and Training in Nanoscience and Technology

Amount: $1,431,691 (total)
Submitted: January, 2007
Role: Co-Investigator (PI: Prof. Sanjeev Mukerjee, Department of Chemistry and Chemical Biology, Northeastern University).

Source: National Institutes of Health, R21 Proposal in Response to PA "NIH Exploratory/Developmental Research Grant Program" (PA-03-107)
Title: Nanoparticle-Based Antimicrobial Photochemotherapy in Biofilms
Amount: $150,170 (Sub-contract total)
Re-Submitted: February, 2007
Role: Principal Investigator on NU Subcontract (PI: Dr. Nikos Soukos, Forsyth Institute, Boston, MA)

Source: National Institutes of Health, R21 Proposal in Response to RFA "NINDS Exploratory/Developmental Projects in Translational Research" (PAR-05-157).
Title: Intranasal Liposomal Gene Delivery to the Brain
Amount: $431,750 (total)
Submitted: February, 2007
Role: Principal Investigator.

Source: National Institutes of Health R01 Proposal in response to RFA "Nanoscience and Nanotechnology in Biology and Medicine" program
Title: Oral Gene Therapy with NiMOS for Inflammatory Bowel Disease
Amount: $1,570,000 (total)
Submitted: February, 2007
Role: Principle Investigator

Source: National Institutes of Health R01 Proposal in response to RFA "Nanoscience and Nanotechnology in Biology and Medicine" program (First review score 251, 31st percentile).
Title: Engineered Nanovectors for Pancreatic Cancer Gene Therapy
Amount: $1,543,780 (total)
Re-Submitted: June, 2007
Role: Principle Investigator

Source: National Institutes of Health, R21 Proposal in Response to RFA "Therapeutics Delivery for Neurodegenerative Diseases" (RFA-EY-07-001).
Title: Intranasal Delivery of GDNF for Parkinson's Disease
Amount: $431,750 (total)
Re-Submitted: June, 2007
Role: Co-Investigator (PI: Prof. Barbara Waszczak, Department of Pharmaceutical Sciences, Northeastern University)

PATENTS AND INVENTION DISCLOSURES

Amiji, M.M. *"Biocompatible Articles and Method of Making Same".* United States Patent Number 5,885,609. Issued: March 1999.

Amiji, M.M. *"Drug Delivery Using pH-Sensitive Semi-Interpenetrating Network Hydrogels"*. United States Patent Number 5,904,927. Issued: May 1999.

Langer, R.S., Lynn, D.M., Putnam, D., **Amiji, M.M.,** and Anderson, D.G. *"Biodegradable Poly(Beta-Amino Esters) and Uses Thereof"*. United States Patent Number 6,998,115. Issued: February, 2006.

Langer, R.S., Lynn, D.M., Putnam, D., **Amiji, M.M.,** and Anderson, D.G. *"Biodegradable Poly(Beta-Amino Esters) and Uses Thereof"*. European Patent Application. (Serial number 019775410-2115-US0131270, Filed: October, 2001).

Amiji, M.M. and Taqieddin, E.S. *"Hybrid Immobilized Catalytic System with Controlled Permeability"* United States Patent Application Pending (Filed: January, 2003).

Amiji, M.M., Shenoy, D.B., and van Vlerken, L.E. *"Nanoparticulate Delivery Systems for Treating Multi-drug Resistance"*. United States Patent Application Pending (Filed: April, 2006).

Amiji, M.M. and Tiwari, S.K. *"Novel Nanoemulsion Formulations"* United States Patent Application Pending (Filed: November, 2006).

Song, Y.-H., **Amiji, M.M.,** and Tiwari, S.B. *"Methods to Prevent SIBS Microsphere Aggregation During Solvent Evaporation Processing"*. Invention disclosed to Boston Scientific Corporation, Natick, MA, April, 2005.

Song, Y.-H., **Amiji, M.M.,** and Tiwari, S.B. *"Practical Methods to Control the SIBS Microsphere Size"*. Invention disclosed to Boston Scientific Corporation, Natick, MA, April, 2005.

Song, Y.-H., **Amiji, M.M.,** and Tiwari, S.B. *"A Method of Improving Surface Smoothness of the SIBS Microsphere"*. Invention disclosed to Boston Scientific Corporation, Natick, MA, April, 2005.

Amiji, M.M. *"Polymer Complexed Silver Nanoparticles"*. Invention disclosed to Northeastern University. December 2004.

Amiji, M.M. and Shenoy, D.B. *"Poly(ethylene oxide)-Modified Nanoparticles for Targeted Drug Delivery"*. Invention disclosed to Northeastern University. January, 2005.

Amiji, M.M., Tiwari, S.K., and Bhavsar, M.B. *"Novel Bioadhesive Microsphere Delivery Systems"* Invention disclosed to Northeastern University. August, 2005.

PRESENTATIONS

American Association of Pharmaceutical Scientists Annual Meeting, Orlando, FL. Poster presentation entitled *"Adsorption Isotherms of Doxorubicin on Oxidized Dextran"*. November, 1988.

Controlled Release Society Annual Meeting, San Francisco, CA. Podium presentation entitled *"Mucoadhesive Hydrogels Effective at Neutral pH"*. March, 1989.

Society for Biomaterials Annual Meeting, Santa Fe, NM. Podium presentation entitled *"The Minimum Amount of Biologically Active Fibrinogen Necessary for Surface-Induced Platelet Activation"*. April, 1989.

NIH Conference on Cardiovascular Science and Technology, Bethesda, MD. Podium presentation entitled *"Mechanism of Surface Passivation by Albumin"*. May 1990.

Surfaces in Biomaterials Foundation First Annual Meeting, Minneapolis, MN. Podium presentation entitled *"Mechanism Study on the Prevention of Surface-Induced Platelet Activation by Adsorbed Albumin"*. March, 1991.

Society for Biomaterials Annual Meeting, Scotsdale, AZ. Podium presentation entitled *"Prevention of Protein Adsorption and Platelet Adhesion by Steric Repulsion.* May, 1991.

American Chemical Society National Meeting, Washington, DC. Podium presentation entitled *"Surface Passivating Effect of PEO/PPO/PEO Triblock Copolymers"*. August, 1992.

American Chemical Society National Meeting, Washington, DC. Podium presentation entitled *"Analysis on the Surface Adsorption of PEO/PPO/PEO Triblock Copolymers"*. August, 1992.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Podium presentation entitled *"Prevention of Protein Adsorption on Surfaces by PEO/PPO/PEO Triblock Copolymers"*. November, 1992.

Society for Biomaterials Annual Meeting, Boston, MA. *"Adsorption Behavior of PEO/PPO/PEO Triblock Copolymers on DDS-Glass"*. April, 1994.

Society for Biomaterials Annual Meeting, Boston, MA. Podium presentation entitled *"Development of Poly(ethylene oxide)-Chitosan Blend Membranes for Hemodialysis"*. April, 1994.

American Chemical Society Annual Meeting, Washington, DC, Podium presentation entitled *"Chitosan-Poly(ethylene oxide) Semi-IPN as a pH-Sensitive Drug Delivery System"*. August, 1994.

American Association of Pharmaceutical Scientists Annual Meeting, Orlando, FL. Podium presentation entitled *"Pyrene Fluorescence Study of Insulin Denaturation and Aggregation at Hydrophobic Interfaces"*. November, 1994.

Controlled Release Society Annual Meeting, Seattle, WA. Poster presentation entitled *"Chitosan-Poly(Ethylene Oxide) Hydrogels for pH-Sensitive Oral Drug Delivery"*. August, 1995.

American Chemical Society's Conference on Formulations and Drug Delivery, Boston, MA. Podium presentation entitled *"Site-specific Oral Delivery of Antibiotics Using pH-Sensitive Hydrogels"*. October, 1995.

American Association of Pharmaceutical Scientists, Eastern Regional Meeting, New Brunswick, NJ. Poster presentation entitled *"Site-Specific Delivery of Antibiotics for the Treatment of Helicobacter pylori Infection in Peptic Ulcer Disease"*. June, 1995.

Fifth World Biomaterials Congress, Toronto, Ontario, Canada. Podium presentation entitled *"Surface Modification of Chitosan Hemodialysis Membranes with Anionic Polysaccharides"*. June, 1996.

Surfaces in Biomaterials '96 Symposium, Chandler, AZ. Poster presentation entitled *"Modification of Chitosan Membrane Surfaces by Complexation-Interpenetration of Anionic Polysaccharides"* September, 1996.

Nineteenth Annual Undergraduate Research Seminar, Morgantown, WV. Poster presentation entitled *"Factors Influencing Stomach-Specific Antibiotic Delivery for H. pylori Infection"*. October, 1997.

First International Symposium on Advanced Biomaterials, Montréal, Quebec, Canada. Podium presentation entitled *"Chitosan Surface Modification with Anionic Poly(Ethylene Glycol) Derivative for Improved Blood Compatibility."* October, 1997.

American Association of Pharmaceutical Scientists Annual Meeting, Boston, MA. Poster presentation entitled *"The Role of Gastric pH and Mucin Permeability on Localized Antibiotic Delivery for H. pylori Infection"*. November, 1997.

American Association of Pharmaceutical Scientists Annual Meeting, Boston, MA. Poster presentation entitled *"Mucoadhesive Chitosan Microspheres for Stomach-Specific Antibiotic Delivery"*. November, 1997.

American Association of Pharmaceutical Scientists Annual Meeting, Boston, MA. Poster presentation entitled *"Surface Modification of Chitosan by Polyelectrolyte Complexation-Interpenetration to Improve Biocompatibility"*. November, 1997.

Society for Biomaterials Annual Meeting, Providence, RI. Podium presentation entitled *"Novel Thermogelling Paclitaxel Formulation for Localized Delivery"*. May, 1999.

Society for Biomaterials Annual Meeting, Providence, RI. Podium presentation entitled *"Surface Modification of Chitosan Microspheres to Improve Biocompatibility"*. May, 1999.

Controlled Release Society Annual Meeting, Boston, MA. Poster presentation entitled *"Membranes Formed by Physical Interpenetration of Chitosan with PEO/PPO/PEO Triblock Copolymers"*. June, 1999.

American Association of Pharmaceutical Sciences Annual Meeting. Indianapolis, IN. Poster presentation entitled *"Preparation and Characterization of Cross-linked Chitosan Microspheres for Delivery of Tetracycline Locally in the Stomach"*. November, 2000.

American Association of Pharmaceutical Sciences, Pharmaceutical Congress of the Americas, Orlando, FL. Poster presentation entitled *"Intratumoral Administration of Paclitaxel in a Thermogelling Pluronic® F-127 Formulation"*. March, 2001.

American Association of Pharmaceutical Sciences, Pharmaceutical Congress of the Americas, Orlando, FL. Poster presentation entitled *"Biodegradable Chitin-Paclitaxel Microparticle Formulations for Localized Drug Delivery"*. March, 2001.

American Association of Pharmaceutical Scientists, Pharmaceutical Congress of the Americas, Orlando, FL. Poster presentation entitled *"Permselective Membranes Prepared by Physical Interpenetration of Chitosan with PEO/PPO/PEO Triblock Copolymers"*. March, 2001.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Poly(epsilon-caprolactone) Nanoparticles for Intracellular Delivery of Tamoxifen"*. April, 2001.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Poly(Ethylene Glycol)-Modified Gelatin Nanoparticles as Long-Circulating Intracellular Delivery Vehicle"*. April, 2001.

American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO. Poster presentation entitled *"Poly(epsilon-caprolactone) Nanoparticles for Intracellular Delivery of Tamoxifen"*. October, 2001.

American Association of Pharmaceutical Scientists Annual Meeting, Denver, CO. Poster presentation entitled *"Perm-Selective Alginate-Chitosan Hybrid Microcapsules for Enzyme Immobilization"*. October, 2001.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Long-Circulating, pH-Sensitive Poly(beta-amino ester) Nanoparticles for Tumor-Selective Paclitaxel Delivery"*. April, 2002.

American Association of Pharmaceutical Scientists Annual Meeting, Toronto, Ontario, Canada. Poster presentation entitled *"Cellular Uptake, Trafficking, and DNA Transfection Studies with Poly(ethylene glycol)-Modified Gelatin Nanoparticles"*. November, 2002.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"In Vitro Evaluation of DNA Delivery to Tumor Cells Using Poly(ethylene glycol)-Modified Gelatin Nanoparticles"*. April, 2003.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Effect of Chemical Crosslinking of Chitosan Microspheres on Gastric Residence and Local Tetracycline Concentrations in Fasted Gerbils for Local Treatment of H. pylori Infection"*. April, 2003.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Chitosan Stabilized Colloidal Gold Complexes: Cationic Probes for Intracellular DNA Trafficking and Delivery"*. April, 2003.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Plasmid DNA Encapsulation in a Hybrid Nanoparticles-in-Microsphere System for Oral Delivery"*. April, 2004.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Preparation of Thiolated Gelatin Nanoparticles for Rapid Intracellular Delivery in Response to Glutathione"*. April, 2004.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Polymeric Nanoparticles for Targeted and Controlled Tamoxifen Delivery in Breast Cancer: In Vitro and In Vivo Investigations"*. April, 2004.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Biodistribution and Targeting Potential of Poly(ethylene glycol)-Modified Gelatin Nanoparticles in Tumor-Bearing Mice"*. April, 2004.

American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, MD. Poster presentation entitled *"Polymeric Nanoparticles for Targeted and Controlled Tamoxifen Delivery in Breast Cancer: In-vitro and In-vivo Investigations"*. November, 2004.

American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, MD. Poster presentation entitled *"Preparation of Thiolated Gelatin Nanoparticles for Rapid Intracellular Delivery in Response to Glutathione"*. November, 2004.

American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, MD. Poster presentation entitled *"Biodistribution and Targeting Potential of Poly(ethylene glycol)-Modified Gelatin Nanoparticles in Tumor-Bearing Mice"*. November, 2004.

American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, MD. Poster presentation entitled *"Nanoparticles-in-Microsphere Hybrid Systems for Oral DNA Vaccine Delivery"*. November, 2004.

Materials Research Society Fall National Meeting, Boston, MA. *"Biomedical Applications of Gold Nanoparticles Functionalized Using Hetero-Bifunctional Poly(ethylene glycol) Spacer"*. December, 2004.

Materials Research Society Fall National Meeting, Boston, MA. *"Biodegradable Polymeric Nanoparticles for Tumor-Selective Tamoxifen Delivery: In Vitro and In Vivo Studies"*. December, 2004.

Materials Research Society Fall National Meeting, Boston, MA. *"Biodistribution and Tumor-Targeting Potential of Poly(ethylene glycol)-Modified Gelatin Nanoparticles"*. December, 2004.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Polymeric Nanoparticles for Targeted and Controlled Tamoxifen Delivery in Breast Cancer: In-Vitro and In-Vivo Investigations"*. April, 2005.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Plasmid DNA Encapsulation in a Hybrid Nanoparticles-in-Microsphere System for Oral Delivery"*. April, 2005.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Improved Oral Delivery of Hydrophobic Drugs with Novel Nanoemulsion Formulations"* April, 2005.

Nano Science and Technology Institute's Nano2005 Conference and Trade Show, Anaheim, CA. *"Biomedical Applications of Gold Nanoparticles Functionalized Using Hetero-bifunctional Poly(ethylene glycol) Spacer"*. May, 2005.

Nano Science and Technology Institute's Nano2005 Conference and Trade Show, Anaheim, CA.. *"Super-paramagnetic Iron Oxide-Gold Core-Shell Nanoparticles for Biomedical Applications"*. May, 2005.

American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled *"Formulation Optimization for the Nanoparticles-In-Microsphere Hybrid Oral Delivery System Using Factorial Design"*. November, 2005.

American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled *"Formulation Development and In Vivo Biodistribution Studies of Poly(ethylene glycol)-Modified Thiolated Gelatin Nanoparticles"*. November, 2005.

American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled *"Novel Nanoemulsions for Improved Oral Delivery of Hydrophobic Drugs"*. November, 2005.

American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled *"Nanoemulsion Formulations for Improved CNS Drug Delivery"*. November, 2005.

American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN. Poster presentation entitled *"Application of Statistical Factorial Design for the Preparation of Poly(styrene-b-isobutylene-b-styrene) Triblock Copolymer Microspheres"*. November, 2005.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Intracellular Delivery of Saquinavir in Biodegradable Polymeric Nanoparticles for HIV/AIDS"* April, 2006.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Improved Oral Delivery of Saquinavir in Nanoemulsion Formulations for HIV/AIDS"*. April, 2006.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Development, Characterization and Transfection of the Plasmid DNA Encapsulated in Nanoparticles-in-Microsphere Formulations for Oral Delivery"*. April, 2006.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. Poster presentation entitled *"Tumor-Targeted Delivery of Hydrophobic Drugs in pH-Sensitive Poly(ethylene oxide)-Modified Poly(beta-amino ester) Nanoparticles"*. April, 2006.

Society for Biomaterials Annual Meeting, Pittsburgh, PA. Podium presentation entitled *"Modulation of Intracellular Ceramide Using Polymeric Nanoparticles to Overcome Multidrug Resistance in Tumor Cells"*. April, 2006.

Society for Biomaterials Annual Meeting, Pittsburgh, PA. Poster presentation entitled *"Development of the Nanoparticles-in-Microsphere Hybrid Formulations for Oral Delivery of Plasmid DNA"*. April, 2006.

Society for Biomaterials Annual Meeting, Pittsburgh, PA. Poster presentation entitled *"Novel Nanoemulsions for Improved Oral Delivery of Hydrophobic Drugs"*. April, 2006.

Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. Podium presentation entitled *"Modulation of Intracellular Ceramide Using Polymeric Nanoparticles to Overcome Multidrug Resistance in Tumor Cells"*. May, 2006.

Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. Poster presentation entitled *"Formulation Optimization for the Nanoparticles-in-Microsphere Hybrid Oral Delivery Systems Using Factorial Design"*. May, 2006.

Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. Poster presentation entitled *"Novel Nanoemulsions for Improved Oral Delivery of Poorly Soluble Drugs"*. May, 2006.

Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. Poster presentation entitled *"Characterization and In Vivo Biodistribution Studies with Poly(ethylene glycol)-Modified Thiolated Gelatin Nanoparticles"*. May, 2006.

Controlled Release Society Annual Meeting, Vienna, Austria. Poster presentation entitled *"Poly(Styrene-b-Isobutylene-b-Styrene) Triblock Copolymer Microspheres for Sustained Release Drug Delivery"*. July, 2006.

Society of Neuroscience 2006 Annual Meeting, Atlanta, GA. Poster presentation entitled *"Brain Delivery of Proteins by the Intranasal Route of Administration Using Cationic Liposomes"*. October, 2006

The First National Cancer Institute's Alliance in Nanotechnology Principal Investigator Meeting. San Diego, CA. Poster presentation entitled *"Multifunctional Nanosystems to Overcome Drug Resistance in Cancer"*. October, 2006.

The First National Cancer Institute's Alliance in Nanotechnology Principal Investigator Meeting. San Diego, CA. Poster presentation entitled *"Modulation of Multidrug Resistance in Cancer with Polymer Blend Nanoparticles"*. October, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled *"Tumor-Targeted Delivery of Hydrophobic Drugs in pH-Sensitive Poly(ethylene oxide)-Modified Poly(beta-amino ester) Nanoparticles"*. November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled *"Development and Characterization of Nanoemulsion Formulations Containing Multimodal Therapeutics for Brain Tumor"*. November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled *"Biodegradable Polymeric Nanoparticles for Intracellular Saquinavir Delivery in HIV/AIDS"*. November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled *"Oral Plasmid DNA Administration and Transfection Using Nanoparticles-in-Microsphere Formulations"*. November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled *"Modulation of Multidrug Resistance in Cancer with Polymer Blend Nanoparticles"*. November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled *"Tumor-Targeted sFlt-1 Gene Delivery Using Long-Circulating Thiolated Gelatin Nanoparticles"*. November, 2006.

American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX. Poster presentation entitled *"Improved Oral Delivery of Saquinavir in Nanoemulsion Formulations for HIV/AIDS"*. November, 2006.

Invited Presentations:

Massachusetts College of Pharmacy and Allied Health. Division of Pharmaceutical Sciences. Boston, Massachusetts. *"Formulation of Controlled Release Dosage Forms"*. May, 1996.

Advanced Magnetics, Inc., Cambridge, Massachusetts. *"Poly(ethylene glycol)-Modified Biomaterial Surfaces"*. January, 1998.

Innovative Imaging Systems, Inc., North Billerica, Massachusetts. *"Polymers for Controlled Drug Delivery Systems"*. August, 1998.

Kuwait University, Faculty of Pharmacy, Safat, Kuwait. *"Medical and Pharmaceutical Applications of Chitosan"*. February, 1999.

Tufts University, Department of Chemical Engineering and Bioengineering and Center for Biotechnology Engineering. Medford, Massachusetts. *"Chitosan-Based Biomaterials and Drug Delivery Systems"*. March, 2000.

Massachusetts Institute of Technology, Department of Chemical Engineering, Cambridge, Massachusetts. *"Polymeric Site-Specific Drug Delivery Systems"*. September, 2000.

Zycos, Inc., Lexington, Massachusetts. *"Cationic Interpenetrating Network Hydrogels for DNA Delivery"*. December, 2000.

Northeastern University, Department of Pharmaceutical Sciences, Boston, MA. *"Novel Biodegradable pH-Responsive Polymers for Intracellular Delivery"*. March, 2001.

Northeastern University, School of Pharmacy, Boston, MA. *"Polymeric Delivery Systems for Drugs and Genes"*. March, 2002.

Cambridge Scientific, Inc., Cambridge, MA. *"Polymeric Drug and Gene Delivery Systems"*. March, 2002.

Marine Polymer Technologies, Inc., Topsfield, MA. *"Chitosan-Based Biomaterials and Drug Delivery Systems"*. April, 2002.

Northeastern University, Biotechnology Academic Steering Committee, Boston, MA. *"Polymeric Biomaterials and Drug Delivery Systems"*. January, 2003.

Northeastern University, Department of Biology, Boston, MA. *"Polymeric Biomaterials and Delivery Systems"*. April, 2003.

Northeastern University, Technology Transfer and Biotechnology Symposium, Boston, MA. *"Polymeric Biomaterials and Drug Delivery Systems"*. April, 2003.

Catalyst Oncology, Inc., Providence, RI. *"Tumor-Targeted Polymeric Nanoparticle Delivery Systems"* December, 2003.

Archemix, Inc., Cambridge, MA. *"Nanotechnology for Drug Delivery"*. May, 2004.

Novartis Institute for Biomedical Research, Cambridge, MA. *"Polymeric Technologies for Delivery of Drugs and Genes"*. August, 2004.

University of Massachusetts at Lowell, Lowell, MA. *"Polymer-Based Technologies for Targeted Delivery of Drugs and Genes"*. February, 2005.

Spherics, Inc., Lincoln, RI. *"Polymeric Delivery Systems for Drugs and Genes"*. April, 2005.

Northeastern University, Department of 2005 Pharmaceutical Sciences Research Showcase, Boston, MA. *"Nanotechnology for Tumor-Targeted Delivery of Drugs and Genes"*. May, 2005.

Nano Science and Technology Institute's Nano2005 Conference and Trade Show, Anaheim, CA. *"Nanotechnology for Medical Diagnosis, Imaging, and Therapy – a Tutorial"*. May, 2005.

Nano Science and Technology Institute's Nano2005 Conference and Trade Show, Anaheim, CA. *"Tumor Targeted Nanocarriers for Drug and Gene Delivery"*. May, 2005.

Pfizer Central Research, Groton, CT. *"Polymeric Biomaterials and Targeted Delivery Systems"*. September, 2005.

Universidad Metropolitana (UMET), Department of Science and Technology, National Science Foundation Sponsored XIV Undergraduate Research Symposium. San Juan, PR. *"Nanotechnology for Medical Imaging and Therapy"*. September, 2005.

Strategic Research Institute, Inc., Cambridge, MA. Nanomedicine: Commercialization of Drug Discovery, Delivery, and Diagnostics Conference. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. October, 2005.

Nano Science and Technology Institute's Tutorial, Washington, DC *"Nanotechnology for Cancer Therapeutics – A Tutorial"* October, 2005.

National Institute of Standards and Technology, Gaithersburg, MD. *"Nanotechnology for Cancer Imaging and Therapy"* December, 2005.

Alkermes, Inc., Cambridge, MA. *"Multi-Functional Nanotechnology for Imaging and Therapy"*. April, 2006.

Nano Science and Technology Institute's Tutorial, Washington, DC *"Nanotechnology for Cancer Therapeutics – A Tutorial"* May, 2006.

Nano Science and Technology Institute's Nano2006 Conference and Trade Show, Boston, MA. *"Nanotechnology in Drug Delivery: An Overview"*. May, 2006.

2006 Cancer Nanotechnology Conference, Paris, France. *"Nanotechnology for Tumor-Targeted Drug and Gene Delivery"*. May, 2006.

Northeastern University, Department of 2006 Pharmaceutical Sciences Research Showcase, Boston, MA. *"Multi-functional Nanosystems for Drug Delivery and Imaging"*. May, 2006.

National Cancer Institute, Center for Cancer Research, Nanobiology "Think Tank" Meeting, Frederick, MD. *"Multi-functional Nanosystems to Overcome Drug Resistance in Cancer"*. June, 2006.

Microfluidics, Inc., Newton, MA. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. June, 2006.

Wyeth Pharmaceuticals, Inc., Andover, MA. *"Nanotechnology and the Promise of Molecular Medicine"*. July, 2006.

Emory University, School of Medicine, Department of Ophthamology, Atlanta, GA. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. July, 2006.

New Jersey Center for Biomaterials, Rutgers – the States University of New Jersey, Piscataway, NJ. *"Polymers for Tumor-Targeted Delivery and Modulation of Multidrug Resistance"*. August, 2006.

Accelrys Nanobiotechnology Seminar Series, Cambridge, MA. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. August, 2006.

Swiss House of Advanced Research and Education (SHARE), Consulate of Switzerland, Boston, MA. *"Nanotechnology for Medical Diagnosis and Treatment"*. September, 2006.

American Academy of Nanomedicine 2nd Annual Meeting, Washington, DC. *"Nanotechnology for Targeted Drug and Gene Delivery"*. September, 2006.

Epic Therapeutics, Inc., Norwoord, MA. *"Nanotechnology for Targeted Delivery of Drugs and Genes"*. September, 2006.

12th Samsung International Symposium on Molecular Medicine, Seoul, Korea. *"Multi-functional Nanosystems for Tumor-Targeted Drug and Gene Delivery"*. September, 2006.

Nanotechnology 2006 Conference, Rensselaer Polytechnic Institute, Troy, NY. *Multi-functional Nanosystems for Targeted Drug and Gene Delivery"*. September, 2006.

Missouri Nanotechnology Alliance – 3rd Annual Meeting, Columbia, MO. *"Multi-functional Nanosystems for Tumor-Targeted Drug and Gene Delivery"*. October, 2006.

Cambridge Healthtech Institute's Targeted Nanodelivery Conference, Baltimore, MD. *"Multi-functional Nanosystems to Overcome Drug Resistance in Cancer"*. October, 2006.

Oncogene Science – A Bayer Healthcare Company, Cambridge, MA *"Nanomedicine: Realizing the Potential for Early Cancer Diagnosis and Molecular Therapy"*. October, 2006.

Northeastern University, Department of Chemistry and Chemical Biology, Boston, MA. *"Multi-functional Nanosystems for Imaging and Drug Delivery"*. November, 2006.

New Jersey Center for Biomaterials – 2nd Annual , Rutger's - The State University of New Jersey, New Brunswick, NJ. *"Multi-functional Nanosystems for Drug and Gene Delivery"*. November, 2006.

American College of Veterinary Pathologists and American Society for Veterinary Clinical Pathology Annual Meeting, Tucson, AZ. *"Nanotechnology for Medical Imaging and Therapy"*. December, 2006.

National Institutes of Health, National Cancer Institute's, Drug Development and Therapeutics Committee, Bethesda, MD. *"Multifunctional Nanosystems to Overcome Drug Resistance in Cancer"*. January, 2007.

Millennium Pharmaceuticals, Inc., Cambridge, MA. *"Nanotechnology Applications in Translational Oncology"*. January, 2007.

Harvard-MIT Health Science and Technology Program, MIT, Cambridge, MA. *"Nanotechnology Applications in Cancer Therapy"*. February, 2007.

New Jersey Center for Biomaterials, Rutger's - The State University of New Jersey, New Brunswick, NJ. *"Polymer Libraries for Tumor-Targeted Delivery and Modulation of Multidrug Resistance"*. March, 2007.

Strategic Research Institute's 2nd Annual Nanomedicine Conference, Washington, DC. *"Nanotechnology for Tumor-Targeted Delivery of Drugs and Genes"*. March, 2007.

Materials Research Society, 2007 Spring Meeting, San Francisco, CA. *"Pre-Clinical In Vivo Efficacy and Safety Studies – a Tutorial"*. April, 2007.

Materials Research Society, 2007 Spring Meeting, San Francisco, CA. *"Multifunctional Nanosystems for Targeted Drug and Gene Delivery"*. April, 2007.

American Association of Pharmaceutical Scientists, Northeast Regional Discussion Group Annual Meeting, Rocky Hill, CT. *"Micro- and Nanotechnology for Oral Drug and Gene Delivery"*. April, 2007.

Genzyme Pharmaceuticals, Inc. – Drug and Biomaterials R&D, Waltham, MA. *"Nanotechnology Applications in Translational Oncology"*. April, 2007.

Vertex Pharmaceuticals, Inc., Cambridge, MA. *"Nanotechnology Applications in Translational Oncology"*. April, 2007.

Dartmouth College, Thayer School of Engineering, Hanover, NH. *"Cancer Nanomedicine: Potential for Targeted Delivery and Molecular Medicine"*. May, 2007.

2007 Association for Research in Vision and Ophthalmology Annual Meeting, Fort Lauderdale, FL. *"Nanotechnology in Advanced Drug Delivery: An Overview"*. May, 2007.

2007 Biotechnology Industry Organization Annual Conference, Cancer Nanotechnology for Early Diagnosis and Therapy Symposium, Boston, MA. *"Multifunctional Nanosystems for Tumor-Targeted Drug and Gene Delivery"*. May, 2007.

PROFESSIONAL CONSULTANCY

GelTex Pharmaceuticals, Inc. (now Genzyme, Inc.)., Waltham, MA. A medium sized pharmaceutical company that is marketing non-absorbable polymeric materials as therapeutic agents. I have consulted on pharmaceutical product development with GelTex's polymeric materials from May 1997 to June 2000.

FzioMed, Inc., San Luis Obispo, CA. A start-up medical device company intending to market polymeric materials to prevent post-surgical adhesions and thrombus formation. I have consulted on improving blood compatibility of the polymeric materials developed by FzioMed from October 1996 to April 1999.

EOS Pharmaceutical Corporation, Natick, MA. A start-up contract formulation company with domestic and international clients. I have consulted EOS Pharmaceuticals on novel bioadhesive polymeric materials for drug delivery from June 1997 to September 2001.

Biopolymer Technologies International, Inc., Westborough, MA. A start-up biotechnology company specializing in the development of polymer-based therapeutics and nutraceuticals. I have been a consultant for Biopolymer Technologies International from December 1997 to July 1999.

Braintree Laboratories, Inc., Braintree, MA. A medium sized pharmaceutical company developing various products, including phosphate binders, poly(ethylene glycol)-based laxatives, and gastric lavage agents. I have consulted for Braintree Laboratories from September 1999 to June 2003.

Catalyst Oncology, Inc., Providence, RI. A biotechnology start-up company, supported by the Slater Foundation, to develop novel target-specific anticancer drugs. I have been consulting Catalyst Oncology on anticancer drug delivery issues from December 2003 to December 2004.

Cytogel, Inc., Stonington, CT. Cytogel is a small pharmaceutical company focusing on hydrogel drug delivery technologies. I have been consulting Cytogel on their hydrogel delivery platforms from September, 2004 to April 2005.

Marine Polymer Technologies, Inc., Burlington, MA. A medium sized biotechnology/medical device company developing poly(acetyl-D-glucosamine)-based products. I have been consulting Marine Polymer on drug formulation and delivery technologies from September 2002 to March 2006.

LifeScan, Inc., Milpitas, CA. LifeScan is a Johnson and Johnson subsidiary developing diagnostic systems for diabetes. I have been consulting LifeScan on their diabetes monitories technologies from August, 2005 to May 2006.

Boston Scientific Corporation, Malborough, MA. A large-cap medical device company that manufacturers drug-coated stents, catheters, and embolic microspheres. I have been consulting Boston Scientific on drug delivery technologies from October, 2003 to September, 2006.

Novavax, Inc., Columbia, MD. A medium-sized pharmaceutical company that focuses on women's healthcare market. I have been consulting Novavax on their micellar nanoparticle and other delivery platforms from February, 2004 to present.

The Round Table Group (RTG), Washington, DC. RTG provides expert witness, intellectual consulting, and professional presentation services to many diverse groups of clients. I serve as a consultant in the area of pharmaceutical product development and biomaterial science and applications since February, 2004 to present.

Grayhead Associates, Wellesley, MA. Grayhead Associates is an international management consulting firm that assists its clients to capitalize on their technological resources and entrepreneurial spirit. I have been consulting Greyhead Associates on biomedical nanotechnology and drug development technologies from October, 2005 to present.

Zydus Research Centre, Ahmedabad, India. Zydus is a medium-sized pharmaceutical company in India developing many different drug formulations for local and international market. I have been providing intellectual consulting on development of novel drug delivery systems from November 2005 to present.

BioCure, Inc., Norcross, GA. BioCure is a medium-sized biomedical device company developing polymer nanotechnology for imaging and drug delivery applications. I have been consulting BioCure on their nanotechnology research portfolio from August 2006 to present.

Morrison and Foerster, LLP, San Jose, CA. Morroson and Foerster is a large law firm that provides professional litigation services in patent infringement lawsuits. I serve as an expert witness on pharmaceutical, medical device, and nanomedicine related patent infringement lawsuits. I have been consulting Morrison and Foester from May, 2007 to present.

TEACHING EXPERIENCES

Courses Previously Taught (1993 – 2003)

Pharm.D. Program:

Pharmaceutical Calculations (PCT 1240, 4 QH): Basic prescription interpretation and calculations for second year pharmacy students.

Dosage Forms (PMD 1323, 4 QH): Theoretical course on pharmaceutical product development, characterization, and quality control issues taught to the third year pharmacy students.

Dosage Forms Laboratory (PCT 1300, 2 QH): A complementary laboratory course for Dosage Forms on prescription compounding skills.

Physical Pharmacy (PMD 1400, 4 QH): Theoretical course on the physicochemical properties of the drug product and their influence on development of pharmaceutical formulations and delivery.

Physical Pharmacy Laboratory (PCT 1320, 2 QH): A complementary laboratory course to Physical Pharmacy on analytical and experimental methods for testing of pharmaceutical products for quality control.

Biopharmaceutics and Pharmacokinetics (PMD 1410, 4 QH): Introduction to biopharmaceutics and pharmacokinetic principles, application of compartmental and non-compartmental modeling for analysis of data, and interpretation of pharmacokinetic data in clinical pharmacy practice.

Graduate Program:

Advanced Physical Pharmacy (PCT 3200, 2 QH): A graduate level physical pharmacy course that with emphasis on physicochemical characterization of drug products.

Advanced Drug Delivery Systems (PCT 3300, 3 QH): A graduate level course on formulation and evaluation of advanced drug delivery systems including polymeric systems, liposomes, micelles, protein and peptide delivery, and DNA delivery systems.

Courses Currently Teaching (2003 – Present)

Doctor of Pharmacy Program:

Pharmaceutics II (PSC U412, 4 SH): Theoretical course on the physicochemical properties of the drug product and their influence on development of pharmaceutical formulations and delivery offered under the semester calendar (for 16 weeks). I coordinate and teach 100% of this course to 4th year students. Approximate class size is about 130-150 students each year.

Directed Study (PSC U921, 4 SH): An elective course for professional pharmacy students interested in performing research under a faculty advisor.

Graduate Program in Pharmaceutical Sciences:

Drug Design, Evaluation, and Development (PSC G210, 2 SH): A graduate level comprehensive course on drug discovery, development, and evaluation from an industrial perspective. I coordinate and teach about 60% of the course to approximately 30-40 MS and PhD students in the Fall semester each year.

Pharmaceutical Science Internship (PSC G401, 1 SH): Coordinator of industrial internship opportunities for graduate students in Pharmaceutical Science. Each year in the Summer, I assist 3-5 MS and PhD students in securing an internship position and evaluating their progress.

Interdisciplinary Graduate Programs:

Introduction to Biotechnology (INT G120, 2 SH): An interdisciplinary graduate course offered to students in the Professional MS program in Biotechnology in the Fall semester each year. I provide 10% effort to this course.

Introduction to Nanomedicine Science and Technology (INT G270, 2 SH): An interdisciplinary graduate course offered under the Nanomedicine Science and Technology IGERT program in the Fall semester of each year. I provide 20% effort to this course.

Nanosystems Design for Biomedical Applications (INT G370, 2 SH): An interdisciplinary graduate course offered under the Nanomedicine Science and Technology IGERT program in the Spring semester of each year. I provide 20% effort to this course.

Topics in Nanomedicine (INT G371, 2 SH): An interdisciplinary graduate course offered under the Nanomedicine Science and Technology IGERT program in the Fall semester of each year. I coordinate this course and provide 60% of the lectures.

TEACHING-RELATED ACCOMPLISHMENTS

Interdisciplinary Doctoral Program in Nanomedicine: With support from the National Science Foundation and the National Cancer Institute Interdisciplinary Graduate Education, Research and Training (IGERT) program, I am involved in the development and implementation of the Nanomedicine Science and Technology doctoral program. The program will admit interdisciplinary fellows who will take didactic courses, participate in internship opportunity, and carry out dissertation project in nanomedicine-related project. The program started in Fall, 2005.

Multi-Track Professional Masters Degree Program in Biotechnology. With the support of the Alfred P. Sloan Foundation, I have worked with faculty members from the Biology and Chemical Engineering Departments at Northeastern University to develop and implement an interdisciplinary Professional MS degree program in Biotechnology with tracks in Molecular Biotechnology, Pharmaceutical Biotechnology, and Engineering Biotechnology. The program started in the Fall of 2003.

Physical Pharmacy Textbook: In collaboration with Professor Beverly Sandmann of Butler University, I have authored *"Applied Physical Pharmacy"* textbook specifically geared to pharmacy students and practitioners. The book contains physical chemical concepts in drug product design with examples that are relevant to practice. The textbook was published in November 2002.

Problem-Based Undergraduate Pharmaceutics Textbook. In collaboration with other pharmaceutics faculty members across the U.S. and Canada, I have authored cases for a textbook entitled "*Cases in Pharmaceutics for Problem-Based Learning and Problem Solving*" edited by Wendy C. Duncan-Hewitt and David L. Mount of the University of Toronto, Canada.

Pharmaceutics Laboratory Exercises Database and CD-ROM: I have contributed eight pharmaceutics laboratory exercises to the database and CD-ROM initative of David L. Mount and others.

Pharmaceutics Instructional Materials on World-Wide Web. With funding from the Dean's "Excellence in Teaching" initiative, I have developed pharmaceutics instructional materials on the Internet. These pages can be accessed through the World-Wide Web at "http://www.pharmsci.neu.edu/Courses/courses.html".

Computer-Aided Pharmaceutics Instruction. I am involved in various aspects of promoting and developing computer aids and tutorial programs for undergraduate pharmaceutics courses. In addition, I strongly advocate the use of pharmacy resources that are available on the Internet.

NABPLEX Review: In the Spring quarter of every year, I provide an extensive review of Calculations, Physical Pharmacy, and Dosage Forms to the senior students who are planning to take the National Board of Pharmacy Licensing Examination (NABPLEX). In addition, I also provide a review of compounding skills to those students taking their NABPLEX exam in states that have a wet-lab section (e.g., New York, Maryland, Wisconsin, etc.).

RESEARCH ADVISING

Research Scientists/Post-Doctoral Associates:

Curtis F. Crasto, PhD	Post-Doctoral Associate	July, 2002 – May, 2004, under the Nanomedicine Consortium
Dinesh B. Shenoy, PhD	Research Associate	June, 2003 – Dec, 2005
Sandipkumar Tiwari, PhD	Post-Doctoral Associate	August, 2004 – June, 2006
Tushar K. Vyas, PhD	Post-Doctoral Associate	Dec, 2005 – Dec, 2006
Dattatri Nagesha, PhD	Post-Doctoral Associate	July, 2004 – Present, under the Nanomedicine Consortium
Harikrishna Devalapally, PhD	Post-Doctoral Associate	November, 2005 – Present
Aliasghar Shahiwala, PhD	Post-Doctoral Associate	August, 2006 - Present

Master's Students:

Mr. Vijaykumar R. Patel — M.S. in Biomedical Sciences – Pharmaceutics Specialization (Graduated, September 1995).

Thesis Title: *Chitosan-Poly(Ethylene Oxide) Semi-Interpenetrating Polymer Network as a pH-Sensitive Drug Delivery System.*

Ms. Amira Ahmed — M.S. in Biomedical Sciences – Pharmaceutics Specialization (Graduated, September 1997).

Report Title: *Novel Drug Delivery Systems for the Treatment of H. pylori Infection.*

Ms. Sweta Shah — M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, September 1999).

Report Title: *Stomach-Specific Antibiotic Therapy for H. pylori Infection.*

Ms. Sarah Nsereko — M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, June 2001).

Thesis Title: *Chitin Microparticles for Localized Delivery of Paclitaxel: In Vitro and In Vivo Studies.*

Mr. Jugminder S. Chawla — M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, April 2002).

Thesis Title: *Poly(Epsilon-Caprolactone) Nanoparticles for Tumor-Targeted Delivery of Tamoxifen: In Vitro Studies.*

Mr. Ehab Taqieddin — M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, April 2002).

Thesis Title: *Enzymes Immobilization in Perm-selective Chitosan-Alginate Hybrid Microcapsules.*

Ms. Anupama Potineni — M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, April 2002).

Report Title: *Poly(Ethylene Oxide)-Modified Poly(Beta-Amino Ester) Nanoparticles: Long-Circulating pH Sensitive Biodegradable System for Paclitaxel Delivery.*

Mr. Srinivasan Namala — M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, June 2003).

Report Title: *Iontophoresis: A Tool to Enhance Transdermal Drug Delivery*

Ms. Pallavi Devurkar M.S. in Biomedical Sciences – Pharmaceutics Specialization
(Graduated, June 2003).

Report Title: *In Vitro Evaluation of Chitosan Microspheres for Stomach-Specific Drug Delivery*

Ms. Lilian van Vlerken — M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, April 2005; matriculated into the PhD program)

Report Title: *Combination Therapy of Ceramide and Paclitaxel Delivered in Poly(Ethylene Oxide)-Modified Poly(Epsilon-Caprolactone) Nanoparticles as a Potential Strategy for Overcoming Tumor Multidrug Resistance*

Mr. Gurinder S. Saini M.S. in Interdisciplinary Studies – Materials Science Specialization
(Co-Advisor, under the Nanomedicine Consortium)
(Graduated, January 2006)

Thesis Title: *Preparation and Characterization of Superparamagnetic Iron Oxide-Gold Core-Shell Nanoparticles for Biomedical Applications*

Ms. Lipa Shah — M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, December 2006)

Thesis Title: *Biodegradable Polymeric Nanoparticles for Intracellular Saquinavir Delivery in HIV/AIDS*

Ms. Ankita Desai — M.S. in Biotechnology – Pharmaceutical Science Track
(Graduated, December 2006)

Report Title: *Multi-functional Nanoemulsion Formulations for Brain Tumor Therapy*

Ms. Jasneet Oberai — M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization
(Graduated, May 2007)

Report Title: *Novel Nanoemulsions with Temperature-Responsive Drug Delivery*

Ms. Sunita Yadav — M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

Thesis Title: *Multifunctional Nanotherapeutic Strategy for MDR-1 Gene Silencing and Chemotherapy Administration to Overcome Multidrug Resistance in Cancer*

Ms. Dipti Deshpande — M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

Thesis Title: *Biodegradable Nanoparticle System for Intracellular Administration of Paclitaxel and Ceramide in Coronary Restenosis*

Ms. Shraddha Babaria — M.S. in Biotechnology – Pharmaceutical Science Track

Report Title: *Nanosystems for Intranasal Gene Delivery to the Brain*

Mr. Shardool Jain — M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

Thesis Title: *Oral Gene Delivery Using Crosslinked Alginate Microparticles*

Ms. Sindhura Ganga — M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

Thesis Title: *Nanoemulsion System for Combination Curcumin and Paclitaxel Delivery in Human Glioblastoma Cells*

Ms. Sunaina Pai — M.S. in Pharmaceutical Sciences – Pharmaceutics Specialization

Thesis Title: *Multifunctional Nanosystems for Survivin Gene Silencing and Apoptosis in Pancreatic Cancer*

Doctoral Students:

Mr. Radi Hejazi — Ph.D. in Pharmaceutics
(Graduated, May 2003)

Thesis Title: *Stomach-Specific Delivery of Tetracycline-Chitosan Microspheres for the Treatment of Helicobacter pylori Infection.*

Ms. Goldie Kaul — Ph.D. in Pharmaceutics

(Graduated, August 2004)

Thesis Title: *Long-Circulating Poly(Ethylene Glycol)-Modified Gelatin Nanoparticles for Tumor-Targeted Gene Delivery.*

Ms. Sushma Kommareddy — Ph.D. in Pharmaceutics
(Graduated, May 2006)

Thesis Title: *Gelatin-Based Nanoparticulate Vectors for Tumor-Targeted Therapeutic Gene Delivery*

Mr. Mayank Bhavsar — Ph.D. in Pharmaceutics

Thesis Title: *Oral Gene Therapy for Inflammatory Bowel Disease Using Nanoparticles-in-Microsphere Hybrid Delivery System*

Ms. Lilian van Vlerken — Ph.D. in Pharmaceutics/Nanomedicine

Thesis Title: *Multi-functional Polymeric Nanoparticles for Tumor-Targeted Delivery and Modulation of Drug Resistance*

Mr. Luis Brito — Ph.D. in Pharmaceutics/Nanomedicine

Thesis Title: *Targeted eNOS Gene Delivery Using Gelatin-Based Nanovectors for Coronary Restenosis*

Ms. Padmaja Magadala — Ph.D. in Pharmaceutics/Nanomedicine

Thesis Title: *HER2/neu Receptor-Targeted Gelatin-Based Nanovectors for Pancreatic Cancer Gene Therapy*

Membership in Graduate Student's Thesis Advisory Committees:

Mr. Mukur Gupta	M.S. in Industrial Pharmacy, Massachusetts College of Pharmacy and Health Sciences (Graduated, June 2001). Ph.D. in Industrial Pharmacy, Massachusetts College of Pharmacy and Health Sciences (Graduated, February, 2004)
Mr. Anurag Singhal	M.S. in Pharmaceutics (Graduated, June 2002)
Ms. Prachi Parulkar	M.S. in Pharmaceutics (Graduated, August 2004)
Mr. Jayesh Vora	Ph.D. in Pharmaceutics (Graduated, June 1994)
Ms. Kamelia Behnia	Ph.D. in Pharmaceutics (Graduated, September 1996)
Mr. Daniel J. Magiera, III	Ph.D. in Biomedical Sciences (Graduated, June 1997)
Ms. Sandhya Ramanathan	Ph.D. in Pharmaceutics (Graduated, September 1997)
Ms. Imran Vural	Ph.D. in Biomedical Sciences (Graduated, June 1998)
Ms. Sujata Vaidyanathan	Ph.D. in Pharmaceutics (Graduated, September 1998)
Mr. Ramin Darvari	Ph.D. in Pharmaceutics (Graduated, December 2001)
Mr. Ram Rammohan	Ph.D. in Biomedical Sciences (Graduated, June 2002)
Mr. Jose DaSilva	Ph.D. in Biomedical Sciences (Graduated, June 2002)
Mr. Srinivas Chakilam	Ph.D. in Pharmaceutics (Graduated, December 2004)
Ms. D. Ece Gamsiz	Ph.D. in Chemical Engineering

Ms. Suman Dandamudi	Ph.D. in Pharmaceutics
Mr. Sarathi Vijay Bodapatti	Ph.D. in Pharmaceutics
Ms. Paula Lampton	Ph.D. in Biology/Nanomedicine
Ms. Heather Brodkin	Ph.D. in Chemistry/Nanomedicine
Ms. Mattia Migliore	Ph.D. in Pharmacology/Nanomedicine

Research Advising to Pharmacy Honors Students:

Mr. Man-Hon (Johny) Lam (B.S., Class of 1994)
Mr. Joseph M. Goreham (B.S., Class of 1995)
Mr. Peter B. Ng (B.S., Class of 1995)
Ms. Rakhee H. Tailor (B.S., Class of 1995)
Ms. Mai-Ki Ly (B.S., Class of 1995)
Mr. Ketankumar Patel (B.S., Class of 1996)
Ms. Susanne Verrico (B.S., Class of 1996)
Ms. Laurie Galvin (B.S., Class of 1996)
Ms. Fiona Duncan (B.S., Class of 1997)
Ms. Ekata V. Shah (Pharm.D., Class of 1997)
- Recipient of Dean's Undergraduate Research Achievement Award, April 1995

Ms. Rina Qaqish (Pharm.D., Class of 1997)
Ms. Gity Roostai-Mills (B.S., Class of 1998)
Ms. Roula Qaqish (Pharm.D., Class of 1998)
- Recipient of Dean's Undergraduate Research Achievement Award, April 1996
- Currently Assistant Professor of Clinical Pharmacy, St. Louis College of Pharmacy, St. Louis, MO

Ms. Phung-Kim Lai (B.S., Class of 1999)
- Recipient of Dean's Undergraduate Research Achievement Award, April 1996
- Recipient of the PhRMA Foundation's Undergraduate Research Fellowship, January 1999

Ms. Tragiang Nguyen (B.S., Class of 1999)
Ms. Trinh Tran (B.S., Class of 1999)
Ms. Bich-Thuy Tran (B.S., Class of 1999)
Mr. Chad McQueen (Pharm.D., Class of 2000)
- Recipient of Dean's Undergraduate Research Achievement Award, April 1999

Ms. Angela L. Silvia (Pharm.D., Class of 2000)
- Recipient of Dean's Undergraduate Research Achievement Award, April 1999

Mr. Kristian Jackson (B.S., Class of 2000)
- Recipient of the University of Connecticut Research Fellowship, June 1998

Mr. Pulin Patel (B.S., Class of 2000)
- Pursued graduate studies in Pharmaceutical Chemistry at the Univ. of Kansas, Lawrence, KS

Mr. Derick Anderson (Pharm.D., Class of 2001)
- Recipient of Dean's Undergraduate Research Achievement Award, April 2000

Ms. Kwai-Dzy Mak (Pharm.D., Class of 2001)

Mr. Chi-Sing Nip (Pharm.D., Class of 2001)
- Recipient of the AAPS-AFPE "Gateway" Research Scholarship, June 2000

Ms. Erica J. Waugh (Pharm.D., Class of 2002)

- Recipient of the PhRMA Foundation's Undergraduate Research Fellowship, January 2001
- Recipient of Dean's Undergraduate Research Achievement Award, April 2002

Ms. Nikita Mody (Pharm.D., Class of 2004)
- Recipient of Northeastern University's Undergraduate Research Award, January 2002
- Recipient of Dean's Undergraduate Research Achievement Award, April 2003

Ms. Stephanie Whalen (Pharm.D., Class of 2006)
- Recipient of the AFPE "Gateway" Research Scholarship, June 2004
- Recipient of Northeastern University's Undergraduate Research Award, November 2004

Ms. Sarah Rogers (Pharm.D., Class of 2008)
- Recipient of Northeastern University's Undergraduate Research Award, November 2004

Mr. Zeu Hong Tzeng (Pharm.D., Class of 2007)
- Recipient of the AFPE "Gateway" Research Scholarship, July 2005
- Recipient of Northeastern University's Undergraduate Research Award, January 2007

Ms. Michelle Drown (Pharm.D., Class of 2009)
- Recipient of Northeastern University's Undergraduate Research Award, August 2005

Ms. Erin Curran (Pharm.D., Class of 2007)
Ms. Christina Guerra (Pharm.D., Class of 2010)

High School Summer Research Interns:

Ms. Phung-Kim Lai (Summer, 1994)
Ms. Luoisy Raymond (Summer, 1995)
Mr. Bao-Tuan Nguyen (Summer, 1995)
Mr. Kong-Jie Kah (Summer, 1997)
- Through Research Science Institute, Center for Excellence in Education, McLean, VA

Mr. Jeremy L. England (Summer, 1998)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in 1999 Intel High School Talent Search Competition

Ms. Iris Wei (Summer, 1999)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in the 2000 Intel High School Talent Search Competition

Mr. Brad M. Rosen (Summer, 2000)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in the 2001 Intel High School Talent Search Competition

Ms. Natalie Karabel (Summer, 2001)
- Research Science Institute, Center for Excellence in Education, McLean, VA

Ms. Feng Tu (Summer, 2002)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in the 2002 Siemens-Westinghouse High School Talent Search Competition

Ms. Maria Elena DeObaldia (Summer, 2003)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Winner of 2004 USA TODAY's All-USA High School Academic First Team

Ms. Joline Fan (Summer, 2004)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Finalist in the 2004 Siemens-Westinghouse High School Talent Search Competition

Mr. Harold Au (Summer, 2004)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Gold Award Winner at the 2005 Singapore Science and Engineering Fair.
- Award Winner at the 2005 Shanghai Science Expo, Shanghai, China.

Ms. Yi-Meng (Sally) Tan (Summer, 2005)
- Research Science Institute, Center for Excellence in Education, McLean, VA
- Semi-Finalist in the 2005 Siemens-Westinghouse High School Talent Search Competition

Ms. Thilini Ariyawansa (Summer, 2006)
- Research Science Institute, Center for Excellence in Education, McLean, VA

Ms. Elizabeth Lawler (Summer, 2006)
- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

Ms. Lili Ge (Summer, 2006)
- Young Scholars Program, Center for STEM Education, Northeastern University, Boston, MA

SERVICE

Professional:

- Membership in Professional and Scientific Societies:
  - American Association of Colleges of Pharmacy (1993-Present).
    Member of the Council of Faculties.
    Member of the Laboratory Instructors Discussion Group.
    Member of the Electronic-Aided Instructional Delivery Discussion Group.
  - American Association of Pharmaceutical Scientists (1987-Present).
    Member of the Polymers in Drug Delivery Special Interest Group.
  - Controlled Release Society (1993-Present).
    Member of Polymeric Biomaterial Discussion Group.
  - Society for Biomaterials (1989-Present).
    Member of the Task Force on the Impact of Biomaterials on Graduate Education.
    Member of the Polymeric Materials Special Interest Group.
  - Surfaces in Biomaterials Foundation (1995-Present).
- Grant Reviewer:
  - National Institutes of Health
    National Heart, Lung, and Blood Diseases Institute (NHLBI) 2004 Program of Excellence in Nanotechnology – Special Emphasis Panel [ZHL1-CSR-K (F1)(R)].
    Center for Scientific Review (CSR) November 2004 Gene and Drug Delivery (GDD) Study Section – SBIR/STTR Programs Special Emphasis Panel [ZRG1-BST-Z (10)].
    National Institute of Allergy and Infectious Diseases (NIAID) 2005 Challenge Grants: Biodefense Product Development – Special Emphasis Panel [ZA11-TS-M (M5)(R)].
    Center for Scientific Review (CSR) July 2005 Gene and Drug Delivery (GDD) Study Section Meeting – Temporary Member.
    National Heart, Lung, and Blood Diseases Institute (NHLBI) October 2005 – Special Review Committee for P01 Program Proposals.
    Center for Scientific Review (CSR), November 2005 Gene and Drug Delivery (GDD) Study Section – SBIR/STTR Programs Special Emphasis Panel [ZRG1 BST-Z 10(B)].
    National Cancer Institute (NCI), March 2006 - Ruth L. Kirschstein NRSA Fellowships (F32/F33) in Cancer Nanotechnology Research (RFA-CA-06-010) Special Emphasis Panel [ZCA1 RTRB-Z(M1)(R)].

Center for Scientific Review (CSR), April, 2006 Gene and Drug Delivery (GDD) Study Section – SBIR/STTR Programs Special Emphasis Panel [ZRG1 BST-Z (10) (B)].
National Heart, Lung, and Blood Diseases Institute (NHLBI) May, 2006 – Special Review Committee for P01 Program Proposals.
Center for Scientific Review, June, 2006 – Special Emphasis Panel on Proposals in Response to RFA "Biology of RNA Interference" [2006/10 ZRG1 BST-Z (52) (R)].
Center for Scientific Review, March, 2007 – Special Emphasis Panel on Proposals in Response to RFA "Small Business: Orthopedics" [ZRG1 MOSS (10)].

- United States Department of Agriculture.
  Investigator initiated proposals.
  SBIR/STTR proposals.
- United States Army Medical Research and Material Command
- American Chemical Society.
  Petroleum Research Funds
- Georgia Cancer Coalition Grant Program
- University of Missouri Intramural Grant Program
- University of Kansas Intramural Grant Program
- Medical Research Council of United Kingdom
- Singapore Science and Engineering Research Council (SERC) – an Agency of Science, Technology and Research Singapore (A*STAR).

- Membership in Journal Editorial Board:

  - Expert Opinion on Drug Delivery
  - Recent Patents on Drug Delivery and Formulations
  - The Open Drug Delivery Journal
  - Drug Design, Development and Therapy
  - Journal of Nano Education

- Reviewer for Scientific Journals (partial listing):

  - Biomacromolecules
  - Biomaterials
  - Cancer Chemotherapy and Pharmacology
  - European Polymer Journal
  - European Journal of Pharmaceutics and Biopharmaceutics
  - European Journal of Pharmaceutical Sciences
  - Gene Therapy
  - International Journal of Cancer
  - International Journal of Pharmaceutics
  - International Journal of Pharmaceutical Compounding
  - Journal of the American Chemical Society
  - Journal of Biomaterial Science, Polymer Edition
  - Journal of Controlled Release

- Journal of Liposome Research
- Journal of Pharmacy and Pharmacology
- Journal of Pharmaceutical Sciences
- Life Sciences
- Pharmaceutical Research
- Polymer International
- Science
- STP Pharma Sciences

- Participation in Short Courses (1990 - Present):

  - Scanning Probe Microscopy Seminar and Workshop. Woburn, MA.
  - Particle Technology Seminar and Workshop. Natick, MA.
  - Application of HTML for Developing Instructional Materials. Boston, MA.
  - Absolute Macromolecular Characterization with Light Scattering. Boston, MA.
  - Scientific and Engineering Applications of Macintosh® Computers. Boston, MA.
  - Surface Characterization of Biomedical Materials. Phoenix, AZ.
  - Hydrogels in Medicine and Pharmacy. Indianapolis, IN.

- American Association of Pharmaceutical Scientists (AAPS), Northeast Regional Discussion Group Planning Committee Member (2001-2005).

- Organizer of the National Cancer Institute/Nano Science and Technology Institute Special Symposium on *"Nanotechnology for Cancer Prevention, Diagnosis, and Treatment"* (2005-Present).

- Scientific Committee Member and Session Chair of the *"Cancer Nanotech Conference: Detecting and Treating Cancer*". Paris, France. (2006-Present).

- Registered Pharmacist in Massachusetts since 1988 (license #: 20415).

University:

- Faculty Delegate to the United States Pharmacopeia (USP) Convention (2003-Present).

- Faculty Advisor - Beta Tau Chapter, Rho Chi Pharmaceutical Honor Society (1993-1999).

- Webmaster - Department of Pharmaceutical Sciences Web Site (1995-2000).

- Coordinator of the American Association of Pharmaceutical Scientists, Visiting Scientist Program (1993-1999).

- Participation in Pharmacy Continuing Education Programs.
  - *Helicobacter pylori* and Peptic Ulcer Disease
  - Advanced Drug Delivery Systems: A Primer for Pharmacists
  - Nano-Medicines: Realizing the Potential of Targeted and Molecular Therapies in Cancer

- Participation in Pharmacy Open Houses and Student Orientations.

- Participation in Pharmacy Alumni Activities.

- Pharmacy Student's Academic Advising/Portfolio Reviewer.

- Committee Assignments:

University:

- Senate Library Advisory Committee (2001-Present).
- University Patent Committee (2002-Present).
- Biotechnology Academic Steering Committee (2002-Present).
- Academic Computing Advisory Committee (2004-Present).
- Education Technology Faculty Advisory Committee (2004-Present)
- Senate Committee for Evaluation of Dean of Nursing (2004-2006).
- Senate Committee for Evaluation of Dean of Libraries (2003-2004).
- Executive Committee of the Molecular Biotechnology Initiative (2002-2004).
- Senate Committee for Department of Pharm. Practice Chair Search (2001-2002).
- Senate Committee for Department of Pharm. Sciences Chair Search (1996-1997).
- University Instructional Technology Task Force (2000-2001).

Bouvé College:

- Bouve Administrative Committee (2005 – Present)
- George D. Behrakis Endowed Professor Search Committee (2002-2004).
- College Technology Committee (1998-2000).
- College Diversity Committee, (1994-1995).
- College Computer Advisory Committee, (1995-1998).
- Graduate Education and Research Task Force (1998-1999).
- Graduate Committee for Biomedical Sciences Program (1998-2000).

School of Pharmacy:

- Pharmacy Steering Committee (2001-2004, 2005-Present).
- Pharmacy Transfer Students Admission Committee, (1994-2001, 2003-Present).
- Graduate Committee of the School of Pharmacy (2002-2006).
- Pharmacy Curriculum Committee (1998-2002).
- Pharmacy Re-Accreditation/Self-Study Committee, (1995-1996).
- Pharmacy Honors and Awards Committee, (1994-2001).
- Pharmacy Progression Requirements Committee, (1996-2000).
- Pharmacy Laboratory Renovation Committee (1997-1999).
- Doctor of Pharmacy Tracking Admission Committee (1998-2000).
- Doctor of Pharmacy Curriculum Working Group (1996-1999)*.

Departmental of Pharmaceutical Sciences:

- BS in Pharm. Biotech. Program Evaluation Committee (2001-2003).

- Merit Review Committee, (1994-1996, 1997-2000, 2002-2003).
- Dept. Faculty Search Committees, (1994-1996, 1998-1999, 2002-2003*).
- Pharmaceutical Sciences Workload Policy Committee (2005 – Present*)

* Chair.

Community:

- Provide Math and Science Tutoring to High School Students.
- Discuss Pharmacy as a Career Choice to High School Students and Parents.
- Counseling Drug Therapy to Neighbors and Friends in the Community.

HONORS AND AWARDS

- NSTI Fellow Award for Outstanding Contributions towards the Advancement in Nanotechnology, Microtechnology, and Biotechnology, 2006.
- Cited in Academic Pharmaceutical Scientists Who's Who, 2004.
- Eurand Award for Outstanding Research in Oral Drug Delivery, Third Prize, 2003.
- Special Faculty Recognition Award from Doctor of Pharmacy Students, Class of 1999.
- Recipient of Rho Chi Advisor Appreciation Award, 1997, 1998, & 1999.
- Recipient of Dean's Excellence in Teaching Award, 1996.
- Cited in Who's Who in Science and Engineering, 1996
- Member of Sigma Xi - The Scientific Research Society, 1996
- Member of Rho Chi - Pharmaceutical Honor Society, 1987.
- Recipient of Dean's Undergraduate Research Achievement Award, 1987.
- Recipient of Burroughs Wellcome Academic Scholarship, 1987.
- Recipient of Dean Leroy Keagle Memorial Scholarship, 1986.

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REDACTED IN THEIR ENTIRETY

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ELAN PHARMA INTERNATIONAL LIMITED,	:	Civil Action
Plaintiff,	:	
v.	:	
ABRAXIS BIOSCIENCE INC.,	:	
Defendant.	:	No. 06-438-GMS

- - -

Wilmington, Delaware
Monday, June 2, 2008
9:30 a.m.
FIRST DAY OF TRIAL

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge,
and a Jury

APPEARANCES:

JOHN G. DAY, ESQ.
Ashby & Geddes
-and-
STEPHEN SCHEVE, ESQ.,
LINDA M. GLOVER, ESQ., and
JEFFREY SULLIVAN, ESQ.
Baker Botts LLP
(Houston, TX)
-and-
GREGORY BOKAR, ESQ.
Counsel - Elan Drug Delivery

Counsel for Plaintiff

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THE COURT: Fair enough. Mr. Jacobs, let me get you to focus a little more sharply on -- let me first make the observation and get you to react to Mr. Scheve's last comment, which I think is not unfair, insofar as my application of the rules. And it does seem that this may be beyond the allotted numbers.

MR. JACOBS: Your Honor, that is why I focused on what had happened over the last couple of weeks. Elan has told the Court several times, and then retracted that it has no case on infringement. I think what we are trying to do, as we work our way through what In re: Seagate means, is figure out how we are going try patent cases, keep them focused on the issues of infringement and not on peripheral issues.

Let me give you an example of a peripheral issue. There is some guilt by association claims that Elan is going to make about one of the members of our scientific advisory board, who had an association with Elan 15 years ago, 12 years ago, something like that. So we are going to be swatting down in the context of an infringement case about whether Abraxane infringes the claims of the '363 patent and whether those claims are valid. We are going to be swatting down these side issues, in the guise of this willfulness or copying claim.

So what we think -- I guess I am arguing to the

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Court, in light of the representations that Elan has made, in light of In re: Seagate and what it sayings says, let's look at that threshold question. How can they possibly make a showing of objective of recklessness, which is what Seagate requires.

Then, as to --

THE COURT: Understanding that, I guess what Mr. Scieve is asking of me, and challenging you in this regard, okay, applying the Court's practice and rules, those rules along with the Federal Rules of Civil Procedure, aren't they adequate to the task that you, I think appropriately, described is before us? What is it that I must do today before we empanel this jury? Mr. Scheve, I think, suggested what Abraxis is trying to do is enlist the Court's assistance in crushing its case, unfairly, essentially.

MR. JACOBS: We are definitely enlisting the Court's assistance. And we would love to crush their case. If I can put those two together I will have succeeded. Mr. Scheve is, of course, right in the sense that we are appealing to the Court on the basis that Elan in phone calls and briefs over the last two weeks essentially, Your Honor, that they should be dismissing their case. They left themselves a little wiggle room. And we are trying to apply that to Seagate. Your Honor, we represented to the Court we

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try to follow your procedures. So if you think this is out of order, I understand that.

THE COURT: I will take a look. NASCAR is in town, so the jury will be a little more delayed than they normally would; I think we are told by about 15 additional minutes. Hopefully that is all it is. Because, as you know, many of our jurors come from the lower two-thirds, downstate, below the canal. They will be running into that traffic this morning. I will have a chance to just take a look through this. If I feel it appropriate to address it in earnest, I will give you, Mr. Scheve, an opportunity to respond to it.

I take it that at least some of what is contained in this submission, Mr. Jacobs, goes to Mr. Scheve's opening?

MR. JACOBS: Yes, Your Honor. That is why we raised it now. That is what triggered it was seeing their slides. In a technical sense, we are objecting to portions of his opening statement, and this is in support of that motion.

THE COURT: Let me ask you this: Let's assume for the moment that I were unwilling to address this right now. Have counsel had a chance to discuss, have the parties had a chance to discuss the opening issues, the opening statements?

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MR. JACOBS: We have identified to each other observations we have with each other's slides. There was a meet-and-confer last night about some slides that would be reflected in the opening.

I think both sides have a lot of issues with each other's opening. Whether we can possibly get to those very small issues, I have no idea.

THE COURT: Assuming I were to hold this matter in abeyance and/or reject the request, the motion, as it were, can we use the time productively to discuss -- of course, that assumes willfulness is here. You have to contend with it.

MR. JACOBS: Let me go to one of those, Your Honor. Another high-level effect of the structure of the opening issue that we did address recently, that is our Court order from last week, and that we believe Elan's case is going to depart from.

That is the question of their basic infringement theory and the testimony that Dr. Munson will give on that.

Now, we have a slide from them, from their opening, that says, essentially, they are going to go back to Dr. Munson's original report. The problem with that report, Your Honor, is that it doesn't adhere to the Court's claim construction, as the Court clarified that construction in the Court's order.

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ELAN PHARMA INTERNATIONAL LIMITED,	:	Civil Action
Plaintiff,	:	
v.	:	
ABRAXIS BIOSCIENCE INC.,	:	
Defendant.	:	No. 06-438-GMS

- - -

Wilmington, Delaware
Tuesday, June 3, 2008
8:43 a.m.
SECOND DAY OF TRIAL

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge, and a Jury

APPEARANCES:

JOHN G. DAY, ESQ.
Ashby & Geddes
-and-
STEPHEN SCHEVE, ESQ.,
LINDA M. GLOVER, ESQ.,
JEFFREY SULLIVAN, ESQ.,
ROBERT RIDDLE, ESQ., and
PAUL FEHLNER, ESQ.
Baker Botts LLP
(Houston, TX)
-and-
GREGORY BOKAR, ESQ.
Counsel - Elan Drug Delivery

Counsel for Plaintiff

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to make formulations involving this milling, ball mill grinding method that's described here?
A. We use a ball mill grinding method. But the chamber would have a lot more grinding media in it. You don't get this stuff, the tear, this shattering thing in there.
If you got that, you would have, first of all, the product coming out of that mill would have loads of contamination from the grinding media. That wouldn't be safe. Everything that we make meets the requirements of the regulatory authorities.
Q. First off, is the milling process that you use, is it only half full of these grinding media?
MR. WALTERS: Objection. Vague as to time. Are we talking about today or at the time of the patent?
THE COURT: Could you be more specific?
MR. SCHEVE: Certainly, sir.
BY MR. SCHEVE:
Q. In terms of the processes that you used at any point in time, did you use a grinding or milling apparatus where it had only half full of particles?
MR. WALTERS: Objection. Relevance as to more recent grinding techniques.
THE COURT: Overruled.
THE WITNESS: We actually described some of these, they are sometimes referred to as sand mills or

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high-energy mills. In some of the examples in the patents, we teach how you use these. And you can take a look at some of them. You can see by the volumes we put in at the grinding media, it is almost totally filled up with the grinding media.
BY MR. SCHEVE:
Q. What happens when the mill is working? Is it smashing or pulverizing or sheering? What's the nature of how it works?
A. There is a little bit of smashing. But most of the force used to reduce to critical size is sheer induced.
Q. With regard to the products that are being marketed that contain the NanoCrystal technology, has the FDA ever come back and concluded or communicated to you that there has been some sort of contamination problem?
A. No. We provided them with all of our data. We measure impurities, because every pharmaceutical has impurities in it. You set limits on them. And we measure those. We report them to the agency.
In fact, and I can't identify which company for confidential reasons, but we used to have a specification on the levels, the low levels of media that could be in a product. And we could never detect them.
After a certain amount of time of doing the manufacturing, the FDA agreed with us, you can just drop

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that test, from having to test for that material in the product because you never detected it.
Q. You mentioned to the jury that there are examples. Could you explain to the jury what purpose the examples within your patent provide?
A. Well, to help someone to learn how to use and utilize our invention, you put in there some examples and they say, Put X grams of this, Y grams of that, and mix it for certain amounts of time. So we give them specific details on how to reproduce those examples.
Q. How many different examples are reflected in your patent of embodiments of your invention?
A. In the '363, I will take a quick look through it, there is 23.
Q. Now, I want to point you, sir, to some specific language of the patent that talks about crystallinity and distinguishing language with regard to amorphous. Do you see that language, sir? It's found in Column 2 of Exhibit '081.
A. Okay, yeah.
Q. Now, so that the jury understands, does your technology deal with crystalline nanoparticles?
A. It encompasses crystalline, yes.
Q. Did it distinguish itself from a particular type of material?

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A. Yes.
Q. Is this the language that states what you distinguish yourself from?
A. Yeah. We were distinguishing ourselves from a pure amorphous phase.
Q. Now, the language is, Crystalline phase differs from amorphous phase, this is language that wasn't highlighted yesterday for the jury, which results from conventional solvent precipitation.
In fact, does the patent actually refer to another specific patent that describes the solvent precipitation process that you distinguish your product from?
A. Yes, it does.
Q. I would like, then, to have you explain to the jury what the concept of solvent precipitation is.
A. It would have been easier with a little thing.
Basically, you will take the drug and you dissolve it -- this is poorly water soluble so you are not dissolving it in water. You will dissolve it in a solvent. And this solvent has properties in the fact that when you add the solvent to water, it can disperse, or the technical term is miscible. That means it goes in there.
A good example might be, you know antifreeze, propylene glycol, that can be a solvent. But when you add

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ELAN PHARMA INTERNATIONAL LIMITED,	:	Civil Action
Plaintiff,	:	
v.	:	
ABRAXIS BIOSCIENCE INC.,	:	
Defendant.	:	No. 06-438-GMS

- - -

Wilmington, Delaware
Wednesday, June 4, 2008
8:30 a.m.
THIRD DAY OF TRIAL

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge,
and a Jury

APPEARANCES:

JOHN G. DAY, ESQ.
Ashby & Geddes
-and-
STEPHEN SCHEVE, ESQ.,
LINDA M. GLOVER, ESQ.,
JEFFREY SULLIVAN, ESQ.,
ROBERT RIDDLE, ESQ., and
PAUL FEHLNER, ESQ.
Baker Botts LLP
(Houston, TX)
-and-
GREGORY BOKAR, ESQ.
Counsel - Elan Drug Delivery

Counsel for Plaintiff

"Answer: Probably not less than 200.
"Question: Okay. And what is your position or Abraxis's position on the average effective particle size of the nanoparticles in Abraxane?
"Answer: We don't use the term average effective particle size. The term we use is the mean particle size. And that's about 130 nanometers.
"Question: Is there a chemical bonding between the human albumin and the particle, paclitaxel?
"Answer: No, there is no chemical bond between the albumin and the paclitaxel.
"Question: Is it true, sir, that the protein molecules of HSA are adsorbed onto the surface of the paclitaxel nanoparticle?
"Answer: Yes.
"Question: Powder. And did Abraxis ever apply nuclear magnetic resonance spectroscopy to nanoparticles derived after centrifugation?
"Answer: Not that I remember.
"Question: So after separating the nanoparticles from free HSA using centrifugation, did Abraxis ever do any test to test the crystallinity of the pelleted material or the nanoparticles?
"Answer: No.
"Question: When you -- when Abraxis represented

to the agency that the nanoparticles were 82 percent paclitaxel and 18 percent HSA --
"Answer: Correct.
"Question: -- did you believe, sir, that the centrifugation did not affect the integrity of that relative ratio of constituents in the nanoparticle?
"Answer: Yes. We wouldn't expect it to affect the amount of the components.
"Question: Did Abraxis represent to the FDA that the nanoparticles of paclitaxel and HSA adsorbed onto the surface were amorphous without ever doing an x-ray diffraction or solid-state NMR testing on the nanoparticles after they were separated from free HSA following centrifugation?
"Answer: Yes, correct.
"Question: Has any of that data been sent to the FDA and its review staff for review?
"Answer: Any of the cross-linking data?
"Question: Correct.
"Answer: No.
"Question: Has any of it been subjected to review by the Center for Drug Research within the FDA?
"Answer: No, it's not been sent to the FDA.
"Question: Have any of the formulation scientists at the FDA been apprised of these tests and those

results?
"Answer: It's not been sent to the FDA."
THE COURT: All right. Ladies and gentlemen, it's up to you, do you want to take your full hour? Or we can take 45 minutes.
Full hour. Okay, we are going to take a full hour.
(Jury leaves courtroom at 1:20 p.m.)
(Luncheon recess taken.)
THE COURT: All right. Mr. Jacobs.
MR. JACOBS: Yes, I apologize for being the one raising issues, Your Honor.
MR. JACOBS: Munson will be up this afternoon. You will recall that we prevailed on the second supplemental Munson report.
THE COURT: Firstly, I am assuming you are withdrawing this motion with regard to Dr. Manning.
MR. JACOBS: It is moot.
THE COURT: Go ahead.
MR. JACOBS: On Munson we have confirmed we have an outstanding dispute. The differences between Munson's original report, in which he mentions there is crystallinity in the entire Abraxane fraction that he measures and doesn't get down to the particle level, and on the slide which we are seeing now is eight percent of the particles are

crystalline. And the particle-based theory in essence is what was struck when the second supplemental Munson report was struck. We believe they should not be able to offer that testimony.
MR. SCHEVE: I will start off by saying, Your Honor, you addressed the specific issue when you denied their motion in limine. But I have got the report here, and I am happy to show it to, you where I am going to follow the original report and everything is here. This is nothing but a rehash of your previous ruling on the motion.
THE COURT: Why isn't this a rehash?
MR. JACOBS: Because in the motion in limine we wished to strike Munson altogether.
THE COURT: Regardless, I ruled in some way on that motion. Why isn't this a rehash?
MR. JACOBS: The motion in limine was a motion to strike Munson in its entirety. The motion the other day that you granted in our favor was a motion to strike Munson's second supplemental report. That was the report he issued after the claim construction clarification in which he shifted from mostly to entirely, and went from a percentage of everything he is measuring, rolled up in a ball, so eight percent crystallinity in this thing I am measuring.
THE COURT: Is it the supplemental, Mr. Scheve,

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that you have in your hands?
MR. SCHEVE: It's the original.
MR. JACOBS: It is not there, Your Honor.
THE COURT: That is the issue.
(The following took place at sidebar.)
MR. JACOBS: This is a slide that we are objecting to, Your Honor, that they have sent over. It says eight percent of all particles are crystalline. So eight percent --
THE COURT: In Abraxane.
MR. JACOBS: Yes. And there is no such opinion here.
THE COURT: You are referring to a demonstrative exhibit of plaintiff's. Right?
MR. JACOBS: Correct.
MR. SCHEVE: The original report, which describes samples of particles, it went on to explain how they were obtained and the procedures are described therein. One method is what is called the freeze-drying or lyophilization method. The other one is the air-drying method. And he went on then to describe it. We get to this paragraph over here.
THE COURT: Paragraph 124.
MR. SCHEVE: The sample prepared using the lyophilization method. Again, the sample is samples of

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particles, lyophilization. The actual area of the crystalline form represented by the peak is eight percent. The air-dried, which is the next slide, he says, seven percent. And then his end opinion is found in Paragraphs 27G and H where he says it is my opinion that Abraxane contains particles consisting essentially of, as construed by the Court, and here are the two constructions from your original construction in August of '07.
THE COURT: You are aware of this report?
MR. JACOBS: Absolutely.
THE COURT: What is the complaint?
MR. JACOBS: The complaint, Your Honor, is that, his opinion on whether particles are crystalline, is that there is a range. And the bottom line is that samples that are on average, such as those discussed above, include individual particles that are mostly crystalline. That's as far as he went.
Here is what he is saying, that there are eight percent of all particles that are crystalline.
Having reread this for the third time, if he will acknowledge on cross-examination that he doesn't know whether eight percent of all particles are entirely crystalline, if we can get that out of him without opening the door to the whole entirely crystalline report, then this can be made clear. Otherwise, it is very ambiguous to the

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jury that he is not testifying to entire crystallinity.
THE COURT: You would certainly be able to cross-examine him in that regard. What is it that you think we can do to prevent a Pandora's Box from opening?
MR. JACOBS: That is the problem. It is proving the negative. You did not testify to the following. Without, then, oh, well, they opened the door.
THE COURT: Let me get you to react first off to Mr. Scheve's citation, I forget which paragraph, to the line where it does, the demonstrative appears to quote from the line out of the report.
MR. JACOBS: All he is saying is the area for the crystalline form represented by the peak is eight percent. I have no problem with him testifying to that.
THE COURT: Okay.
MR. SCHEVE: That's what the chart says.
MR. JACOBS: No. The chart says eight percent of the particles are crystalline.
MR. SCHEVE: This, he is going to say, are particles with amorphous medicament, particles with crystalline medicament, and that this number is eight percent.
MR. JACOBS: I have no problem with him saying what he put in his report, that the actual area of the form is eight percent.

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THE COURT: It seems to me that you are agreeing, essentially. Maybe you are reading the demonstrative differently?
MR. JACOBS: Perhaps, yes.
MR. SCHEVE: I think he would prefer that the opinion not come into the case, which is again rehashing the amendment issue.
MR. JACOBS: No. I have no problem --
THE COURT: With the statement in Paragraph 24.
MR. JACOBS: Yes. For purposes of this discussion.
THE COURT: Your concern is that this demonstrative doesn't say, doesn't repeat the words in 24, or could be interpreted differently.
MR. JACOBS: Exactly.
THE COURT: Mr. Scheve seems to have the doctor interpret the demonstrative differently from that which is written, or argue to the jury, I am assuming?
MR. SCHEVE: I was simply going to ask him, when you did this, sir, did you find crystals? Yes. Of the total amount of paclitaxel, how much was crystalline? He is going to say eight percent. Or the particles, because he separated the particles. You can't say eight percent of the total because the only thing he tested was particles. And eight percent of that, of all particles, were crystalline.

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That's what he says.
MR. JACOBS: We are getting granular here. This is what the fight is about. So forgive me. He is saying -- the way I read this, the way I think he is trying to have it interpreted, he is saying out of a hundred particles, eight percent of those particles are, quote, crystalline, within the meaning of the claims. The Court said, in order for particles to infringe, the paclitaxel in those particles must be entirely crystalline.
THE COURT: Yes.
MR. JACOBS: By changing the words subtly, he is trying to imply that this testimony meets the entire limitation.
MR. SCHEVE: Which is really, I think, the major misunderstanding, Your Honor. Please don't shoot me.
Our case is that within this product, there are particles that are completely crystalline. He wants to be able to argue, wait a minute, every one of them has got to be crystalline, which is clearly not the law. If I have a car and I put two bolts in it that infringe a patent, I have infringed.
All I am saying is, my case has been since day one, they have done tests, they have found crystallinity. And he will offer the opinion in Paragraph 27, this product contains particles that meet the claim limitation of your

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August order.
And what is happening here is a basic misunderstanding of what the claim construction is. I have read your claims a lot of times. I have a journalism background. I am not very smart. I understood Your Honor to say, Mr. Scheve, if you put up evidence, if you don't put something in the record that says particles which are, maybe it's ten, 50, or a trillion, but if it contains particles where the medicament is entirely crystalline, I have met your claim limitation. He wants to be able to argue, I got to be all crystalline. I have never said we could prove that. This test shows that there is eight percent crystallinity, only of the particles. That is all he tested. They separated the free, got the particles, put them in the NMR. Eight percent of all those particles is crystalline. That is what he is saying. I will ask him. I am going to simply ask, sir, do you have an opinion, to a reasonable degree of scientific certainty, whether that has a formulation that has eight percent of particles crystalline. And he will say yes, and I will sit down.
MR. JACOBS: The issue here is not about what Mr. Scheve said. Let's suppose there were a hundred particles and each of the particles was eight percent crystalline. This allows for that that possibility.
THE COURT: Paragraph 24.

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MR. JACOBS: Yes. Allows for, we read Paragraph 24 saying he doesn't know whether it's all concentrated in some subset of particles or spread out.
THE COURT: I think the safe way to handle this, because as District Judges often do, we shoot from the hip a little bit, is keep you to the ruling, keep the demonstrative out. Let him testify -- Mr. Jacobs isn't objecting, nor do I --
MR. SCHEVE: If I take that line out?
MR. JACOBS: I have no problem with the picture.
MR. SCHEVE: How about putting the word eight percent.
MR. JACOBS: I have no problem with eight percent, exactly, no problem at all.
THE COURT: That is fine with me.
MR. SCHEVE: I will do it right now.
(End of sidebar conference.)
MR. SCHEVE: I would be speaking from a position of lack of knowledge one way or the other here.
THE COURT: We were going to play videotapes.
MR. SCHEVE: We were planning to go right ahead with Dr. Manning.
MR. JACOBS: You told me you were putting on Salvaraj.
MR. SCHEVE: We are prepared to do either.

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MR. JACOBS: These demonstratives, we would submit, should not go to the jury.
THE COURT: Fine. Have you two discussed that?
Counsel, I am going to tell the jury when they come out that we are going to start at 9:30 tomorrow. I have a Judges' meeting in the morning.
MR. SCHEVE: We are ready to go, Judge.
THE COURT: Okay. Ms. Walker.
(Jury enters courtroom at 2:42.)
THE COURT: All right, ladies and gentlemen. Please take your seats. Permit me to apologize on behalf of the parties and the Court. Sometimes it does come to pass, as you know from our trips to sidebar, that we need to have a discussion about a legal issue. Sometimes those discussions can be rather extended. That's what happened here. So you got a little more time than you bargained for. But we are ready to go. Okay.
MR. SCHEVE: May I proceed, Your Honor?
THE COURT: Yes, Mr. Scheve, please.
MR. SCHEVE: At this time, Plaintiff, Elan, would call Dr. Eric Munson to the stand.
...ERIC MUNSON, having been duly sworn as a witness, was examined and testified as follows ...
THE COURT: Mr. Scheve, proceed.
MR. SCHEVE: Thank you, Your Honor.

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ELAN PHARMA INTERNATIONAL LIMITED,	:	Civil Action
Plaintiff,	:	
v.	:	
ABRAXIS BIOSCIENCE INC.,	:	
Defendant.	:	No. 06-438-GMS

- - -

Wilmington, Delaware
Friday, June 6, 2008
8:45 a.m.
FIFTH DAY OF TRIAL

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge, and a Jury

APPEARANCES:

JOHN G. DAY, ESQ.
Ashby & Geddes
-and-
STEPHEN SCHEVE, ESQ.,
LINDA M. GLOVER, ESQ.,
JEFFREY SULLIVAN, ESQ.,
ROBERT RIDDLE, ESQ., and
PAUL FEHLNER, ESQ.
Baker Botts LLP
(Houston, TX)
-and-
GREGORY BOKAR, ESQ.
Counsel - Elan Drug Delivery

Counsel for Plaintiff

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MR. JACOBS: We call Dr. Jerry Atwood.
...JERRY LEE ATWOOD, having been duly sworn as a witness, was examined and testified as follows ...
DIRECT EXAMINATION
BY MR. JACOBS:
Q. Dr. Atwood, now that you are seated in front of the microphone, could you please introduce yourself to the jury?
A. Yes. Good morning. My name is Jerry Atwood. I am a professor of chemistry and head of the chemistry department at the University of Missouri in Columbia, Missouri.
Q. What exactly is your position at the University of Missouri, Dr. Atwood?
A. My position is actually in terms of curator, professor, that is the title that is given by our governing board, which is the board of curators, which is given to few people at the university.
Q. How many people at the university are curators professors?
A. I think probably 12 to 15 on campus.
Q. Out of a faculty of how many?
A. Probably 900 or something like that.
Q. Mr. Broyles, can we put DX-472 up on the screen, please.
Doctor, what is DX-472?
A. DX-472 is my resume or my CV.

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Q. It's a multi-page document, is it not, Dr. Atwood?
A. It is. The first page we were looking at is the summary of the CV.
Q. If you need to, Dr. Atwood, we have the exhibits up on the screen in the binder in front of you, so feel free to look at your binder.
A. That would be fine, Mr. Jacobs. But would you happen to have a pointer?
Q. I would?
THE COURT: Please.
THE WITNESS: Thank you very much.
BY MR. JACOBS:
Q. Just spend a minute, Dr. Atwood, walking us through your professional carrier?
A. I started my professional carrier at the University of Alabama. I was there 26 years. I moved from assistant professor up through the university research professor, which was the highest title given at the University of Alabama.
I then went effectively back home to Missouri. And I have been there in my current position for 14 years.
Q. Do you teach at the university?
A. Yes, I did.
Q. What do you teach sir?
A. I teach everything from first year chemistry through

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to graduate courses.
Q. Do you do research?
A. Yes, I do. One of my main functions is to do research.
Q. What is the focus of your research, sir?
A. My research is generally in two areas. Supramolecular chemistry, we call it, which is a way of starting from molecules and building large structures. It is a little like a brick mason. You start with bricks and you build large structures. We are trying to learn the fundamental principles upon which my processes, for example, are based.
The second area is crystallography.
Q. What is crystallography, sir?
A. Crystallography is the study generally of the way the x-rays diffract from solid material, either crystalline or amorphous material.
Q. Dr. Atwood, I have brought a couple of books with me today. Can you just identify what this book is about, Supramolecular Chemistry by D. Atwood.
A. Supramolecular Chemistry is the basic text for supramolecular chemistry. We published that in 2000. We have a second edition which has just gone to press in the last couple of months.
The second edition, showing the impact of nanotechnology on supramolecular chemistry, for example, the

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second edition is comprised of 15 chapters. The 15th chapter is titled Nanochemistry.
Q. I brought along Organic Nanostructures by Atwood and Steed. What is that about?
A. This is an edited volume that my colleague from England, John Steed, and I put together a year and a half ago. It just came out in February of this year. In this volume, we are talking about the way that nanotechnology, particularly with regard to organic solids, the way this is impacting industry, basic science, at many different levels.
Q. Are you currently writing peer-review articles, sir?
A. Yes. I do 12 to 20 peer-reviewed articles per year.
Q. Could you explain what "peer-reviewed" means?
A. In a peer-reviewed article, either myself or some of my graduate students or post-docs or undergraduate students go into the lab and we carry out some experiments. And we use the scientific method to try to learn fundamental things about nature.
If we make a good discovery, we write this up for a journal, a scientific journal.
The paper is then submitted to the editor of the scientific journal. The editor then, with the aid of referees, makes a decision about whether the paper is acceptable or not.
Q. Do you also serve in that kind of reviewing or

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molecules and other small molecules of interest.
Q. Dr. Atwood, when we asked you to get involved in this lawsuit, what was one of the first things you did?
A. Well, the first thing I did was, I read the '363 and the '025 patents.
Q. Could we have DDO15 on the screen, please.
What does this slide represent, Dr. Atwood?
A. This particular slide has three separate quotations from the '363 patent. And highlighted is the word "crystalline."
Q. When you read the '363 patent, looking at it from the technical perspective, what did you understand the '363 patent to be conveying about crystallinity and amorphousness and the particles that were being described?
A. It's very clear that the '363 patent, as it says in the third bullet point, the anticancer agent present in one or more discrete crystalline phases, and by "crystalline phases," that just means a crystalline solid, so the anticancer agent of the invention was present in one or more discrete crystalline phases.
Continuing on with the third bullet point, the crystalline phase differs from an amorphous, i.e., non-crystalline phase. So there was a clear differentiation in the '363 between crystalline and amorphous materials.
Q. When you read through the '363 patent, did you read

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other related documents?
A. I did. I particularly read the '684 patent, which has been described here as the mother of the '363 patent.
Q. Did you review the so-called file history for the patents?
A. Yes, I did. I reviewed all the documents that were submitted while trying to gain issue of these patents.
Q. Looking at the totality of that, what did you understand, from the technical perspective, the applicants for those patents, we will call them "Elan" for short, what did you understand Elan to be conveying about the distinction between crystalline and amorphous substances?
A. They were very clear that crystalline is different from amorphous. And they are very clear in the '684 and the '363 patents that the patents are covering crystalline, not amorphous materials.
Q. Again, just from a scientific perspective, did you see any indication that they were talking about nanoparticles with small bits of crystalline material in the particles?
A. No, not at all. The patents are very clear that the patents relate to crystalline, not amorphous material.
MR. SCHEVE: Your Honor, this gets into claim construction. I object. Your Honor construed the claims. He is now asking him what the patents mean. That is beyond the --

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THE COURT: Sustained.
MR. JACOBS: Can I re-ask the question from a technical perspective?
THE COURT: Yes.
BY MR. JACOBS:
Q. Sticking to the scientific information that is conveyed in the specifications of those patents, what did you understand, from the scientific perspective, the distinction that was being drawn there between crystalline and amorphous substances?
A. Yes, first of all, I wasn't meaning to construe the claims.
THE COURT: That's not a problem.
THE WITNESS: I am familiar with that term. I was meaning to give my technical interpretation of what the '363 patent and the '684 patents were doing.
They are contrasting crystalline versus amorphous, and clearly covering, as the invention, crystalline materials.
BY MR. JACOBS:
Q. Dr. Atwood, let's take a look at a slide to try and illustrate this difference to the jury. What is represented here on this slide?
A. On the slide, in the left section, under the heading "Crystalline," we have a well-ordered array of red and blue

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balls. It's clear that this represents high order. And as I understand, crystalline is defined as long-restraining order, order that stretches over a long distance in crystalline salt.
Q. On the right side, sir?
A. On the right side, under the heading "Amorphous," is what I would term sort of a random array of red and blue balls. There is no regular order to this.
Q. What are we looking at in this model? Are we looking at Micron sizes, millimeter sizes?
A. This is just a model. If I had to relate this to paclitaxel, for example, I would say that probably a red and a blue would be a paclitaxel, so that on the crystalline, you could see that those are arranged in a very systematic and orderly fashion; whereas, the red and the blue on the right-hand side under "Amorphous" are arranged very much in a random fashion.
Q. What are we looking at? Are we looking at very small, tiny things, or larger things? What is the scale here?
A. What we are looking at here would be, if a red and a blue dot combined was a paclitaxel molecule, we would be looking at about two nanometer sections.
Q. Compare that with the size that we have heard in this trial of the particles in Abraxane?
A. Yes. Abraxane is about 130 nanometers in diameter.

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(End of sidebar conference.)
THE WITNESS: May I hear the question again?
BY MR. JACOBS:
Q. Did you analyze the question whether DSC is potentially useful in this matter for determining the question of crystallinity in the paclitaxel in the nanoparticles in Abraxane?
A. Yes. There is two issues --
MR. SCHEVE: Objection, Your Honor. This is beyond the scope of his report.
THE COURT: Do you want to rephrase the question consistent with our discussion, Mr. Jacobs?
BY MR. JACOBS:
Q. What is DSC, Dr. Atwood?
A. DSC stands for differential scanning chemistry. It is a big term, but it measures the heat flow into a sample.
Q. Can potentially DSC provide useful characterization?
A. DSC can provide useful characterization in terms of crystallinity.
MR. SCHEVE: Your Honor, I object. That is not in his report.
MR. JACOBS: I will withdraw it, Your Honor.
MR. SCHEVE: May the answer be stricken?
THE COURT: Yes. Ladies and gentlemen, I will direct you to disregard the doctor's answer.

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BY MR. JACOBS:
Q. Did you review Abraxis's New Drug Application?
A. I did.
Q. Did you review it to determine, to look at the various analytical techniques that were described there?
A. Yes, I did.
Q. Did you review the New Drug Application section on DSC?
A. I did.
Q. Did Abraxis there represent that DSC was being used to characterize the amorphous or crystalline nature of the paclitaxel in the nanoparticles in Abraxane?
A. No, it did not. It used DSC for a completely different purpose.
Q. Let's talk about another technique, which is SEM and TEM. What is TEM and what is SEM?
A. SEM and TEM are variants on what is referred to as electron microscopy. If we use the normal sort of microscope that we see in the lab, this can go down to, it can magnify materials that are quite small. But it can't begin to approach the nano region. So one has to use something which is more powerful.
Q. Let's take a look at some pictures, Dr. Atwood.
Can you tell us what these are?
A. Yes. On the left, we have a scanning electron

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microscope, which does an SEM test. On the right, we have a transmission electron microscope, or TEM.
What we see here is, for example, if you look at the TEM, you can see the binocular piece, this is where one would look if one wanted to visualize what was happening with the eye. Normally, this will be recorded on film or something like that or on a computer disk.
But, you know, this representation makes it look like it's a really big microscope, which it is.
Q. Dr. Atwood, let's take a look at some pictures. Can you explain what is represented by these photographs drawn from DX-239 and JX-5?
A. Yes. DX-239 is Elan's crystalline nanotaxol. As we see here, the scale is such that we are looking at a few hundred nanometer size. But we see that these, to me, look sort of like needle-like crystals. They have a definite shape associated with them.
Whereas on the right, we are looking at Abraxane, the paclitaxel or the particles in Abraxane. And what we see here is no definite shape other than this sort of mushy, ill-defined round shape, characteristic of an amorphous material.
So on the left is what an electron microscope will provide one with a crystalline material. On the right is what the electron microscope will provide one with an

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amorphous material.
Q. On the left side of this slide, what is the scale of the photograph?
A. The scale looks to me like it's provided right here. I think these dots show two microns or 2000 nanometers.
Q. So looking at this, can you take a guess -- not a guess -- can you tell us what you think the size of the nano-taxol particles is?
A. What we see going across here, if we go halfway across, that would be a thousand nanometers. That would be 500 nanometers. So I am sweeping out with my -- a couple of divisions, probably about 400 nanometers. So it looks to me like the particles that we have, some are quite long. Some are close to a thousand nanometers long.
But the diameter of most of them, of these needle-like crystals, the diameter of most of them is probably of the order of a hundred nanometers, something like that.
Q. If you look at these, at the Abraxis photograph on the right, what information does this give you about whether the paclitaxel in those nanoparticles is crystalline or amorphous?
A. This gives us information that the particles themselves have the appearance of amorphous. There is no appearance of crystalline.

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I should add that if we take a crystalline material, such as we see on the left, and if we put a surface layer of modifier on that, which these particles probably have, the crystallinity of the interior, these hundred to 200 nanometer particles, the paclitaxel crystalline interior, generally enforces a shape on the surface modifier.

So this could look a little bit like, if we are getting a Christmas present, and it's a rectangular box, even though it's got wrapping paper on the outside which is not of any particular shape, it's molded by virtue of being associated with the box, so that it has the shape of the box that's contained underneath.

Q. Dr. Atwood, let's take a look at the photograph that Dr. Berkland discussed. This is taken from DX-40, an Abraxis lab notebook.

Dr. Berkland said he saw suggestion of crystallinity there. What is your opinion on what Dr. Berkland said?

A. I have looked at this micrograph before.

MR. SCHEVE: Your Honor, in fairness, this is a photocopy. Dr. Berkland's was taken from the actual images. So this is not the image that Dr. Berkland referenced. I would object to the characterization that this is the image that Dr. Berkland dealt with.

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THE COURT: Fair enough. Fair enough.

MR. JACOBS: So agreed.

THE COURT: All right.

THE WITNESS: I see no evidence of crystallinity here.

By the way, the idea of angularity, this is not -- this is an attribute of crystallinity. But crystallinity is more than that. If you remember, on the previous slide, on the left-hand panel, if you go back to that one, so on the left-hand side we see angularity, we see straight lines. But more than that, we see what appears to be needle-like crystals.

So we are not just seeing one straight line with a lot of fuzzy blob off the other side. We are not just seeing one sort of angle with a lot fuzziness on the other side.

We are seeing a crystal, which has a regular shape. It has what we call a morphology, a shape associated with it.

So if we go back to the -- this particular panel here, are we seeing angularity? I don't know. There are some lines that look somewhat straight. But overall, the impression I get is that this is not something of high order.

I don't see a morphology that I would associate

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with crystallinity.

Q. That word "morphology," Dr. Atwood, could you explain that, please?

A. Morphology just means shape. It's just a scientific term. I think it probably came originally out of biology. It just means shape.

Q. Dr. Atwood, at any time in this lawsuit, have you seen any TEM or SEM photographs generated by Elan scrutinizing Abraxane?

A. I don't recall seeing any from Elan scrutinizing Abraxane.

Q. Dr. Atwood, let's turn now to the topic of ssNMR. At some point in this litigation, did you review ssNMR data and information generated by Elan's experts?

A. Yes, I did.

Q. Why don't we walk through your understanding of what Elan did. And let's describe that for the jury.

So we have on the left, Dr. Atwood, the label "Crystalline Control" and on the right "Amorphous Control."

What is depicted here?

A. What is depicted on the left is crystalline paclitaxel, solid state NMR pattern, a spectrum for crystalline paclitaxel. I believe this came from Dr. Munson's work. We have on the right so-called amorphous control, and this was amorphous paclitaxel, which Dr. Munson

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used in his solid state NMR work. In fact, I think these are spectra from Dr. Munson.

Q. Earlier on, you analyzed the question of the suitability of ssNMR for analyzing the question in this lawsuit. Correct?

A. Yes, I did.

Q. Can you explain to the jury your views on the overall suitability of ssNMR for the context here?

A. SsNMR, it is a subsidiary technique. It's a secondary technique. It's a technique that can provide information. In fact, I think Dr. Munson's studies do provide information about the crystallinity or, in fact, lack of crystallinity. But it's not the first technique. The first technique one would use is x-ray powder diffraction.

Q. Is ssNMR referred to as the gold standard for testing crystallinity or amorphousness in nanoparticulate substances?

A. No, it's not.

Q. Have you ever seen any sort of representation to that effect?

A. No, I have not.

Q. Now, what did Dr. Munson actually test when he did see ssNMR work?

A. In Dr. Munson's initial report, there were six tests. He tested two different crystalline controls. He tested an

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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ELAN PHARMA INTERNATIONAL LIMITED,	:	Civil Action
Plaintiff,	:	
v.	:	
ABRAXIS BIOSCIENCE INC.,	:	
Defendant.	:	No. 06-438-GMS

- - -

Wilmington, Delaware
Wednesday, June 11, 2008
9:40 a.m.
EIGHTH DAY OF TRIAL

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge,
and a Jury

APPEARANCES:

JOHN G. DAY, ESQ.
Ashby & Geddes
-and-
STEPHEN SCHEVE, ESQ.,
LINDA M. GLOVER, ESQ.,
JEFFREY SULLIVAN, ESQ.,
LISA A. CHIARINI, ESQ.,
ROBERT RIDDLE, ESQ., and
PAUL FEHLNER, ESQ.
Baker Botts LLP
(Houston, TX)
-and-
GREGORY BOKAR, ESQ.
Counsel - Elan Drug Delivery

Counsel for Plaintiff

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it has windows.
(Recess taken.)
(The following took place at sidebar.)
THE COURT: Ms. Walker reports that it's going to be about another hour. I don't understand that. But it is what it is.
So I am going to have Ms. Walker advise the jury, we have ordered their lunch, we have their orders, we haven't placed it yet. We will have it delivered at 11:30. I am going to tell the jury in the meantime they can go about whatever they want to do and come back at around 11:30, and hopefully we will be ready to instruct them by noon.
So you, ladies and gentlemen, should get some food, because we are going to go straight through after that.
MR. SCHEVE: Your Honor, just so I am perfectly clear and don't inject any error into my closing, when you said that contributory and inducing was out, is that out both on the literal and DOE.
THE COURT: Yes. Let me also remind you my preference, and I think the appellate courts prefer this as well, I know that counsel are loathe to interrupt during closing speeches. I prefer you do, so that we can correct any error that you perceive to be injected into the case

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improper closing and if necessary I can give a curative instruction at that time.
I don't know how you practice, Mr. Jacobs, Mr. Scheve.
MR. SCHEVE: I am real loathe to do something that the jury would get upset about.
THE COURT: I will leave it to you. Judges don't want to micromanage these kinds of cases.
MR. SCHEVE: Would you prefer we ask for a sidebar?
THE COURT: Yes; Judge, may we see you at sidebar.
MR. JACOBS: If we can get a sense of ground rules. Is it okay to put the instructions on the Elmo and walk the jury through them?
THE COURT: I have no difficulty with that.
This is what I will have already told the jury. This is one of the reasons I instruct first. There is no issue about what the jury has been told is the law.
MR. JACOBS: Otherwise, of course, it's argument, and we can argue from the evidence.
THE COURT: Absolutely. To the extent there is some passing in the night, as we alluded to earlier, it may happen. We will do the best we can. It is an imperfect system, but for the most part, it works.

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(End of sidebar conference.)
(Recess taken.)
THE COURT: All right. Take your seats. I understand there is one more issue. Mr. Scheve, what is it?
MR. SCHEVE: Your Honor, I raised with Mr. Jacobs, Your Honor granted the motion on the damages theory. I suggested to him that it seemed to me the only question, then, for the jury, if there is a jury question, is where between six and eight percent. Mr. Jacobs thought that maybe the ruling was different than that and suggested that we speak with you about that.
THE COURT: I think what I intended to convey in my ruling was that there is evidence from only one side on the issue of damages.
MR. JACOBS: Your Honor, when you came out and said -- there are two things here, what did I agree to and, two, what is your ruling.
When you came out and asked me if I agreed that there is only one theory of damages, I said, yes, there is only one theory.
THE COURT: There is only one set of numbers.
MR. JACOBS: Well, I think the jury doesn't have to accept because, for example, he was cross-examined on this, the jury doesn't have to accept the Elan quantification of the reasonable royalty. For example, if

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the jury were to discredit Dr. Jarosz' testimony --
THE COURT: They would be free to do that.
MR. JACOBS: -- because he decided that a hundred percent of the value was associated with the Elan patents --
THE COURT: They could do that.
MR. JACOBS: Then they could go well below six or eight percent. So that the jury still has a jury question as to amount. I agree that there is only one theory of damages.
THE COURT: Mr. Scheve?
MR. SCHEVE: I would only suggest, Your Honor, if he is going to argue that there ought to be some different combination of numbers or percentages, there has been no affirmative evidence by Abraxis and, therefore, they would be arguing from something that is not in the record. So rather than disrupt his closing, I thought it would be appropriate to raise that.
THE COURT: Well, I guess Mr. Jacobs is arguing that he was able to achieve certain responses to questions asked during cross, and that those answers, as evidence, would support an argument of some type. I am just hypothesizing.
Would you disagree that if a witness in response to a question, albeit posed on cross, the question resulted

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in the adducement of evidence, that that would not be appropriate?
MR. SCHEVE: Certainly, the jury is free, Your Honor, with any witness to disregard their testimony. But if in any sort of alternative, you ought to come with three percent for this reason and that reason, there is no evidence in this record upon which to suggest a different theory.
THE COURT: Let's talk about that then.
Mr. Jacobs.
MR. JACOBS: Two points. First, they put in Mr. Musika's calculation of one percent. I think I can cut through this, Your Honor. I don't intend to argue in my closing for an alternative quantification of damages.
MR. SCHEVE: I think we have resolved the dispute, Judge.
THE COURT: That's great.
Ms. Walker, you can bring the jury back.
Mr. Sullivan, compliments to you in getting these in shape.
MR. SULLIVAN: Thank you, Your Honor. And. Mrs. Walters as well.
(Jury enters courtroom at 12:27 p.m.)
THE COURT: Ladies and gentlemen, please take your seats. The time has arrived, and the Court on behalf

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of the parties wishes to extend its gratitude to you for your patience.
These are best estimates sometimes we make with regard to time. Please believe me, that was our best estimate, 10:00. I apologize for any inconvenience, and there has been a tremendous inconvenience. Jury service is a, I guess, probably by some called an inconvenience. It is a duty. We deeply appreciate your assiduous attention to your duty and your indulgence.
You each have a copy of the instructions and the verdict form.
Ladies and gentlemen, now it's time for me to instruct you about the law that you must follow in deciding this case.
If you read along, you are free to do that, but it is probably just as easy for you to just watch me or to listen. But feel free, if you are more comfortable reading along. You may see from time to time a small deviation from the literal language, as just now, of the instructions, but hopefully I will not deviate in any material aspect.
I will start by reminding you about your duties as jurors and instructions you heard at the beginning of the case. I will then explain the positions of the parties and the law that you will apply in this case.
Last, I will explain the rules that you must

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follow during your deliberations in the jury room, and the possible verdicts that you return.
I expect that both sides are going to talk about the verdict form that you have been provided. I am probably, therefore, not going to spend a lot of time on that. I think it is pretty self-explanatory, in any event.
Please listen carefully to everything that I have to say.
Ladies and gentlemen, remember your duties as jurors, as I explained them to you at the beginning of the case. You must decide what the facts are from the evidence you saw and heard here in this courtroom. Nothing I have said or will say should influence your determination of the facts in any way. Do not guess or speculate and do not be influenced in any way by any personal feeling of sympathy for, or prejudice against, either side in this case. All parties are entitled to the same fair and impartial consideration.
You must take the principles of law that I will now explain to you and apply them to the facts in reaching your verdict, the facts that you find.
You are bound by the oath you took to follow my instructions, even if you personally disagree with them. All of my instructions are important, including the ones that I from time to time gave you during the course of the

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trial, and the preliminary instructions. You should consider them together as a whole.
I will not repeat my earlier instructions about evidence and how to weigh and consider it. You have copies of these instructions. Again, you may feel free to reference them as you need to.
Perform these duties fairly. Do not let any bias, sympathy, or prejudice that you may feel toward one side or the other influence your decision in any way.
As you know, this is a civil case in which the plaintiff, Elan, is accusing the defendant, Abraxis, of patent infringement. Elan alleges that Abraxis has infringed the asserted claims of the '363 patent. Elan has the burden of proving its allegations of patent infringement and its alleged damages by what is known as a preponderance of the evidence. That means Elan must produce evidence that, when considered in light of all the facts, leads you to believe that what Elan claims is more likely true than not.
To put it differently, if you were to put Elan's and Abraxis's evidence on opposite sides of a scale, the evidence supporting Elan's claims would have to make the scales tip somewhat to its side.
Elan also alleges that Abraxis's alleged infringement was willful. Elan must prove its claim of