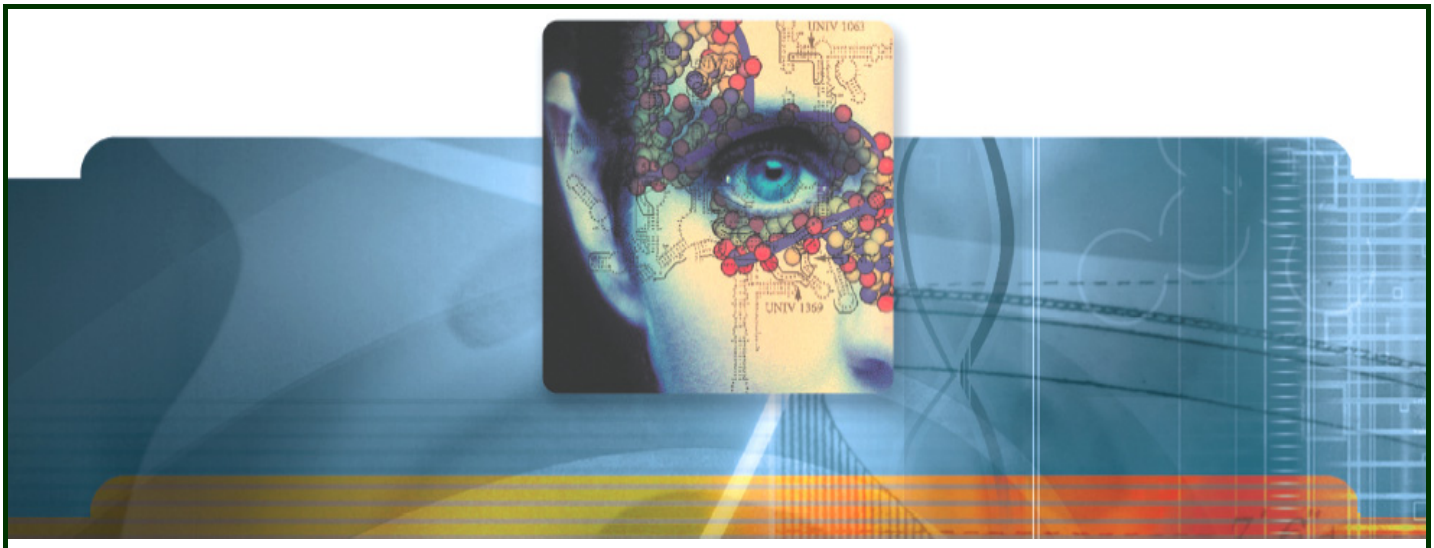

NanoBiotech 2009

A conference exploring the global opportunities in nanobiotechnology, nanomedicine, and related science and engineering fields

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- **Delong America (Montreal, Canada)**

October 19, 2009

Center for Biotechnology and Interdisciplinary Studies
Rensselaer Polytechnic Institute, Troy, NY

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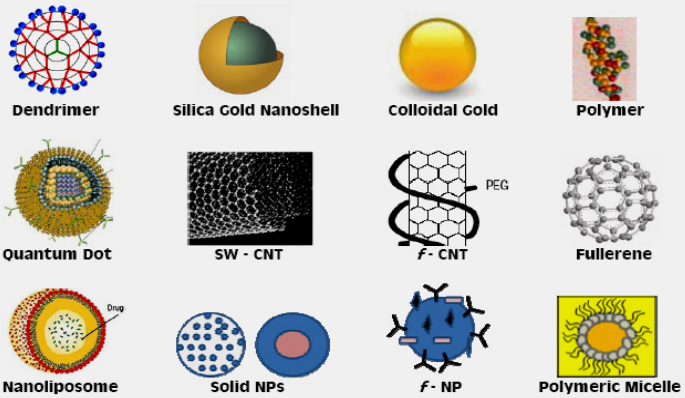

ORGANIZING COMMITTEE

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- Susan Gilbert, PhD - Rensselaer Polytechnic Institute (Troy, NY)
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- Lindsay A. Maurer - Rensselaer Polytechnic Institute (Troy, NY)
- Raj Bawa, MS, PhD - Bawa Biotechnology Consulting (Ashburn, VA); Rensselaer Polytechnic Institute (Troy, NY) *Chair*

Registration Site: http://www.alumni.rpi.edu/nanobio2009.html

WELCOME

Welcome to the *Center for Biotechnology and Interdisciplinary Studies* at Rensselaer Polytechnic Institute for this year's conference titled *NanoBiotech 2009*.

NanoBiotech 2009 is an international multi-disciplinary conference, now in its seventh year, which explores commercialization opportunities of nanotechnology, medicine, pharma, biotechnology and related science and engineering fields. While exploring innovative research and development efforts that are underway globally, presenters at the conference will highlight the urgent need for vigilance with regard to "nanotoxicity." Ethical, business, FDA and patent law issues will also be examined to ensure a fruitful future for the science of manipulating and building at the molecular level.

This conference will offer networking opportunities to researchers, engineers, physicians, ethicists, environmental scientists, intellectual property practitioners, lawyers, business professionals, technology transfer specialists, policy makers and venture capitalists. Please approach them during the conference, especially during the networking luncheon. All presentations will be fast-paced and focused.

Selected papers from the conference will be published in the peer-reviewed journals: *(1) International Journal of Nanomedicine, (2) Journal of Bionanoscience*, and *(3) Nanotechnology Law and Business*. If you have any questions or suggestions regarding *NanoBiotech 2009*, or wish to be a speaker at next year's conference, please contact Dr. Raj Bawa at bawa@bawabiotech.com or 703-582-1745. The kind assistance of Ellen Johnson and Antonette Yamin is gratefully acknowledged.

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CONFERENCE PROGRAM

On-site Registration and Media Interviews: 8:00am – 9:00am

Welcome and Introduction: 9:00am
Jeffrey M. Schanz
Assistant Vice President for Alumni Relations
Executive Director of the Rensselaer Alumni Association
Rensselaer Polytechnic Institute (Troy, NY)

NanoBiotech in Pictures – An Overview: 9:15am
Raj Bawa, PhD
Patent Agent, Bawa Biotechnology Consulting (Ashburn, VA)
Adjunct Associate Professor, Rensselaer Polytechnic Institute (Troy, NY)
Acting Secretary, American Society for Nanomedicine (Ashburn, VA)

Keynote 1: 9:30am – 10:00am
Biocatalysis – A Natural Marriage of Life Sciences and Nanotechnology
Jonathan S. Dordick, PhD
Director of the Center for Biotechnology and Interdisciplinary Studies
Howard P. Isermann Professor, Department of Chemical and Biological Engineering
Professor, Department of Biology, Rensselaer Polytechnic Institute (Troy, NY)

Keynote 2: 10:00am – 10:30am
Control of Growth and Differentiation of Cells with Physical Interaction
Rutledge Ellis-Behnke, PhD
Associate Professor, Department of Anatomy
University of Hong Kong (Hong Kong SAR, China) and
Research Affiliate, Department of Brain and Cognitive Sciences
MIT (Cambridge, MA)

Session 1: Innovations in NanoBiotech
10:30am – 11:30am
Chair: Raj Bawa, MS, PhD, Patent Agent, Bawa Biotechnology Consulting, Ashburn, VA, Adjunct Associate Professor, Rensselaer Polytechnic Institute, Troy, NY, and Acting Secretary, American Society for Nanomedicine, Ashburn, VA

Toward an Artificial Golgi –
Redesigning the Biological Activities of Heparan Sulfate on a Digital Microfluidic Chip
Robert J. Linhardt, PhD
Ann and John Broadbent, Jr. '59 Senior Constellation Professor
Professor of Chemical and Biological Engineering
Professor of Chemistry and Chemical Biology
Professor of Biology
Rensselaer Polytechnic Institute (Troy, NY)

Protein Systems for Bionanoelectronics and Biofuel Cell Applications
Gerald F. Audette, PhD
Associate Editor, Journal of Bionanoscience
Assistant Professor, Department of Chemistry and
Centre for Research on Biomolecular Interactions
York University, Toronto (Canada)

Advances in Cryopreservation by Vitrification
Milton Chin, MS, MBA
President, Vitriscience LLC (Trumbull, CT)

Nanocarrier Delivery of siRNA and MicroRNA – Promises of Cancer Gene Therapy
Jagat R. Kanwar, PhD
Associate Professor of Immunology and Cell Biology
Institute of Biotechnology, Deakin University (Australia)

Networking Coffee Break (15 minutes)

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Session 2: Commercializing New Technologies
11:45pm – 12:45pm

Co-Chairs: Theodore Hagelin, JD, LLM, Crandall Melvin Professor of Law and Director of the New York State Science and Technology Law Center, Syracuse University College of Law, Syracuse, NY
Ronald Kudla, PhD, MBA, Executive Director, Office of Intellectual Property, Technology Transfer and New Ventures, Rensselaer Polytechnic Institute, Troy, NY

Commercializing University Inventions
Theodore Hagelin, JD, LLM
Crandall Melvin Professor of Law
Director, New York State Science and Technology Law Center
Syracuse University College of Law (Syracuse, NY)

Commercializing Medical Devices – How to Get From Here to There
Joseph D. Bronzino, PhD, PE
The Vernon Roosa Professor of Applied Sciences, Trinity College (Hartford, CT)
President and Executive Director, Biomedical Engineering Alliance and Consortium (Hartford, CT)
Editor, The Biomedical Engineering Handbook (CRC Press)

CNSE Nanobioscience – Overview and Case Study
James Castracane, PhD
Professor, Head of Nanobioscience Constellation
College of Nanoscale Science and Engineering (CNSE)
University at Albany-SUNY (Albany, NY)

A Solution to the Worldwide Organ Shortage
Lauren Brasile, PhD
Executive Vice President and Chief Scientific Officer
Breonics, Inc. (Albany, NY)

Networking Lunch: 12:45pm – 1:40pm

Raffle Drawings – 1:40pm

Keynote 3: 1:45pm – 2:15pm
A Tumor-targeting Nanodelivery Platform in Clinical Trials
Esther H. Chang, PhD
Professor of Oncology, Lombardi Cancer Center
Georgetown University Medical Center (Washington, DC)
Acting President, American Society for Nanomedicine (Ashburn, VA)

Keynote 4: 2:15pm – 2:45pm
Nanomedicine – Where Have We Been And Where Are We Going?
Thomas J. Webster, PhD
Associate Professor, Division of Engineering and Orthopedics
Editor, International Journal of Nanomedicine
Co-director, Indo-US Center for Biomaterials for Healthcare
Brown University (Providence, RI)

Session 3: Patent Law, Regulatory Issues and Nanoethics
2:45pm – 4:15pm

Chair: Leon Radomsky, MS, JD, Partner and Chair, Nanotechnology Industry Team, Foley & Lardner LLP, Washington, DC

FDA's Regulation of Nanotechnology – Controversies and Impacts on Nanomedicine
Ricardo Carvajal, MS, JD

Of Counsel
Hyman, Phelps & McNamara (Washington, DC)
Former Associate Chief Counsel, Office of Chief Counsel, FDA (Silver Spring, MD)

Ten Best Practices to Commercialize Your Invention (What Investors Look For)
Leon Radomsky, MS, JD
Partner
Chair, Nanotechnology Industry Team
Foley & Lardner LLP (Washington, DC)

Patent Procurement and Enforcement in the US
William J. Simmons, PhD, JD
Associate
Sughrue Mion, PLLC (Washington, DC)

The Ethical Dimensions of Nanotechnology
Summer Johnson, PhD
Executive Managing Editor
The American Journal of Bioethics (New York, NY)

Intellectual Property Mapping – A Corner Stone of Long Term IP Strategy
Jeffery P. Langer, PhD
Patent Agent
Finnegan, Henderson, Farabow, Garrett & Dunner LLP (Washington, DC)

Legislative Issues Effecting the Development of Nanotechnology
Robert T. Dombrowski, MS
President/Principal Scientist
Nanoview Associates LLC (East Brunswick, NJ)

Session 4: Environmental, Health and Safety Issues
4:15pm – 5:15pm

Chair: Sara Brenner, MD, MPH, Assistant Vice President for NanoHealth Initiatives and Assistant Professor of Nanobioscience, UAlbany College of Nanoscale Science & Engineering, Albany, NY

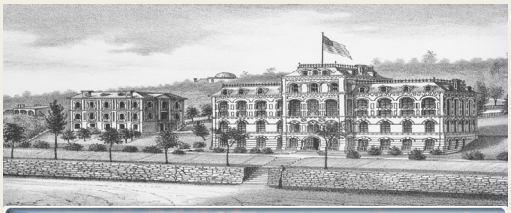
Biosafety and Health Concerns Associated with NanoBiotech Research
Glenn Monastersky, PhD
Director of Operations and Associate Director
Center for Biotechnology and Interdisciplinary Studies
Rensselaer Polytechnic Institute (Troy, NY)

Biological and Toxicological Impact of Nanomaterials –
Urgent Needs for Health Hazard Assessments
Alok Bhushan, PhD
Professor and Assistant Chair
James C.K. Lai, PhD
Professor of Pharmacology and Toxicology
Department of Biomedical & Pharmaceutical Sciences, College of Pharmacy
Idaho State University (Pocatello, ID)

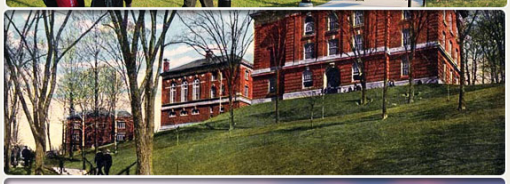
Current Environmental Law Issues in Nanotechnology
John Monica, JD
Partner
Head, Environmental Law Group
Porter Wright LLP (Washington, DC)

Pharmaceutical Nanoexcipients – Balancing Toxicity and Safety
Marianna Foldvari, DPharmSci, PhD
Canada Research Chair in Bionanotechnology and Nanomedicine
Professor of Pharmaceutical Sciences
Associate Editor, Nanomedicine: NBM
University of Waterloo (Canada)

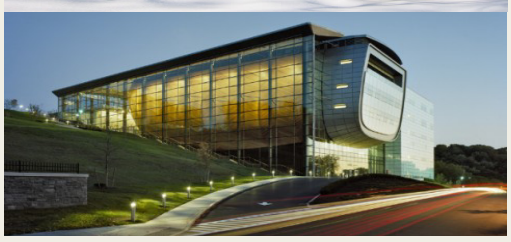
Conclusion of Conference – 5:15pm











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Rensselaer Polytechnic Institute, founded in 1824 and located in Troy, NY, is the nation's oldest technological university. The school offers degrees in engineering, the sciences, information technology, architecture, management, and the humanities and social sciences. Rensselaer faculty is known for pre-eminence in research conducted in a wide range of research centers that are characterized by strong industry partnerships. The Institute is especially well known for its success in the transfer of technology from the laboratory to the marketplace so that new discoveries and inventions benefit human life, protect the environment and strengthen economic development. *U.S. News & World Report* consistently places Rensselaer among the nation's top 50 universities. Rensselaer's undergraduate engineering program continues to be rated among the top 25 in the country. The Rensselaer faculty of over 450 members includes National Science Foundation Presidential Faculty Fellows, members of the National Academy of Engineering, the National Academy of Sciences, and other eminent professional organizations.

Bawa Biotechnology Consulting is a biotechnology consulting and patent law firm based in Ashburn, VA. The firm, founded in 2002, has broad expertise in biotechnology, nanotechnology, drug delivery, medical devices, HIV/AIDS, and biodefense-related scientific, legal and business issues. In addition, the firm specializes in all aspects of biotechnology, chemical and pharmaceutical patent law, including prosecution, application drafting, prior art searching, freedom-to-operate searching and technology research opinions. Currently, Bawa Biotechnology Consulting, LLC represents both national and international clients from industry, academia and government. The firm is dedicated to providing its customers with personalized, cost-effective service that is of the highest quality.

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Finnegan is dedicated to protecting the ideas and innovations that drive businesses around the world. With 350 lawyers, nine offices, and four decades of experience focusing solely on intellectual property law, Finnegan offers intellectual property coverage in virtually every technology and product category. Its practice includes all aspects of patent, trademark, copyright, and trade secret law, including counseling, prosecution, licensing, and litigation. Finnegan also represent clients on IP issues related to international trade, portfolio management, the Internet, and government contracts.

Sughrue Mion, one of the world's leading intellectual property law firms, handles a wide range of intellectual property matters for clients around the world. Sughrue Mion has managed traditional and non-traditional intellectual property rights, advocated the proper application of established law and helped create new law. Upon a cornerstone of solid technical knowledge and an equally solid legal foundation, the firm has built a platform where constant exposure to a wide variety of scientific and business developments has positioned them to anticipate advances, adapt the law to new circumstances and maintain our clients' place ahead of the competition.

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American Society for Nanomedicine is a professional non-profit, medical society headquartered in Ashburn, VA. It promotes worldwide seminal research activities in nanomedicine and explores the applications of nanotechnology in the pharmaceutical, device and biotechnology industries. Members also discuss issues such as ethics, toxicity, patents and commercialization. They are drawn from diverse and overlapping fields such as biotechnology, engineering, medicine, policy and law.

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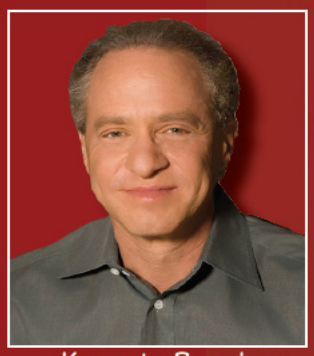

Keynote Speaker
Ray Kurzweil

TOPICS:

1. Telemanagement of Very Small *In Vivo* Devices
2. Technology Development Pathways for Medical Nanobots
3. Nanomedical Structures and Devices in Development Today
4. Nano-Bio Interfaces and Hybrids
5. Nanomedical Functionality
6. Telemedical *In Vivo* Devices in Development Today
7. Telemedical Control of Medical Nanobots
8. Systems Biology to Accelerate Therapeutics

ABSTRACTS:

100 Words, Specific to a Topic. Please Specify Oral or Poster Presentation.

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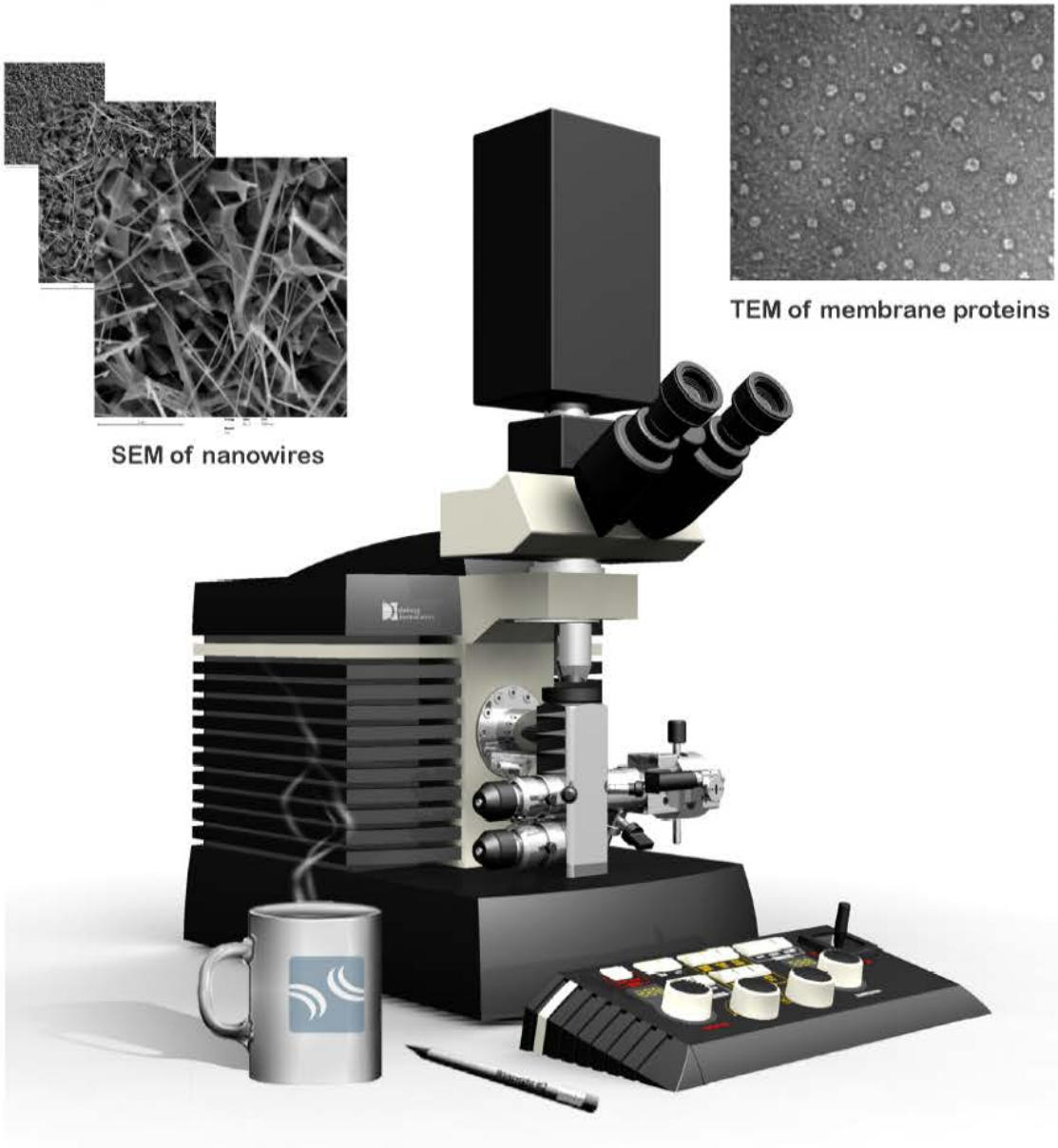

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Nanotechnology Practice

By its very definition, the term "nanotechnology" involves a broad array of technologies. The scientific expertise and legal experience of our Nanotechnology Group spans the range of technical fields necessary to effectively deal with the many applications of nanotechnology, as well as the various types of legal challenges that this unique, multidisciplinary field presents.

With regard to technical expertise, the Group's members have backgrounds in physics, chemistry, biology, health care, computer science, and manufacturing. Many of the Group's members have doctorates in these fields, and have conducted ground-breaking research in microfluidics, self-assembling systems, MEMS, nanoparticles, quantum dots, carbon nanotubes, and other aspects of nanotechnology. Some of them have authored and presented major technical papers on their research, and have received U.S. patents for their inventions.

With regard to legal experience, nanotechnology is no different from other technologies in requiring legal skill in obtaining IP protection, providing counseling as to IP issues, assisting with licensing and other transactions, and, when necessary, asserting or defending against patent claims. However, the unique nature of nanotechnology presents new questions and issues for the patent practitioner. Members of the Group are well qualified to handle such issues by virtue of their experience as Examiners in the U.S. Patent & Trademark Office, as corporate legal counsel, and as experts in patent prosecution, licensing, and litigation.

The Group's scientific expertise is complemented by its legal experience, which enables it to identify patentable applications, draft the necessary documents to define and claim rights to the inventions, advocate and secure patent protection, create strategies to maximize a patent portfolio's value, structure cooperative relationships relating to the development and commercialization of the technology, license or transfer rights to the underlying intellectual property, and enforce the patents in court.

About Finnegan

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP is the world's largest firm focused exclusively on intellectual property law. Each of our 375 lawyers and every member of our support team is an IP professional. Our dedication to providing quality services for our clients has made us a leader in protecting, licensing and enforcing patents, trademarks, trade secrets, and copyrights.

Contact Us

For more information about our Nanotechnology practice, please contact:

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202.408.4109
john.paul@finnegan.com

Ronald Bleeker, Nanotechnology practice group leader
202.408.4030
ronald.bleeker@finnegan.com

Mr. Paul and Mr. Bleeker lead the firm's nanotechnology practice group, each bringing over 25 years of experience in counseling clients and leading teams of attorneys on a full range of intellectual property matters including strategic portfolio management, IP due diligence investigations, prosecution, licensing, and litigation in a wide variety of technologies. Mr. Paul's technical focus has been in the mechanical and electrical areas, and Mr. Bleeker's technical focus has been in the chemical and life sciences area.

Rensselaer Campus Map

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- ▲ Partial Access for the Disabled
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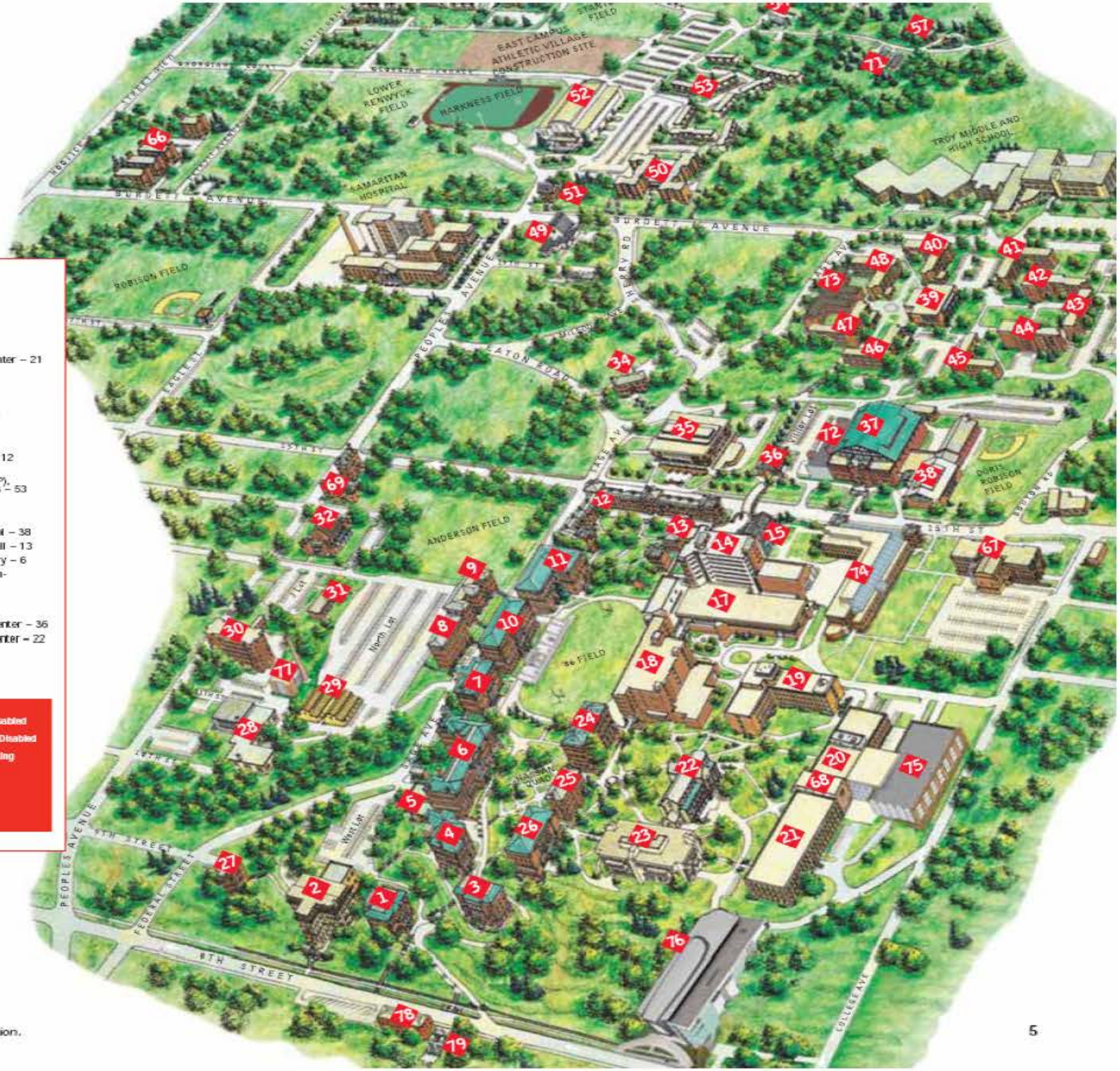
- → Shuttle Route
- ● Shuttle Stop



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Newly formed American Society for Nanomedicine (ASNM) to hold first conference

(Ashburn, Virginia, Sept 4, 2009 /PRNewswire-USNewswire/) Nanomedicine – the science and technology of diagnosing, treating and preventing disease to improve human health using nanotechnology – has the potential to revolutionize healthcare. Current and future products range from miniaturized "smart pills" that precision-target certain cancers to nanosensors that are capable of navigating through the body for early detection of disorders. These approaches have the ability to reduce toxicity for the patient, thereby improving efficacy and patient compliance. The newly formed American Society for Nanomedicine (ASNM) is holding its inaugural conference on October 22-25, 2009 in the Washington DC area, where some of the biggest stakeholders in this emerging technology operate and practice.

This major interdisciplinary international conference is designed for physicians, scientists, policy-makers, engineers, lawyers and educators from government, academia and industry. The conference venue is the Bolger Center in Potomac, Maryland, USA (http://www.dolce-bolger-center-hotel.com/).

This four-day conference will highlight numerous cutting-edge presentations broken up into various sessions focusing on innovations in nanomedicine and applications of nanotechnology to the pharmaceutical, device and biotechnology industries. It will feature more than forty speakers, who are among the top researchers and leaders in various facets of nanomedicine throughout the world. The areas of emphasis are clinical applications of nanotechnology enabling successful vaccine development, effective cancer therapy and novel drug delivery approaches. In addition, issues such as ethics, safety and toxicity, patent law, intellectual property and commercialization will be addressed. Poster sessions, an award ceremony and numerous networking opportunities are included.

About American Society for Nanomedicine
American Society for Nanomedicine (ASNM) is a professional non-profit, medical society headquartered in Ashburn, Virginia, USA. It promotes worldwide seminal research activities in nanomedicine and explores the applications of nanotechnology in the pharmaceutical, device and biotechnology industries. Members also discuss issues such as ethics, toxicity, patents and commercialization. They are drawn from diverse and overlapping fields such as biotechnology, engineering, medicine, policy and law. Members enjoy numerous benefits, including reduced rates to attend ASNM conferences and discounted rates to ASNM-affiliated journals.

Contacts
Dr. Esther Chang, Acting President, American Society for Nanomedicine; Professor of Oncology, Georgetown University Medical Center, 3970 Reservoir Road NW, Washington, DC 20057, USA; Phone: +202 687 8418 esther.chang9@gmail.com

Dr. Raj Bawa, Acting Secretary, American Society for Nanomedicine; President, Bawa Biotechnology Consulting, 21005 Starflower Way, Ashburn, Virginia, USA; Phone: +703 582 1745 bawa@bawabiotech.com

Conference Information/Registration: www.amsocnanomed.org

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Meeting Summary

NanoBiotech 2008: Exploring global advances in nanomedicine

Raj Bawa, MS, PhD*

Bawa Biotechnology Consulting LLC, Ashburn, VA, USA
Biology Department, Rensselaer Polytechnic Institute, Troy, NY, USA

Speakers presenting at *NanoBiotech 2008* (http://www.alumni.rpi.edu/nanobio2008.html) focused on innovations in nanomedicine and applications of nanotechnology to the pharmaceutical and biotechnology industries. While exploring some of the cutting-edge research efforts globally underway, the presenters highlighted the urgent need for vigilance with regard to toxicity. Ethical issues were also explored to ensure a fruitful future for the science of manipulating and building things at the molecular level. This is a popular annual conference, now in its sixth year that is held on the beautiful campus of Rensselaer Polytechnic Institute in Troy, New York, USA (http://www.rpi.edu/). It is multi-disciplinary in nature and attracts world-wide participation for its in-depth focus on pharma, nanomedicine and biotechnology. About 150 researchers, engineers, physicians, ethicists, lawyers, business professionals, policy makers, and venture capitalists attended this year's conference.

NanoBiotech 2008 highlighted 23 cutting-edge presentations broken up into various sessions. The sessions ranged from innovations in nanomedicine to current trends in nanotechnology law and business. Some of the diverse subject matter discussed included nanoparticle-based therapeutics in humans, targeted drug delivery vehicles for tumor angiogenesis, reforming the US patent system, nanobiotechnology patents in Europe, ethical implications of nanomedicine, women in nanotechnology, bio-safety issues of nanoparticles and intellectual property as collateral.

Some of the topics discussed at the conference that are currently transforming medicine, big pharma as well as the biotechnology industry, are highlighted below:

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What is nanotechnology?

During the pre-conference media session, a number of speakers stated that one of the major problems regulators and lawyers face regarding nanotechnology is the confusion and disagreement about its definition. One often used, yet clearly wrong, definition of nanotechnology is that proposed by the U.S. National Nanotechnology Initiative (NNI). It limits nanotechnology to "dimensions of roughly 1 to 100 nanometers." Government agencies such as the FDA and the US Patent & Trademark Office (PTO) continue to use a similar definition based on a scale of less than 100 nm. This NNI definition presents difficulties. For example, although the sub-100 nm size range may be important to a nanophotonic company where quantum effects depend on particle size, this size limitation is not critical to a drug company from a formulation, delivery, or efficacy perspective because the desired property (e.g., improved bioavailability, reduced toxicity, lower dose, enhanced solubility, etc.) may be achieved in a size range greater than 100 nm. In fact, several examples of nanopharmaceuticals on the market or in the process of being introduced by pharma highlight this specific point. In view of this confusion, the following definition of nanotechnology unconstrained by an arbitrary size limitation, has been developed by this author. It was adopted as the official definition for this conference: *"The design, characterization, production, and application of structures, devices, and systems by controlled manipulation of size and shape at the nanometer scale (atomic, molecular, and macromolecular scale) that produces structures, devices, and systems with at least one novel/superior characteristic or property."* The speakers agreed that this definition of nanotechnology should aid regulators, policymakers and lawyers in confronting the legal, patent, ethical, environmental, health and regulatory issues raised by nanotech.

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Advances in nano-drug delivery

This author presented on nanoparticle-based therapeutics (nanopharmaceuticals) in humans. Nanopharmaceuticals are colloidal particles of 10 to 1,000 nanometers (1 micron) that are diverse in size, shape and composition. They often offer an advantage as compared to their "bulk" counterparts primarily because of reduced size (i.e., an enormously increased surface area). Specifically, as a particle's size decreases, a greater proportion of its atoms are located on the surface relative to its core, often rendering the particle more reactive and more soluble in water. Nanopharmaceuticals can be split into two classes: (1) those where the therapeutic molecules are themselves the drug (i.e., the therapeutic compound itself also functions as its own carrier); and (2) those where the therapeutic molecules are directly coupled (functionalized, entrapped, or coated) to a nanoparticle carrier.

In recent years, patent expirations have been driving big pharma to search for new competitive technologies and business strategies. In this regard, drug delivery via nanopharmaceuticals presents novel opportunities for active agents (drugs or genes) that were previously unsuitable for traditional oral or injectable drug formulations. Specifically, nanopharmaceuticals have enormous potential to address the failures of traditional drugs that could not be effectively formulated due to factors such as poor water solubility or a lack of target specificity. As a result, nano-drug delivery allows active agents to be delivered efficaciously while minimizing side effects, thereby enhancing patient compliance.

Although there are only a few FDA-approved nanopharmaceuticals on the market today, these formulations are already impacting medicine and promise to alter healthcare. Based on their ability to reduce time-to-market, extend the economic life of proprietary drugs and create additional revenue streams, nanopharmaceuticals should greatly impact medical practice and healthcare. However, if this is to happen effectively, there are a few key biological requirements for nanopharmaceuticals to fulfill: (i) they must exhibit "stealth" qualities to evade macrophage attack and the immune response; (ii) be nontoxic and traceable; (iii) display effective pharmacokinetic properties; (iv) be biodegradable following systemic administration through any route (but the polymer must protect the embedded active); and (v) they must be selective to be effective in targeting specific tissue sites.

Shelton D. Caruthers, PhD, Associate Director of Cardiovascular MR Laboratories at Washington University School of Medicine (St. Louis, MO) presented on theranostic nanoparticles as image-based biomarkers and targeted drug delivery vehicles for tumor angiogenesis. Dr. Caruthers reported on liquid perfluorocarbon nanoparticles that home in on new blood vessels growing around small tumors. These nanoparticles, visible with magnetic resonance imaging, allow high resolution three-dimensional maps of the new vessels, thus allowing not only the characterization of the tumors, but also the prediction of response of the tumor to anti-angiogenic chemotherapy. The same nanoparticles also deliver and concentrate medicine at the site of tumor growth while minimizing the overall injected drug dose and related side effects.

Jagat R. Kanwar, PhD, Associate Professor of Immunology and Cell Biology at Deakin University (Australia) presented on engineered nanoparticle-based nanopharmaceuticals for cancer therapy. He stated that nanopharmaceuticals offered unique advantages as compared to other small-molecule therapeutics due to relatively large payloads and surface polyvalency. He also highlighted the benefits of site-specific targeting of these therapeutics, thereby reducing systemic side-effects as compared to conventional anticancer agents.

Glenn Monastersky, PhD, Director of Operations, Center for Biotechnology and Interdisciplinary Studies at Rensselaer Polytechnic Institute (Troy, NY) presented on safety issues and biocompatibility of engineered nanoparticles.

Neeraj Vij, PhD, Assistant Professor in the Department of Pediatrics-Pulmonary at Johns Hopkins University School of Medicine (Baltimore, MD) presented on challenges of nano-delivery in airway diseases. According to him, one of the biggest challenges in designing novel therapeutic nano-delivery systems for chronic airway inflammatory diseases like cystic fibrosis, COPD, asthma and chronic bronchitis is the mucus barrier. Given this, his lab is focusing on delivery systems that can not only bypass the mucus barrier but also are biodegradable, non-inflammatory and provide sustained drug or gene delivery.

Metabolic fate of nanopharmaceuticals

Srikumaran Melethil, PhD, JD, Chair and Professor of Pharmaceutical Sciences at the University of Findlay (Findlay, OH) discussed the metabolic fate of nanopharmaceuticals upon delivery to the human body. He presented pharmacokinetic data relating to numerous nanoparticulate drugs and highlighted the critical role of the FDA in nanomedicine. According to him, further knowledge of how the human body transports, distributes and clears nanoparticles via the vascular and lymphatic systems (i.e., biodistribution of nanoparticles) is also needed to get a handle on metabolic and toxicity issues.

Nanocapsule delivery for gene therapy of cancer

Esther H. Chang, PhD, Professor of Oncology at Georgetown University School of Medicine (Washington, DC) in her keynote address presented recent research efforts (with collaborator Dr. Kathleen Pirollo) on developing a tumor-targeting nanocapsule delivery system for use in nanomedicine. These nanoscale virus-like particles are composed of a cationic lipid capsule surrounding the payload, with an anti-transferrin receptor single chain antibody fragment (TfRscFv) decorating the surface which

serves as the tumor targeting moiety. The presence of the TfRscFv moiety bestows exquisite tumor specificity when administered through the blood stream, targeting and efficiently delivering its payload to metastatic as well as primary cancer cells wherever they reside in the body, including in the brain. This agent is being evaluated in a Phase I, dose escalation trial which began in 2008 at the Mary Crowley Medical Research Center in Dallas under the direction of Dr. John Nemunaitis. This is a platform technology with a variety of potential applications because these nanocapsules can be employed to deliver a variety of molecules as the payload.

A battery device powered by blood, sweat or tears

Robert Linhardt, PhD, Senior Constellation Professor of Biocatalysis and Metabolic Engineering at Rensselaer Polytechnic Institute (Troy, NY) in his keynote address discussed how researchers in his lab have combined the anticoagulant drug heparin with cellulose to fabricate a membrane that can be used in kidney dialysis or for other filtering applications. He indicated that this membrane is also a step towards developing a "paper battery," where the membrane is strengthened with carbon nanotubes and then folded over to create a capacitor or battery upon incorporation of an electrolyte. This battery is now being developed further into an energy storage device that could be implanted in the body and powered by the body's own electrolytic fluids. The battery can be used to operate everything from pacemakers to defibrillators.

NASA space technology for microbe detection

Neil Gordon, MBA, PEng, President and CEO of Early Warning, Inc. (Montreal, Canada) in his keynote address presented on NASA's revolutionary biosensing nanotechnology for detecting pathogenic microbes during space missions and how this technology was being commercialized by his company for applications on Earth. He described how its soon-to-be-marketed biohazard analyzer will rapidly detect specific pathogens on a chip to reduce illnesses from contaminated water and food.

Ethical issues in nanomedicine

Ginger Gruters from the President's Council on Bioethics (Washington, DC) presented on ethical considerations that are likely to play a significant role in nanomedicine. She stated that, as with other biomedical advances coming before it, nanomedicine will face significant ethical challenges as it moves from proof-of-concept to the clinic. Along the way, ethical questions regarding social justice, privacy and confidentiality, long-term risks and benefits, and human enhancement are certain to arise.

Women in nanotechnology

Annette I. Kahler, JD, Director of the Science & Technology Law Center at Albany Law School (Albany, NY) presented on the role of women in the nanotech revolution. With nanotech workforce needs anticipated to grow from the currently available 20,000 researchers to more than 2 million in the next 15 years, the talk focused on the tremendous opportunities available for women to enter and advance in the field and overcome traditional barriers facing women in science, technology and engineering fields.

Recent developments in nano-patent law

Leon Radomsky, MS, JD, Partner and Chair of the Nanotechnology Industry Team at Foley & Lardner LLP (Washington, DC) presented on what impact pending patent reform legislation and rulemaking would have on nanotech start-ups and universities. He also pointed out that, due to the potential market value of nanomedical products, every entity in the international race for technological dominance views patents as critical and is making every effort to obtain the broadest protection possible for new nanoscale polymers, devices, and systems.

David M. Longo, PhD, JD, Associate at Finnegan LLP (Washington, DC) spoke on current case law pertaining to nanotechnology. Jeffery P. Langer, PhD, Patent Agent at Finnegan LLP (Washington, DC) discussed the use of intellectual property as a financial asset and its role in creating value for start ups and high tech companies. Kurt Ehresman, JD, Co-chair of the Patent Services Group at Saul Ewing LLP (Harrisburg, PA) discussed the various modes of making nanotechnology intellectual assets attractive to investors.

Robert Harrison, PhD, JD, Partner at 24IP Law Group (Munich, Germany) reported on research that he had done showing that US companies have consistently filed about 50% of patents relating to nanobiotech in Europe over the past ten years. He indicated that based on his patent prosecution experience, all major patent offices want to see evidence of novel, unexpected features or properties in the filed nanobiotech patent application before granting a patent.

Conclusions and outlook

Nanomedicine will eventually become an integral part of mainstream medicine and a standard in the drug industry. For example, the market impact of nanopharmaceuticals on the pharmaceutical and biotech industries is already being felt. However, for nanomedicine to be a viable commercial entity, desperately needed reforms to overhaul the PTO along with clearer regulatory guidelines and safety standards from federal agencies such as the FDA will be needed.

Nanotech audience gets business advice

Applied BioPhysics chief recounts firm's early struggles

The Daily Gazette (Schenectady, NY)

September 26, 2006, Section: A: Business, Edition: Schenectady/Albany; Final, Page: A6
MICHAEL MULLANEY, Gazette Reporter

Nobel Prize Laureate Ivar Giaever shared three bits of advice with the crowd of students, scientists and entrepreneurs attending Rensselaer Polytechnic Institute's Nanotechnology 2006 conference Monday morning. First, before even trying to start a technology company, hire a lawyer. Then hire an accountant. Finally, hire a marketing specialist -- someone as good or better than the guy who made $1 million selling Pet Rocks in the 1970s, Giaever suggested. "You can still buy those on eBay," he said Monday. "They key is marketing." Giaever, a physicist who received his doctorate from Rensselaer in 1964, is co-founder and president of Applied BioPhysics in Troy. He opened the two-day nanotechnology conference with candid words about the humble beginnings of his 15-year-old company, which sells nanotech-powered machines made to investigate the invasive nature of cancer cells.

The firm was only a few months old when New York State fined Giaever and his partner $20,000 for missing a tax payment deadline. They also encountered difficulty securing grants because the work they were doing was an interdisciplinary combination of biology and physics. And it also wasn't long before the pair found faults with the old adage claiming that if you build a better mousetrap, people will beat a path to your door. "Unfortunately, this is not true," Giaever said. But what about another old myth claiming that scientists are not good at running a business? "Unfortunately, this is true," he said, getting a chuckle out of the crowd. Applied BioPhysics is still plugging along today. Giaever and his team now have several models of their flagship Electric Cell-substrate Impedance Sensing machine, which allows researchers to track in real time the activities of cells stimulated by electricity. He's hopeful that the technology will one day provide a map for doctors to objectively test whether cancer cells are malignant or benign. "Today, there's no simple way to diagnose cancer," Giaever said. The current method for diagnosing cancer involves a doctor looking at a biopsy and noting if the cells are healthy and growing in a clear pattern, or cancerous and growing randomly. "It's completely subjective," he said. Giaever marveled at the strength of nanotech to further human innovation, but balked at the recent splurge of publicity and hype surrounding the industry. He said nanotech is as old as life itself, and that the bulk of biological, physical and chemical systems have always functioned on the nano level. The way living cells -- and now scientists in labs -- can replicate DNA is a prime example, he said. By simply putting the right ingredients together and mixing them together, you can build the building blocks of living organisms. "Imagine putting car parts in a big box" and shaking it up. "You can't make a car that way," he said. "Life is an example that nanotechnology works."

Other speakers at the conference Monday tackled topics ranging from the emerging environmental considerations surrounding nanotechnology to using nanotech for treatments aimed at returning the sight of patients suffering brain damage-induced blindness. Raj Bawa, chair of the conference, who heads his own consulting firm out of Ashburn, Va., and advises Rensselaer on legal issues, agreed with Giaever and said nanotechnology is wildly promising but often overblown in media and industry reports. Last year, the government has spent $4.6 billion on nanotechnology research while private industry has spent $4.3 billion, Bawa said. Venture capitalists, meanwhile, have sunk only $497 million into nanotech. Together, the total $9.5 billion is formidable but still pales in comparison to the $189 billion spent in the 1960s to put a man on the moon, he said.

Bawa said the industry is just now breaching threshold of nanotechnology's promise. Nanotechnology's role in creating stain-free pants and strong tennis rackets has made headlines over the past two years, but he expects a forthcoming "golden era" of nanotech to bring real breakthroughs in medicine, electronics and biotechnology.

Reach Gazette reporter Michael Mullaney at 395-3198 or *mmullaney@dailygazette.net*

What is nanotechnology?

European Commission on Nanotechnology

*Nanotechnology is the study of phenomena and fine-tuning of materials at atomic, molecular and macromolecular scales, **where properties differ significantly from those at a larger scale**.*

Raj Bawa

*The design, characterization, production and application of structures, devices and systems by **controlled manipulation** of size and shape at the nanometer scale (atomic, molecular and macromolecular scale) that produces structures, devices and systems with **at least one novel/superior characteristic or property**.*

Zyvex Corporation

When it's unclear from the context whether we're using the specific definition of "nanotechnology" (given here) or the broader and more inclusive definition (often used in the literature), we'll use the terms "molecular nanotechnology" or "molecular manufacturing." Whatever we call it, it should let us, (i) Get essentially every atom in the right place. (ii) Make almost any structure consistent with the laws of physics that we can specify in molecular detail, and (iii) Have manufacturing costs not greatly exceeding the cost of the required raw materials and energy.

Center for Responsible Nanotechnology

*A basic definition is: **engineering of functional systems at the molecular scale**. This covers both current work and more visionary concepts. More narrowly, 'nanotechnology' refers to the projected ability to construct items from the bottom up, using techniques and tools being developed today to make complete, highly advanced products.*

Dr. K.E. Drexler from his Paper, "Nanotechnology: From Feynman to Funding"

Although now used more broadly, the term nanotechnology has been used since the mid-1980s to label a vision first described by Richard Feynman in his classic talk, "There's Plenty of Room at the Bottom" (R. Feynman, 1961). The Feynman vision (and rhetoric echoing it) motivated the U.S. National Nanotechnology Initiative (NNI). An early NNI document (National Science & Technology Council [NSTC], 2000) stated under "Definition of Nanotechnology" that "the essence of nanotechnology is the ability to work at the molecular level, atom by atom, to create large structures with fundamentally new molecular organization." An NNI promotional brochure (NSTC, 1999) spoke of "Feynman's vision of total nanoscale control," calling it "the original nanotechnology vision." In his speech proposing the NNI, President Clinton (2000) invoked this vision on Feynman's home ground: "My budget supports a major newNational Nanotechnology Initiative, worth $500 million. Caltech is no stranger to the idea of nanotechnology —the ability to manipulate matter at the atomic and molecular level."

The US National Nanotechnology Initiative (NNI)

Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications.

The US Nanotechnology Research and Development Act of 2003, Section 2(5)

The term 'nanotechnology' means science and engineering aimed at creating materials, devices, and systems at the atomic and molecular level.

Welcome and Introduction

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Jeff Schanz is currently the Assistant Vice President for alumni relations at Rensselaer Polytechnic Institute in Troy, N.Y. and Executive Director of the Rensselaer Alumni Association. Mr. Schanz joined Rensselaer in 2000 and served as Associate Director of Alumni Relations prior to his appointment to Director of Alumni Relations in 2003 and Annual Giving in 2006. Under his direction Rensselaer alumni programs have received fourteen national and district awards from Council for the Advancement and Support for Education (CASE) for student programs, alumni communications, career assistance, volunteer relations and special interest groups.

Mr. Schanz is a regular speaker at professional conferences and has presented on a number of topics, including the importance of advancement communities of best practice, benchmarking in alumni relations and the role of special interest groups in alumni programs. Mr. Schanz also serves as Chair of the CASE Newcomers Conference on alumni relations. He is a member of the board of directors of the Association of Private College and University Alumni Directors (PCUAD), where he maintains the group's assessment and metrics database. He is a longtime supporter of his alma mater, Marist College, where he is currently the president of the alumni association and alumni representative to the Marist College Board of Trustees. He received a Bachelors of Arts in Political Science and a Master of Public Administration from Marist College, as well as earning a Masters of Science in Educational Administration and Policy Studies from the University at Albany in Albany, NY.

NanoBiotech in Pictures – An Overview

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Dr. Raj Bawa is President of Bawa Biotechnology Consulting LLC, a biotechnology and patent law firm founded in 2002 and based in Ashburn, Virginia. He is a biochemist and microbiologist by training and is a registered patent agent licensed to practice before the US Patent and Trademark Office (PTO). He specializes in all aspects of biotechnology, nanotechnology and pharmaceutical patent law, including prosecution, patent strategy, application drafting, prior art searching, freedom-to-operate searching and technology research opinions. Currently, Dr. Bawa is an Adjunct Associate Professor at Rensselaer Polytechnic Institute in Troy, New York as well as an Adjunct Professor of Natural and Applied Sciences at the Extended Learning Institute of Northern Virginia Community College in Annandale, Virginia. Previously he held various positions at the PTO, including Primary Examiner (6 years); Supervisory Patent Examiner (acting); and Instructor at the US Patent Academy. Dr. Bawa has served as an NIH grant reviewer and participated in NSF's merit review process. He has authored 65 scientific, legal and business publications and has presented at over 100 conferences and symposia worldwide. He is a Life Member of Sigma Xi, Founding Director and Secretary (acting) of the American Society for Nanomedicine, Advisory Board Member for the Albany Law School Center for Law & Innovation and serves on the Global Advisory Council of the World Future Society.

Presently, Dr Bawa currently serves on the editorial boards of the following peer-reviewed journals: *International Journal of Nanomedicine*, *Cancer Nanotechnology: Basic, Translational and Clinical Research, Recent Patents on Biomedical Engineering, Nanotechnology Law and Business*. He is an Associate Editor of two peer-reviewed journals: *Journal of Bionanoscience* and *Nanomedicine: NBM*. He is a Co-Editor of a book titled *Clinical Nanomedicine - from Bench to Bedside* (Pan Stanford Publishing, 2010), *Nanotechnology – Law, Business and Commercialization* (Pan Stanford Publishing, 2010) and the Section Editor of the *Biomedical Engineering Handbook, 4th edition* (CRC Press/Taylor Francis, 2011). His biographical record appears in the 2009 edition of *Marquis Who's Who in the World*. Some of Dr. Bawa's awards include: Innovations Prize from the Institution of Mechanical Engineers, London, UK (2009); Appreciation Award from the Undersecretary of Commerce, Washington, DC (2001); Talbot Travel Award of the US Biophysical Society (1988); Research Fellowship and Teaching Assistantship from Rensselaer (1985-90); Director's Award (2001) and Key Award (2005) from Rensselaer's Office of Alumni Relations.

Abstract:

New paradigms are shrinking our world and a classic technological revolution in medicine is unfolding. Nanomedicine is the science and technology of diagnosing, treating and preventing disease and improving human health, using nanotechnology. One of the greatest impacts of

nanomedicine is taking place in the context of drug delivery where novel nanotherapeutics and nanocarriers are addressing various fundamental problems of traditional drugs ranging from

poor water solubility, toxicity issues, low bioavailability and a lack of target specificity. This is coupled with the fact that there are numerous market forces and drivers dictating a change in pharma's current business models to those that increasingly rely on miniaturization, nanotechnology and high-throughput. Clearly, new ground rules and competitive business strategies are needed in the post-blockbuster world.

With this backdrop, my presentation will highlight:

- Nanotechnology and nanomedicine? – definitions, hype, realities and trends;
- Commercial activity in the nanodrug delivery space – size-driven innovations in pharmaceutical drug delivery technologies and medical devices (FDA-approved or in clinical testing);
- Patenting nanotherapeutics in light of the current "patent gold rush" and emerging "patent thickets" – critical issues, strategies, challenges and opportunities; and
- Impact and interplay of federal bodies (FDA, US Patent Office, Congress) on commercialization efforts in nanomedicine.

Biocatalysis –
A Natural Marriage of Life Sciences and Nanotechnology

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Biography:

Dr. Dordick received his B.A. degree in Biochemistry and Chemistry from Brandeis University and his Ph.D. in Biochemical Engineering from the Massachusetts Institute of Technology. He has held chemical engineering faculty appointments at the University of Iowa (1987-1998), where he also served as the Associate Director of the Center for Biocatalysis and Bioprocessing, and Rensselaer Polytechnic Institute (1998-present) where he is the Howard P. Isermann Professor of Chemical and Biological Engineering and Professor of Biology. In 2008 he took over as Rensselaer's Director of the Center for Biotechnology & Interdisciplinary Studies. Dr. Dordick has received numerous awards, including the 2007 Marvin J. Johnson Award, the 2007 Elmer Gaden Award, the 2003 International Enzyme Engineering Award, the 1998 Iowa Section Award of the American Chemical Society and an NSF Presidential Young Investigator Award in 1989. He was elected as a Fellow of the American Association for the Advancement of Science in 2004 and a Fellow of the American Institute of Medical and Biological Engineers in 1996. He presently serves on the scientific advisory boards for several biotechnology companies and venture capital firms. Dr. Dordick was a cofounder of EnzyMed, Inc. a pharmaceutical and agrochemical discovery company acquired by Albany Molecular Research in 1999, and is a cofounder of Solidus Biosciences, Inc., a venture-stage human drug and cosmetics toxicology company. Dr. Dordick has published 240 papers and is an inventor or co-inventor on 32 patents and patent applications.

Control of Growth and Differentiation of Cells with Physical Interaction

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Rutledge Ellis-Behnke is Associate Director of the Technology Transfer Office at the University of Hong Kong, as well as an Associate Professor at the University's Li Ka Shing Faculty of Medicine's Department of Anatomy; State Key Lab for Brain and Cognitive Sciences; and Research Centre of Heart, Brain, Hormone and Healthy Aging. He is also a Research Affiliate in the Brain and Cognitive Sciences Department at MIT. His primary interest is using nanobiotechnology to reconnect disconnected parts of the central nervous system. He received his PhD in Neuroscience from MIT, BS from Rutgers University and graduated from Harvard Business School's International Senior Manager's Program (AMP/ISMP). Prior to returning to school to pursue his PhD, Ellis-Behnke held various management positions including Senior Vice President of a public company for testing and consulting services and Co-founder/CEO in 1995 of one of the first internet companies to do online commerce in computer memory. Ellis-Behnke is Associate Editor/Neurology for the journal *Nanomedicine: NBM,* member of the Board of Directors and the Scientific Advisory Board for the Glaucoma Foundation, member of the China Spinal Cord Clinical Trial Network, Society for Neuroscience, American Chemical Society, Association for Research in Vision and Ophthalmology and Sigma Xi. *Technology Review* named his nanotechnology discoveries one of the "Top 10 Emerging Technologies of 2007." In addition to his work in neuroscience and nanomedicine, Ellis-Behnke introduced the TabletPC to MIT and the University of Hong Kong as part of the migration to the paperless classroom to deliver all course material and texts to the students digitally.

Abstract:

Structure drives function, and function can be transformed by the modulus of the structure. Within the emerging field of stem cells there is a need for an environment that can regulate cell activity, to slow down differentiation or proliferation, *in vitro* or *in vivo* while remaining invisible to the immune system. By creating a nano environment surrounding PC12 cells, Schwann cells and neural precursor cells (NPCs), we were able to control the proliferation, elongation, differentiation and maturation *in vitro*. The method was extended, using self-assembling nanofiber scaffold (SAPNS), to living animals with implants in the brain and spinal cord. That the cells can survive in a serum-free (SF) condition is very beneficial because it provides much greater control over the medium chosen to grow the cells *in vivo*, before implanting them into

tissue. In culture, using disassociated hippocampal cells from embryonic animals, lower branching rates were observed in the SF conditions, signaling that the growth and differentiation of the cells can be controlled by the physical structure. In every cell type tested SF branching was a fraction of what was found for the serum-added condition. By manipulating the cell density and SAPNS concentration the nano environment surrounding PC12 cells, Schwann cells and NPCs were able to be controlled, thereby controlling the proliferation, elongation, differentiation and maturation *in vitro*. Control of the nano environment using SAPNS was also extended to implants in the brain and spinal cord without cells. Conclusion: when cells are placed in a defined system their proliferation, differentiation and maturation can be delayed, depending on the density of the cell population, density of the matrix, and the local environment.

Toward an Artificial Golgi – Redesigning the Biological Activities of Heparan Sulfate on a Digital Microfluidic Chip

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Biography:

Robert J. Linhardt received his B. S. from Marquette University (1975), his Ph.D. degree from the Johns Hopkins University (1979) and was a postdoctoral student with Professor Robert Langer at the Massachusetts Institute of Technology (1979-1982) and served on the faculty of University of Iowa from 1982-2003. Dr. Linhardt is currently the Ann and John H. Broadbent, Jr.'59 Senior Constellation Professor of Biocatalysis and Metabolic Engineering at Rensselaer Polytechnic Institute, holding joint appointments in the Departments of Chemistry and Chemical Biology, Biology and Chemical and Biological Engineering. He also currently holds an Adjunct Professor appointment at Albany College of Pharmacy. His honors include the University of Iowa F. Wendell Miller Distinguished Professorship, Teaching Award and Iowa Regents Award for faculty excellence. He received the American Chemical Society Horace S. Isbell Award in carbohydrate chemistry. Dr. Linhardt has received the highest award available in Pharmaceutical Sciences, the AACP Volwiler Research Achievement Award, as well as the highest award in Carbohydrate Chemistry, the Claude S. Hudson Award from the American Chemical Society. His research focuses on the structure and activity of heparin and the pharmaceutical application of enzymology in the fields of glycobiology, glycochemistry and glycoengineering. Since his arrival at Rensselaer, Dr. Linhardt has been actively involved in the emerging field of nano-biotechnology focused on developing an artificial Golgi and cellulose-based energy storage devices. In 2008, he co-founded The Paper Battery Company. Professor Linhardt has published over 475 peer-reviewed manuscripts and holds over 36 patents. Dr. Linhardt served as the Acting Director of the Rensselaer Center for Biotechnology and Interdisciplinary Studies from 2006-2008.

Abstract:

Using digital microfluidics, recombinant enzyme technology, and magnetic nanoparticles, we have created a functional prototype of an artificial Golgi organelle. Analogous to the natural Golgi, which is responsible for the enzymatic modification of glycosaminoglycans immobilized on proteins, this artificial Golgi enzymatically modifies glycosaminoglycans, specifically heparan sulfate (HS) chains immobilized onto magnetic nanoparticles. Sulfo groups were transferred from adenosine 3′-phosphate 5′-phosphosulfate to the 3-hydroxyl group of the D-glucosamine residue in an immobilized HS chain using D-glucosaminyl 3-*O*-sulfotransferase. After modification, the nanoparticles with immobilized HS exhibited increased affinity for

fluorescently labeled antithrombin III as detected by confocal microscopy. Since the biosynthesis of HS involves an array of specialized glycosyl transferases, epimerase, and sulfotransferases, this approach should mimic the synthesis of HS *in vivo*. Furthermore, our method demonstrates the feasibility of investigating the effects of multienzyme systems on the structure of final glycan products for HS-based glycomic studies. This microfluidic prototype of an artificial Golgi organelle mimics part of the little-understood cellular component's role in the posttranslational protein glycosylation.

Protein Systems for Bionanoelectronics and Biofuel Cell Applications

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Biography:

Dr. Gerald F. Audette is an Assistant Professor in the Department of Chemistry at York University in Toronto, Canada. His research takes a multi-faceted approach in which X-ray crystallography and other biophysical methods are coupled with functional biochemical studies to produce a comprehensive view of the protein's role within its biochemical context. Current research directions in his laboratory include structure/function studies of proteins involved in bacterial conjugation (lateral gene transfer) systems, the characterization and development of protein-based nanosystems for applications in bionanotechnology, and the development of protein nanocomposite systems for alternate energy development. His research, currently funded by the Natural Sciences & Engineering Research Council of Canada (NSERC) and the Canadian Foundation for Innovation (CFI), has been published in international journals including *Biochemistry*, the *Journal of Molecular Biology*, *Microbiology*, and *Nano Letters*. Dr. Audette is a member of the Centre for Research in Biomolecular Interactions at York University, and is an Associate Editor of the *Journal of Bionanoscience*.

Abstract:

Bio-fuel cells (BFC) are energy-conversion devices based on bio-electrocatalysts leveraging on enzymes or micro-organisms, which derive electrical power through the biochemical catalysis of substrate molecules. Long-term objectives of BFC development is for the use in powering small implantable devices such as glucose monitors, pacemakers or bladder control valves. A challenge in BFC development is the adaptation of targeted enzymes for use in BFCs through interaction with inorganic conducting components and increasing working lifetimes. Indeed, the two largest obstacles with BFCs that must be overcome are increasing the power density and preserving the structural integrity of the enzyme in carbon nanotube (CNT) adducts/composites. Understanding the determinants governing the direct electron transfer from the enzyme to a CNT backbone, the mutation of enzymes to tune the redox potential, etc. are critical to the development and commercialization of enzyme-based BFCs. Dr. Audette's group is currently focusing on the enzyme Glucose Oxidase (GOx) as a model system for the development of protein-CNT composites for BFC design and development. He will present some promising data towards the increasing of desired power density in these GOx-CNT nanocomposites, and discuss the on-going challenges and approaches to GOx-based BFC development.

Advances in Cryopreservation by Vitrification

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Biography

Milton Chin is a graduate of Rensselaer Polytechnic Institute with BS and ME degrees in Chemical Engineering. He also holds an MBA from the University of Missouri. In addition to the patent pending concepts described above, he has been awarded two US patents. Milton's professional career spans engineering, sales and marketing. He has held several managerial roles in the marketing of medical devices in the fields of endoscopy, patient monitoring, and women's healthcare. Milton Chin is President of Vitriscience LLC, an entrepreneurial company through which his vitrification innovations are marketed. Vitriscience and other successful ventures have been well received by medical device companies as measured by the earnings of over $700k in royalty fees for his inventions and ideas. This success draws from Milton's abilities to develop unique technologies that address a market need. Milton uses his business instincts and his technical knowledge to develop valuable IP that a scientist or a businessman alone cannot create.

Abstract

Infertility, the inability to have children afflicts 15% of all couples often leaving profound psychological scars behind. In most cases, in-vitro fertilization ("IVF") is the only intervention that can lead to successful pregnancies. In this process, the fertilization of human gametes is performed outside the body, literally in a Petri dish, forming a cohort of embryos. Only a fraction of the cohort, (typically 2-3 embryos) is transferred to the woman at any time. Embryos that are not transferred are cryopreserved for future use. Cryopreserved embryos are valuable biomaterials that dramatically improve the efficacy of IVF by enabling multiple transfers.

Cryopreservation is the chilling of the embryo to cryogenic temperatures where all biological activity is halted for an extended period of time. But, uncontrolled chilling forms intracellular ice that severely damages the cell. Ice formation can be avoided altogether using a cryopreservation method called vitrification. By using cryoprotectants ("CPAs") in conjunction with extremely rapid chilling, intracellular water attains an amorphous, glassy ('viteous') state that does not damage the embryo. CPAs are toxic to embryos and the required concentration needed to vitrify is inversely related to chilling speed. The faster one can chill, the lower the CPA concentration (hence less toxic) one can use to vitrify. Liquid nitrogen ("LN2") is a common chilling agent and is not aseptic. The potential of infection has led to the use of sealed cryocontainers where the chilling LN2 does not contact the embryo. But, the very surfaces that protect the embryo also impede heat transfer, thereby reducing chilling speeds and hence, necessitating the use of higher concentration CPAs. Development of an effective sealed cryocontainer for vitrification has proven to be a difficult challenge due to this conflict of purpose. My presentation will describe a sealed vitrification cryocontainer that circumvents this conflict by using the special attributes of shape memory alloys. Another barrier to rapid chilling in vitrification is the insulating gas layer that forms around a cryocontainer plunged into LN2. This well-known "Leidenfrost effect" is at odds with the need for rapid chilling in vitrification. This presentation will describe a device that prevents the Leidenfrost effect and thus improves the vitrification chilling speed.

Nanocarrier Delivery of siRNA and MicroRNA – Promises of Cancer Gene Therapy

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Biography:

Dr. Jagat Kanwar is an immunologist and molecular biochemist. He is the head of the Laboratory of Immunology and Molecular Biomedical Research at the Centre for Biotechnology and Interdisciplinary Biosciences at Deakin University, Australia. His group carries out research in the areas of nanotechnology-based drug delivery to cancer and chronic inflammatory diseases. Apart from industry-funded projects, his research focuses on siRNA and miRNA technology and drug discovery. His research focuses on exploring the roles of molecular mediators, antioxidants and cellular communication in the pathophysiological mechanisms of inflammatory diseases, including cancers. He is also working on nanotechnology-based peptides, siRNA and miRNA delivery systems for targeting survivin (an attractive cancer target), HIF-1α and apoptotic cell signaling molecules expression in the colon, retinoblastoma and breast cancers. A number of *in vitro* human cell or tissue based co-culture models for cancer, chronic inflammatory diseases (osteoarthritis, inflammatory bowel disease), gut health, neurodegeneration and immunomodulation have been developed in his laboratory in the past two years. The laboratory further aims the translation of discoveries into new approaches for the diagnosis, treatment and prevention of human diseases like cancer, inflammatory bowel disease (IBD), neurodegenerative, cardiovascular and pulmonary diseases. Four of his patents have been licensed for commercialization to different biotech companies and are now in Phase-III clinical trials and one drug (DMXAA) has been marketed for cancer therapy. Dr. Kanwar has trained 12 PhD and 10 MSc students. He is the member of editorial board of five journals. He is the consultant to five biotechnology-based companies. During the past five years, he has obtained more than 2.5 million dollars from various funding sources. He has extensive and close collaborations with colleagues in New Zealand, Australia, Singapore, India, China and the USA.

Abstract:

Various techniques have been developed to prepare nanoparticles for the delivery of drugs. More recently, we were able to load cell permeable dominant negative survivin R9 (DNSurR9) and survivin and HSP-90 antagonists, “shepherdin” on alginate gel-encapsulated, chitosan ceramic nanocores (ACNC) nanocarriers and able to induce apoptosis and disintegration of mitochondria of colon and breast cancer cell lines (but not normal control cells) more efficiently in vitro cell based assays. MicroRNAs (miRNAs) play important regulatory roles in by targeting mRNAs for cleavage or translational repression. miRNAs may function as oncogenes or tumor suppressors. In the present study we loaded siRNA to survivin and oncogenic antisense microRNA-27a (as-miR-27a) on ACNC-NPs and transferred to human breast cancer MDA-MB-231 and MCF-7 cell lines. Our results show that as-miR-27a loaded ACNC-NPs exhibits oncogenic activity. Suppression of miR-27a inhibits breast cancer cell growth. siRNA to survivin and oncogenic as-

miR-27a loaded ACNC-NPs results in down expression of genes that are important for cell survival and angiogenesis. In addition, these responses were accompanied by decreased expression of survivin, and angiogenic genes, including survivin, vascular endothelial growth factor (VEGF), and VEGF receptor 1(VEGFR1). We also demonstrated the down-regulation of survivin expression in western blot in the siRNA to survivin and oncogenic as-miR-27a loaded ACNC-NPs treated cells. TUNEL assay, caspase activity assay and changes in mitochondrial membrane potential reveal that cell death was mainly through intrinsic apoptosis pathway. Oral delivery of siRNA to survivin and oncogenic as-miR-27a loaded ACNC-NPs induced apoptosis, necrosis and cytotoxicity in the xenograft breast cancer model. Oral administration of ACNC-NPs also inhibits angiogenesis in the xenograft breast cancer mice model. We also compared our results with the doxorubicin and taxol loaded ACNC-NPs. Taken together, our results are highly encouraging for the development of combination nano-therapeutic strategies that combine gene silencing and drug delivery to provide more potent therapeutic, especially in late and metastatic tumors.

Commercializing New Technologies – Session Chair

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Biography:

Dr. Ronald Kudla currently serves as the executive director of intellectual property, technology transfer, and new ventures at Rensselaer Polytechnic Institute. Dr. Kudla oversees the strategic development, protection, marketing and licensing of promising innovations arising from the Institute's research activities. In his most recent position as director of academic liaison for North America within the Genetics and Discovery Alliances Group at GlaxoSmithKline, he was responsible for establishing strategic research alliances, consortium agreements, technology in-licensing agreements, multi-year research grants, consulting relationships, material transfer agreements and new technology assessments with North American universities and government research entities. Dr. Kudla previously served as the director of the Office of Technology Licensing at the University of Florida, and director of patents and licensing at the Wisconsin Alumni Research Foundation (WARF) in Madison, Wisconsin. He also has extensive experience in product development in the pharmaceutical industry. He served as the Director of Licensing and Business Development and Director of Worldwide Product Development for G.D. Searle Inc. At Lederle Laboratories, Dr. Kudla served as the Manager of International Medical Product Development. He also served as the CEO of PharmaServe International, Inc., a firm that is currently developing software for tracking and completing contract negotiations over the worldwide web. Dr. Kudla has served as an expert witness on the setting of royalty rates in several patent infringement litigation cases. He is also an inventor of several issued patents. Dr. Kudla received his Ph.D. in pharmaceutics with a major in biopharmaceutics from the University of North Carolina, Chapel Hill and an MBA in pharmaceutical marketing from Fairleigh Dickinson University, Teaneck, NJ.

Commercializing University Inventions – Case Studies

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Biography:

Professor Hagelin is the Crandall Melvin Professor of Law, and the Founder/Director of the Technology Commercialization Research Center at Syracuse University College of Law. He currently serves as the Director of the New York State Science and Technology Law Center, a statewide center funded by the New York State Foundation for Science, Technology and Innovation. Professor Hagelin has supervised over one hundred research projects in his role as Director of the Technology Commercialization Research Center. These research projects have been undertaken on behalf of universities, federal laboratories, non-profit research centers, and large, medium, small and start-up companies. Professor Hagelin teaches in the fields of intellectual property and technology commercialization law. His research and writing focus on the areas of technology commercialization strategy, patent valuation and intellectual property policy. He lectures and publishes frequently on these topics. Professor Hagelin has been granted two patents on a new Method to Value Intellectual Property.

Professor Hagelin received a B.S. in Economics from the Wharton School at the University of Pennsylvania, a J.D. from Temple University Law School and a LL.M. from Harvard University Law School. Professor Hagelin is a member of the New York State Bar, the Pennsylvania State Bar, the Licensing Executive Society, the American Intellectual Property Law Association and the Association of University Technology Managers.

Abstract:

This presentation will briefly review the work of the NYSTAR-designated New York State Science & Technology Law Center (NYS STLC) at Syracuse University College of Law. The NYS STLC prepares technology commercialization research reports on behalf of start-up and early-stage companies, universities and non-profit research centers. The NYS STLC also maintains a webpage with extensive resources to support technology commercialization, publishes a monthly newsletter with current information on a host of technology commercialization topics, and organizes state-wide conferences on subjects most relevant to technology commercialization. Special emphasis will be placed on the need to integrate science, engineering, marketing, management, finance, licensing and intellectual property factors in order to successfully bring early-stage technologies to market. A short case study of a medical device technology will be used to illustrate the importance of a multi-disciplinary approach to technology commercialization.

Commercializing Medical Devices – How to Get From Here to There

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Biography:

Joseph D. Bronzino received his B.S.E.E. degree from Worcester Polytechnic Institute (Worcester, MA) in 1959, his M.S.E.E. degree from the Naval Postgraduate School (Monterey, CA) in 1961, and his Ph.D. degree in electrical engineering from Worcester Polytechnic Institute in 1968. He is presently the Vernon Roosa Professor of Applied Science, an endowed chair at Trinity College, Hartford, CT and President of the Biomedical Engineering Alliance and Consortium (BEACON) which is a non-profit organization consisting of academic and medical institutions as well as corporations dedicated to the development of new medical technology. To accomplish this goal, BEACON facilitates collaborative research, industrial partnering and the development of emerging companies.

He is the author of over 200 journal articles and 15 books, including: *Technology for Patient Care* (C.V. Mosby, 1977), *Computer Applications for Patient Care* (Addison-Wesley, 1982), *Biomedical Engineering: Basic Concepts and Instrumentation* (PWS Publishing Co., 1986), *Expert Systems: Basic Concepts* (Research Foundation of State University of New York, 1989), *Medical Technology and Society: An Interdisciplinary Perspective* (MIT Press and McGraw-Hill, 1990), *Management of Medical Technology* (Butterworth/Heinemann, 1992), *The Biomedical Engineering Handbook* (CRC Press, 1st Edition, 1995; 2nd Edition, 2000; 3rd Edition, 2006), *Introduction to Biomedical Engineering* (Academic Press, 1st Edition, 1999; 2nd Edition, 2006), *Biomechanics: Principles and Applications* (CRC Press, 2002), *Biomaterials: Principles and Applications* (CRC Press, 2002), *Tissue Engineering* (CRC Press, 2002), and *Biomedical Imaging* (CRC Press, 2002).

Dr. Bronzino is a Fellow of IEEE and the American Institute of Medical and Biological Engineering (AIMBE), an honorary member of the Italian Society of Experimental Biology, past chairman of the Biomedical Engineering Division of the American Society for Engineering Education (ASEE), a charter member of the Connecticut Academy of Science and Engineering (CASE), a charter member of the American College of Clinical Engineering (ACCE), a member of the Association for the Advancement of Medical Instrumentation (AAMI), past president of the IEEE-Engineering in Medicine and Biology Society (EMBS), past chairman of the IEEE Health Care Engineering Policy Committee (HCEPC), and past chairman of the IEEE Technical Policy Council in Washington, DC. He is a member of ETA KAPPA NU, Sigma Xi, and TAU BETA PI. He is also a recipient of the IEEE Millennium Medal for "his contributions to biomedical engineering research and education" and the Goddard Award from Worcester Polytechnic Institute for Outstanding Professional Achievement in 2005. He is presently the editor-in-chief of the Academic Press/Elsevier Biomedical Engineering Book Series.

Abstract:
The success of nanotechnology is highly dependent on *commercialization* of the new products that evolve from its use in applied research. This is especially true in the medical application of nanotechnology, i.e., in the prevention, diagnostics and treatment of diseases. These applications include drug delivery, tissue repair and replacement, implantable sensors, implant coatings, smart materials, etc. In order for nanomedicine applications to be commercialized in an effective and efficient manner there needs to be a strong *bridge* between academia (where research of nanotechnology takes place) and industry (where viable nanotechnology products are brought to the marketplace.) Industrialists need to know more about what is taking place in the research laboratories within academic institutions and academics need to know more about the significant interests of companies competing in the global market place. In addition, it is imperative that all entrepreneurs know the steps in the commercialization process that begins with an idea of proof of concept and ends with the sale of a manufactured product. This presentation will focus on the various steps in the commercialization process and highlight the activities that take place at each step, as well as, the sources of funds needed to achieve success. Finally, BEACON will be introduced as an organization that can assist entrepreneurs go from one step to another in the commercialization process.

CNSE Nanobioscience – Overview and Case Study

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Biography:

Dr. Castracane is Professor (Founding Faculty) and Head of the Nanobioscience Constellation in the College of Nanoscale Science and Engineering (CNSE) at the University at Albany-SUNY Dr. Castracane received his BS degree in Physics from Canisius College (1976) and his Ph.D. in Physics from The Johns Hopkins University (1982). Dr. Castracane has received research funding from numerous Federal agencies including NIH, NSF, DOD, DOE, DARPA, and NASA as well as a significant portfolio of State and corporate sponsors. His publication record spans over 100 articles, numerous invited or keynote presentations and 10 patents issued/pending. Dr. Castracane is a member of APS, OSA and SPIE. His research interests encompass fundamental materials science, nanobisocience, optoelectronics, MEMS, and emerging fields such as molecular electronics and spintronics. Under Dr. Castracane's guidance, CNSE has assembled a multi-faceted Nanobioscience program to establish the critical technologies for effective integration of tailored biochemistries of cells/tissues/proteins with innovative nanofabricated structures. Prior to joining CNSE in 1998, Dr. Castracane's private sector experience involved positions at high technology R & D companies including Chief Operating Officer at InterScience, Inc. from 1994-98. As Director of the Center for Advanced Technology in Nanomaterials and Nanoelectronics from 2004-2009, Dr. Castracane continued to assist in the development of the business potential of numerous companies through technical interactions and management counseling.

Abstract:

This presentation will focus on a selected set of ongoing Nanobio-related projects at the College of Nanoscale Science and Engineering (CNSE) of the University at Albany which is being carried out in collaboration with corporate partners. This will include an overview of the infrastructure, personnel and operational model used by CNSE to integrate basic research with eventual technology deployment and commercialization objectives.

To illustrate this, one such project, in a complementary presentation, will detail the development of a non-invasive metabolic sensor system for clinical organ transplantation in association with Breonics, Inc. This effort serves to address the worldwide transplant organ shortage by creating a method to accurately monitor the resuscitation and repair of ischemically damaged organs to increase the useful pool of viable units. The work incorporates a CNSE developed sensor based on a combination of thermal micro-ablation followed by a customized sampling electrode array to monitor glucose levels. This sensor when combined with Breonics' Exsanguinous Metabolic Support (EMS) System is expected to make a significant positive impact on the harvesting and successful transplantation of human organs.

A Solution to the Worldwide Organ Shortage

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Biography:

A Founder, Executive Vice President and Chief Scientific Officer of BREONICS, Inc., Dr. Brasile is the inventor on 20 patents that cover BREONICS' "Exsanguineous Metabolic Support and Immunosuppressive technologies." Dr. Brasile successfully procured the combined venture and corporate funding needed to complete the pre-clinical testing phase necessary to position the technology for the clinic. She has over 30 years experience in transplantation medicine, immunology and organ preservation, with numerous publications in medical journals as well as three chapters in textbooks. Dr. Brasile has served as the Principal Investigator on 3 previous SBIR grant awards and was recently awarded a 2-year special emphasis grant from the National Institutes of Health (NIH). As the Director of Research Laboratories for the Department of Surgery at Albany Medical Center her work lead to more than $2-million in research funding from the NIH. While Director, she supervised a staff of 19 research fellows and technologists. She also served as the supervisor of the Transplant Research Laboratories at Ohio State University in the 1970's with a joint appointment in the Clinical Histocompatability Laboratory supporting the Clinical Transplantation Program. In this capacity she was involved in the manufacture of Anti-lymphocyte Globulin (ALG), an immunosuppressive drug given to transplant recipients.

Dr. Brasile received her Ph.D. in Medical Sciences and Surgery from the University of Maastricht, The Netherlands. She is a member of the American Society for Artificial Internal Organs (ASAIO), the American Society of Transplantation (AST) and the International Transplant Congress (ITC). In 1998 Dr. Brasile was honored as "Inventor of the Year" by the Eastern New York State Intellectual Property Law Association.

A Tumor-targeting Nanodelivery Platform in Clinical Trials

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Biography:

Professor Esther H. Chang is a Professor in the departments of Oncology and Otolaryngology at the Lombardi Comprehensive Cancer Center of Georgetown University Medical Center since 1996. Before joining Georgetown University, Dr. Chang held positions at the National Cancer Institute, as a professor in the Department of Surgery at Stanford University, and as a Professor in the Departments of Pathology and surgery at the Uniformed Services University of the Health Sciences. Dr. Chang is also the Acting President of the American Society for Nanomedicine (ASNM). Dr. Chang has been a pioneer and contributor to understanding genetic influences on both the development and suppression of cancerous tumors, as well as to understanding the tumor's resistance to radio/chemotherapy. More recently, her research has focused on the application of a nanodelivery platform in cancer therapy, diagnosis and prevention. When systematically administered, this nanocomplex can efficiently and selectively deliver nucleic acid-based molecular therapeutics, diagnostic MRI contrast agents and small molecules to not only primary tumors but also metastases in animal models of a number of human cancers. The tumor-targeting delivery of various molecular therapeutics has also been shown to dramatically synergize with conventional radio- and chemotherapies. This approach is now in Phase I clinical trials. Dr. Chang has over 130 publications and has served as a member of a number of scientific advisory boards for the National Cancer Institute, NASA, the US Military Cancer Institute and the US Department of Energy.

Abstract:

A platform nanodelivery system has been developed comprising a self assembled, biodegradable, cationic liposomal nanoparticle, which bears targeting molecules that home to receptors, such as the transferrin receptor, on the surface of tumor cells. When systemically administered, this nanocomplex can efficiently and selectively deliver nucleic acid-based molecular therapeutics, diagnostic MRI contrast agents, and small molecules to not only primary tumors, but also metastases. The nanodelivery of imaging agents results in a marked improvement in the sensitivity and resolution in detection of minute metastatic lesions. Use of this nanocomplex for gene therapy has been shown to dramatically sensitize a number of human tumors, including prostate cancers, in mouse models to radiotherapy and chemotherapy. This synergy has resulted in long term tumor elimination and life span prolongation in the animals. Based upon our pre-clinical data, we hypothesize that this combinatorial approach could ultimately result in lower effective doses of both radiation and chemotherapy, thus reducing the current adverse side effects of these standard treatments. This nanodelivery system, carrying the human tumor suppressor gene p53, has now entered a Phase I clinical trial as a single agent; the trial is nearing completion. Minimal side effects have been noted. The updated trial data will be reported.

Nanomedicine –
Where Have We Been And Where Are We Going?

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Biography:

Thomas J. Webster is an associate professor in the division of engineering and department of orthopaedics at Brown University. His degrees are in chemical engineering from the University of Pittsburgh (B.S., 1995) and in biomedical engineering from Rensselaer Polytechnic Institute (M.S., 1997; Ph.D., 2000). Prof. Webster's research addresses the design, synthesis and evaluation of nanophase (that is, materials with fundamental length scales less than 100 nm) materials as highly effective biomedical implants. Prof. Webster is the current director of the Nanomedicine Laboratory (28 members) and has completed extensive studies on the use of nanophase materials to regenerate tissues. To date, his lab group has generated 5 textbooks, 37 book chapters, 186 invited presentations, 283 peer-reviewed literature articles and/or conference proceedings, 435 conference presentations, and 17 provisional or full patents. Some of these patents led to the formation of NanoVis, Inc. (Lafayette, IN) and NanoRose, Inc. (Providence, RI) in which he serves as the Director of the Advisory Board for both companies. His research on nanophase materials has received attention in media/publications such as MSNBC (October 10, 2005); NBC Nightly News (May 14, 2007), PBS DragonFly TV (winter, 2008), ABC Local Nightly News via the Ivanhoe Medical Breakthrough Segment (winter, 2008) and *Time Magazine* (Spring 2009). His work has been on display at the London and Boston Science Museums. He is the founding editor-in-chief of the *International Journal of Nanomedicine* (the first international journal in nanomedicine). Other honors include: 2002, Biomedical Engineering Society Rita Schaffer Young Investigator Award; 2003, Outstanding Young Investigator Award Purdue University College of Engineering; 2005, American Association of Nanomedicine Young Investigator Award Finalist; 2005, Coulter Foundation Young Investigator Award; and 2006, Fellow, American Association of Nanomedicine. He was recently appointed Director of all U.S. Activities for the new Indo-U.C. Center for Biomaterials for Healthcare.

Abstract:

Nanotechnology is being used to mimic structural components of tissues in synthetic materials intended for various implant applications. Recent studies have highlighted that when compared to flat or micron rough surfaces, surfaces with nanofeatures promote optimal initial protein interactions necessary to mediate cell adhesion and subsequent tissue regrowth. This has been demonstrated for a wide range of implant chemistries (from ceramics to metals to polymers) and for a wide range of tissues (including bone, vascular, cartilage, bladder, skin, and the central and peripheral nervous system). Importantly, these results have been seen at the in vitro and in vivo level. This talk will cover some of the more significant advancements in creating better vascular, cardiovascular, and orthopedic implants through nanotechnology efforts. It will also cover recent in vitro and in vivo studies which highlight better tissue regeneration. This talk will also address recent concerns of nanoparticle toxicity and the role industry has played in nanomedicine to date.

FDA's Regulation of Nanotechnology – Controversies and Impacts on Nanomedicine

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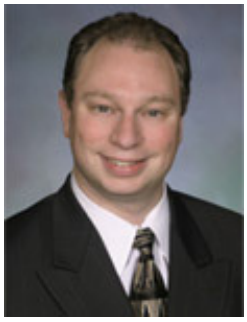
Biography:

Ricardo Carvajal is of counsel with Hyman, Phelps & McNamara, P.C., the largest dedicated food and drug law firm in the U.S. Prior to that, he served as Associate Chief Counsel in FDA's Office of Chief Counsel, where he participated in the formulation of regulatory responses to advances in food biotechnology and nanotechnology. Mr. Carvajal provides FDA regulatory counseling to manufacturers and marketers of foods, drugs, devices, and cosmetics. He has substantial experience with regulatory issues pertaining to foods, including dietary supplements. He has worked on GMP and HACCP compliance issues, and on a wide array of labeling compliance issues, including those that arise from the use of health, nutrient content, structure/function, and disease claims. He has worked on due diligence review teams for major acquisitions and initial public offerings, helped manufacturers to determine the regulatory status of products, and provided advice on labeling, advertising, and promotion issues. Mr. Carvajal is an active member of the Food and Drug Law Institute, the American Bar Association, and the Institute of Food Technologists, for which he has authored numerous publications on various aspects of food law and regulation. He holds a J.D. from Northwestern University School of Law and an M.S. in Biology from the University of Michigan. He is admitted to practice in the District of Columbia.

Abstract:

FDA's regulatory authority over drugs and medical devices derived through nanotechnology is generally considered to be adequate to ensure that potential safety issues raised by those products are addressed prior to marketing. However, the agency has acknowledged that its authority over foods and cosmetics (which are generally subject only to postmarket oversight) is less comprehensive. Perceived gaps in the agency's authority over foods and cosmetics derived through nanotechnology have prompted numerous expressions of concern about whether the safety of those products has been properly addressed. This presentation will provide an overview of the FDA's regulation of products derived through nanotechnology, with examples of different products that are already on the market as well as those that are still on the drawing board. The presentation will also examine controversies involving existing FDA-regulated products that could have an impact on the development of nanomedicine, and will address the potential impact of state initiatives that target nanotechnology.

Ten Best Practices to Commercialize Your Invention (What Investors Look For)



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Biography:

Leon Radomsky is a partner and chair of Foley & Lardner's Nanotechnology Industry Team. He is a member of the firm's Chemical & Pharmaceutical and Electronics Practices and the Emerging Technologies and Energy Industry Teams. Mr. Radomsky focuses on strategic client counseling, IP due diligence and agreements, opinions and all phases of U.S. and international patent portfolio development, including patent application drafting, prosecution, appeals, reissues and reexaminations in the areas of nanotechnology, semiconductor devices and processing, materials science, solar cells and fuel cells. Prior to joining Foley, Mr. Radomsky worked as a patent examiner in the U.S. Patent and Trademark Office, where he examined patent applications in semiconductor device processing and developed a broad knowledge of semiconductor device and liquid crystal display fabrication technologies. Prior to that, he was a doctoral research assistant and teaching assistant at Columbia University, where he gained expertise in semiconductor physics and testing, metallurgy and electronic materials processing.

Mr. Radomsky was recognized in the Legal 500 US: Volume II: Intellectual Property, Media, Technology, and Telecom 2007 Guide as a top attorney for patent prosecution. He has also been named one of the Top Ten Intellectual Property Lawyers Influencing Nanotechnology by *Nanotechnology Law & Business*. Mr. Radomsky has authored numerous legal articles and book chapters. He authored a chapter on IP due diligence in "Structuring Patent Licensing Transactions" published by Aspatore Books and was featured in ReedLogic Video Leadership Seminars on IP due diligence and on providing superior client service to generate referrals to new clients. While still in law school, Mr. Radomsky was awarded the Rossman Memorial Award as the author of an article in the *Journal of the Patent and Trademark Office Society* that made the greatest contribution to the fields of patents, trademarks and copyrights in 1997-98. In addition, Mr. Radomsky has also authored articles which have appeared in numerous publications, including I*ntellectual Property Today, Patent Strategy & Management, Berkeley Technology Law Journal, Nanotechnology Law & Business and R&D Journal.* The articles have covered diverse legal topics, including claim interpretation, an analysis of world wide semiconductor chip layout protection laws, government rights in nanotechnology patents, a summary of the first Federal Circuit nanotechnology decision, and patent inventorship and ownership issues facing nanotechnology companies. Mr. Radomsky has also co-authored numerous articles on semiconductor physics. Mr. Radomsky is an active member of the American Intellectual Property Law Association, where he served as past chair of its Chemical Practice and Young Lawyer's Committees. Mr. Radomsky frequently serves as an instructor at the annual AIPLA Patent Prosecution Basic Training for New Lawyers seminars and prepared portions of the seminar textbook. Mr. Radomsky has also made numerous presentations at AIPLA committee meetings on subjects ranging from IP due diligence for venture capital investment in start-up

companies to opinions of counsel to recent case law. Mr. Radomsky received the AIPLA project award as a co-author of the AIPLA International Patent Handbook. Mr. Radomsky is also a member of the American Bar Association, Intellectual Property section. Mr. Radomsky is active in industry organizations as well. He is a frequent speaker at nanotechnology conferences on intellectual property issues facing nanotechnology start-up companies and investors. Mr. Radomsky is an active member of U.S. Patent & Trademark Office semiconductor and nanotechnology partnerships and was a speaker at several semiconductor partnership meetings.

Mr. Radomsky graduated from Columbia University (B.S, metallurgical engineering; M.S., materials science) and George Mason University School of Law (J.D., magna cum laude), where he was a member of the Law Review. While in law school, Mr. Radomsky was a national finalist in the Giles S. Rich Moot Court Competition in Intellectual Property and was also the winner of a regional best brief award. Mr. Radomsky has been admitted to practice in the District of Columbia and Virginia, and before the U.S. Patent and Trademark Office. He is fluent in Russian.

Abstract:
When inventors seek to commercialize their invention, they often turn to angel and venture capital investors to fund a start-up company that will commercialize the invention. Often, the start-up's only initial asset is the IP associated with the invention. Thus, in many cases, the funding decision is based on the quality of the IP in addition to the business plan and the experience of the founders/inventors.

The inventors should take the following steps before seeking financing. First file at least a provisional patent application covering the invention to lock in the filing date. Make sure that the invention was not disclosed publicly or offered for sale prior to the application filing date. Determine what features of the invention provide a competitive advantage in the market place and make sure that it is covered by the claims of the application. Be prepared to answer whether the claimed invention is novel and non-obvious. Be prepared to answer whether the commercial version of the invention will infringe patents of others. Determine who should be named as an inventor of the patent application. Determine who owns the invention based on the inventors' employment and other agreements. Make sure that all inventors have not assigned or licensed their rights in the invention to third parties (other than a university in case of the university inventors). Make sure that all inventors will assign or license their rights to the start-up company directly or through the university in case of university inventors. Determine if certain features of the invention can be protected as trade secrets and make sure not to disclose them without a non-disclosure agreement.

Taking these steps should increase the inventors' chances of receiving financing for the start-up company.

Patent Procurement and Enforcement in the US

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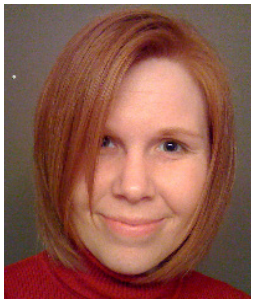
Biography:

Dr. William ('Will') Simmons is an associate at Sughrue Mion and works out of the Washington office. His practice focuses on worldwide procurement, defense and enforcement of patents in the biotechnology, chemical and nanotechnology industries. Dr. Simmons works in all areas of patent law, including interferences, reexaminations, oppositions and prosecution. He prepares opinions regarding patentability and infringement and conducts freedom-to-operate analyses. He conducted primary scientific research for over a decade, including during a post-doctoral fellowship funded by the National Institutes of Health at New York University where he investigated mechanisms of immunity, oncology and, specifically, cell signaling by conducting differential studies on the proteomes of normal and aberrant cells. His work included nucleic acid and protein engineering and mammalian genetic engineering. He began his work at New York University in the laboratory originally founded by Nobel Laureate Dr. Baruj Benacerraf, a laboratory later maintained by Dr. Jeanette Thorbecke. Dr. Simmons has extensive experience in molecular biology and molecular immunology and was a member of various collaborations including pre-Phase I clinical trials.

The Ethical Dimensions of Nanotechnology



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Biography:
Dr. Summer Johnson is the Executive Editor of *The American Journal of Bioethics*, a highly rated journal in health law, ethics and policy. Dr Johnson is also the Executive Editor of *The American Journal of Bioethics Neuroscience*. Dr. Johnson is co-founder and owner of Bioethics Education Network, an innovative organization that serves more than 24 million readers every year with information about ethics in medicine and science, the world's most utilized bioethics resource and a partner of Google and Apple. Dr. Johnson received her PhD in Bioethics and Health Policy from The Johns Hopkins University at 25. She is a former recipient of both a Fulbright and a Jacob Javits fellowship. She is a summa cum laude, Phi Beta Kappa graduate of Indiana University, where she designed the university's bioethics major. Dr. Johnson has become a national expert in nanomedicine and the ethics of innovations. Johnson has delivered named and/or endowed lectureships, has testified, and has reviewed numerous papers and grant proposals. Most important though she has been hailed as a teaching innovator and been nationally praised for creating one of the most innovative graduate education programs online in medical ethics. Dr. Johnson has been quoted about her research on a number of national television and radio news programs, and has authored columns and a number of articles for a general audience.

Abstract:
Will nanomedicine transform our industrial base and have a dramatic impact on healthcare and our long-term quality of life? As envisioned here, applications of nanomedicine hold out a wealth of promise, given the many applications in drug delivery, diagnostics, detection, discovery, sensing and imaging. However, nanomedicine has been so enthusiastically promoted that the hype and expectations may far exceed reality, especially given the immense lag time between R&D and the appearance of commercially-viable products in the marketplace. Therefore, for nanomedicine to truly become a global megatrend, this hype must be separated from reality.

It is also important to ensure that advances in medical care due to nanotechnology do not come at the expense of fairness, safety or basic understanding of what it means to be a healthy human being. The changes that nanomedicine is likely to bring about should be addressed and managed through strategic planning and ethical analysis. As scientific advances occur, the responsible development of nanomedicine requires that societal and ethical concerns be addressed. Even if many of these issues are not new or unique, it will still be essential to address these questions and arrive upon justifiable answers for them. Initially, some of the important ethical concerns will continue to focus on risk assessment and environmental management. Later on, classic ethical questions regarding social justice, privacy, confidentiality, long-term risks versus benefits and human enhancement are certain to arise. Eventually, novel ethical issues and unforeseen dilemmas will emerge as the field advances further and intercepts other areas of biomedical research, including genomics, personalized medicine, bioinformatics and neurobiology.

Intellectual Property Mapping – A Corner Stone of Long Term IP Strategy

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Biography:

Jeffery Langer is involved in the patent preparation, prosecution, and reexamination practices at Finnegan. He provides technical assistance for opinion work, litigation, and due diligence projects. He is also a member of the firm's alternative energy and nanotechnology groups. Dr. Langer is an expert on semiconductor processing. He developed novel processing methods used in the fabrication of antimonide based superlattices detectors and silicon carbide based power electronics during graduate school. Dr. Langer also contributed to the development of optical character recognition software at Bell Labs.

Dr. Langer obtained his doctorate in electrical engineering from Rensselaer Polytechnic Institute in Troy, NY, where he received the Joseph H. Smith, Jr. Award for Exemplary Achievement in Engineering and Science for his doctoral work. He is also Rensselaer Medal Recipient. Dr. Langer attended the Columbus School of Law at the Catholic University of America where he was elected to law review, received an Academic Merit Scholarship, and graduated *cum laude*. Dr. Langer frequently speaks and writes on topics related to intellectual property law. He has taught in the United States and the People's Republic of China. He is a member of the Giles S. Rich American Inn of Court, the Institute of Electrical and Electronics Engineers and the Materials Research Society.

Abstract:

Intellectual Property Mapping, or IP mapping, is a cornerstone of a long-term intellectual property strategy. In essence, IP mapping provides a comprehensive representation of a patent "landscape" at a given point in time. Understanding a patent landscape can prove extremely useful in assisting an entity to meet short-term and long-term goals on the path to successfully developing and commercializing the entity's intellectual property. In emerging technologies, such as nanotechnology where patent protection is diverse and dense, IP mapping can provide an entity with insights that are critical to success. Academic researchers and governmental agencies can use IP mapping to identify areas of research that may yield valuable intellectual property. For inventors and investors, IP mapping may identify problem areas early in the commercialization process of a product or product line. Publicly available IP maps may provide a general overview of a landscape in a particular field and can serve as a starting point in the IP mapping process. Further customization of an IP map may yield beneficial results, such as additional details that define and illuminate the contours of the patent landscape by invention type, jurisdictional considerations, and/or other parameters.

Legislative Issues Effecting the Development of Nanotechnology

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Biography:
Robert T. Dombrowski is the President and Principal Scientist of the Technical/Scientific Consultancy, Nanoview Associates, LLC. He is a highly experienced Technical Manager/Executive & multidisciplinary Scientist who has successfully used his broadly based business and technical expertise to solve critical organizational problems for technology based companies, academic institutions and life sciences/hi-tech clients of his consultancy (15 years prior technical consulting experience). One of the key knowledge competencies that Mr.Dombrowski employs in carrying out his work as a Consultant is Nanotechnology - including the characterization of Nano materials. Mr. Dombrowski has served as a hands-on Researcher, Laboratory Manager, Technical Project Manager & Business Development Manager in Pharmaceutical (Johnson & Johnson, Carter Wallace) , Personal Care/Consumer Products (Colgate Palmolive Research) & Biodegradable Polymers (Novon Products – Warner Lambert) companies along with Contract Analytical/Materials Characterization Laboratory (EMSL Analytical, Inc.) and independent consulting positions. He has also held academic appointments at Rutgers University, New Jersey Center for Biomaterials & the Medical Device Concept Laboratory at the New Jersey Institute of Technology (NJIT). Mr. Dombrowski has been involved with the characterization of Nano materials (engineered liquid formulations) since the late 1980's – early 1990's when nano was not even called nano. Back then they called everything "colloid like materials" with "sub micron" size specifications & related properties. Mr. Dombrowski has been recognized for his biodegradable materials science/microstructural characterization studies with the inclusion of his Biographical Sketch in *Marquis Who's Who in the World, Marquis Who's Who in the United States* and *Marquis Who's Who in Science & Engineering*.

Abstract: In response to the wide spread recognition of the tremendous scientific & economic potential of nanoscale science & technology, a federal interagency working group was formed in 1996 to consider the creation of a National Nanotechnology Initiative (NNI). The NNI was established and around $1 Billion has been directed toward NNI research since the start of Fiscal Year (FY) 2001. The four stated goals of the NNI are: (i) advance a world-class nanotechnology Research & Development (R&D) program; (ii) foster the transfer of new technologies into products for commercial and public benefit; (iii) Develop and sustain - educational resources, a skilled workforce and the supporting infrastructure/tools to advance nanotechnology; and (iv) support responsible development of nanotechnology.

Recently, the passing of H.R. 554 – National Nanotechnology Initiative Amendments Act of 2009 by the U.S. House of Representatives in February 2009 strengthens the goals set forth by the

establishment of the NNI. The text of H.R. 554 (the Bill) offers the following major added support to the initial goals established for the NNI. H.R. 554 strengthens funding of the National

Nanotechnology Coordination Office with the Office being supported by funds from each agency participating in the National Nanotechnology Program (the Program). It requires the National Nanotechnology Coordination Office to develop a database providing information to the public concerning projects funded under the Environmental, Health & Safety, Education/Societal Dimensions and the Nano-manufacturing program component areas. The Office will also develop and publicize information on nanotechnology facilities supported under the Program, which may include information on nanotechnology facilities supported by the states that are accessible for use by individuals from academic institutions and industry.

The Bill requires the Director of the Office of Science & Technology Policy to designate an Associate Director of the Office of Science & Technology Policy as the Coordinator for Societal Dimensions of Nanotechnology. The Coordinator will convene a panel to develop a research plan for the Environmental and Health & Safety program component area. The panel will solicit and be responsive to recommendations from any advisory subpanels and the agencies responsible for Environmental and Health & Safety regulations associated with nanoscale materials and products. It also requires agencies supporting nanotechnology research facilities to provide access to such facilities to assist companies develop prototypes of nanoscale products, devices, or processes. H.R. 554 establishes industry liaison groups for all industry sectors that would benefit from nanotechnology applications. It requires the Nano-manufacturing, Industry Liaison & Innovation Working Group of the National Science and Technology Council to actively pursue such liaison groups. It requires the Program to include support for nanotechnology Research & Development (R&D) activities directed toward areas that have the potential for significant contributions to national economic competitiveness and other significant societal benefits – i.e. nano-electronics, energy efficiency, health care & water remediation/purification.

The Program must also implement a plan for fostering the transfer of research discoveries and the results of technology demonstration activities to industry for commercial development. The Program permits R&D activities to be supported through interdisciplinary nanotechnology research centers organized to investigate basic research questions and carry out technology demonstration activities. It requires the Nano-manufacturing program component area to include research on: (a) the development of instrumentation and tools required for the rapid characterization of nanoscale materials and for monitoring nanoscale manufacturing processes; (b) the development of techniques for scaling the synthesis of new nanoscale materials to achieve industrial-level production rates. Finally the Program directs interdisciplinary research centers to include activities relating to green Nano-manufacturing research.

In this time of limited economic/funding resources there may be constraints placed on the implementation of the nanotechnology R&D/commercialization goals outlined in H.R. 554. This presentation will offer some possible models for public-private collaborative efforts that can help facilitate the achievement of both the added nanotechnology R&D/commercialization goals of H.R. 554 & the initial goals of the NNI.

Environmental, Health and Safety (EHS) Issues – Session Chair

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Biography:

Dr. Sara Brenner is a preventive medicine and public health physician at the UAlbany College of Nanoscale Science & Engineering serving as the Assistant Vice President for NanoHealth Initiatives and an Assistant Professor of Nanobioscience. Her research and initiatives aim to develop novel nanotechnology applications in the life sciences, including medicine and public health. She is also leading health and safety research initiatives related to nanoparticle and nanomaterial exposures in the workplace, consumer marketplace, and environment. Sara is addressing gaps in our understanding of the safety and risk associated with the unique characteristics of nanoscale materials by incorporating theory from many disciplines such as physics, engineering, biology, genetics, medicine, public health, epidemiology and environmental science. As part of these efforts, she is advancing risk assessment and reduction strategies for occupational exposures, monitoring of materials that may impact population health and public safety, and the development of industrial practice standards for product safety. She is working proactively with collaborators and partners to develop monitoring and surveillance techniques to assess the environmental and ecological impact as well as the biopersistence of engineered nanomaterials in the Capital District. Her team is building a framework to employ custom-tailored strategies to mitigate potential risks associated with nanotechnology-based products that are currently on the market as well as those under development. Dr. Brenner is an active member of the American College of Preventive Medicine and has served as president of the medical student section and resident physician section as well as on the code of ethics committee, the graduate medical education committee, and planning committees for several national meetings. She is active in the federal health policy scene and frequents D.C. Congressional offices to advance preventive medicine, public health, and biotechnology initiatives. She is both personally and professionally dedication to prevention and practices what she preaches by participating in the local fitness scene. She races road, trail and snowshoe distances up to 50-mile “ultramarathons” and teaches swing and ballroom dance.

Biosafety and Health Concerns Associated with Nanobiotechnology Research

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Biography:

Dr. Glenn Monastersky joined Rensselaer in 2006. His priorities include the development and enhancement of the Center's Research Cores, faculty recruitment, the facilitation of interdepartmental faculty collaborations, management of Center operations and the acquisition of external research partnerships. At Rensselaer, Dr. Monastersky serves as the Chair of the Institutional Biosafety Committee (IBC), Chair of the Institutional Animal Care and Use Committee (IACUC) and as a member of the Institutional Stem Cell Research Oversight Committee (ISCRO). Dr. Monastersky also serves on the IACUC at the Stratton VA Medical Center, the Steering Committee of Bioconnex, the Executive Committee of the Upstate New York Consortium for Health Care Research and Quality (UNYCHCRQ) and the Board of the Upstate New York Translational Research Network.

Dr. Monastersky received his Ph.D. in Cell and Developmental Biology from Rutgers University and the University of Medicine and Dentistry of New Jersey followed by postdoctoral studies at Harvard Medical School and Integrated Genetics. He has held international positions in research and corporate management at Genzyme, Charles River Laboratories, AviGenics and Hoffmann-La Roche. His research areas have included mammalian gene regulation and expression, transgenic disease models, pharmacogenomics, cancer cell biology and vaccine design.

Biological and Toxicological Impact of Nanomaterials – Urgent Needs for Health Hazard Assessments

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Biography:

Dr. Bhushan is an Assistant Chair and Professor in Department of Biomedical and Pharmaceutical Sciences, College of Pharmacy at Idaho State University in Pocatello. Dr. Bhushan received his B. Sc. (Honors) and M. Sc. degree in chemistry from University of Delhi, India. He received his Ph.D. in Biochemistry from Punjab Agricultural University, India. He was a post-doctoral fellow at Johns Hopkins School of Medicine, Medical University of South Carolina and University of Vermont. He has held faculty positions at Department of Pharmacology, School of Medicine, University of Vermont and Department of Biomedical Pharmaceutical Sciences, College of Pharmacy, Idaho State University. He has over 20 years of experience in cancer research.

Dr. Bhushan's areas of interest include cancer pharmacology and signal transduction focused on treatment and prevention. His research areas are 1) understanding mechanisms to block glioblastoma invasion in brain and synthesis of novel agents that target the process of invasion; 2) understanding the mechanism of the role of isoflavones in preventing breast and oral cancer; 3) characterization and cloning of a novel reduced folate transporter which plays role in methotrexate and cisplatin resistance; 4) natural drug discovery for prevention and treatment of cancer; and 5) Pharmacology of Nanomaterials. Dr. Bhushan has several publications, reviews, and abstracts to his credit. He has served as major advisor to several Ph.D. and Master's students at Idaho State University. He has been invited to several national and international meeting to present lectures. He was invited to give talk at the Oxford Round Table. Bhushan teaches cancer related courses, FDA regulation, Pharmcogenomics, Nanosciences, principles of phamcodynamics and case studies in College of Pharmacy, Idaho State University. He also teaches in the Nursing program at Idaho State University. He also participates in teaching in the Complementary and Alternate Medicine course. Dr. Bhushan attended a Boot Camp for Teachers at Leadville, Colorado.

Dr. Bhushan is coordinator of the graduate program in the Department of Pharmaceutical Sciences. He has chaired Curricular Affairs Committee, Faculty Affairs Committee and Steering Committee for Minor in Pharmaceutical Sciences in the College of Pharmacy and Faculty Professional Policies Council at Idaho State University. He has been member of the Assessment Committee, Patent Committee, Honors Committee, ISU Biomedical Research Institute steering committee and Cultural Affairs Committee. He serves as an advisor to the Association of Graduate Students in Pharmacy and Association of Indian Students at Idaho State University. He is member of American Association of Cancer Research, American Association of Colleges of

Pharmacy, American Association of Advancement of Science, American Society of Nanomedicine, Sigma Xi, Rho Chi, American Society for Biochemistry and Molecular Biology, Idaho Academy of Sciences, Idaho Cancer Researchers Association, and Cancer Prevention and Treatment Center. He serves on the executive committee of the Idaho Academy of Sciences.

Abstract:
Proliferation of new nanomaterials in our society and around the world is expected in the coming decades. Nanomaterials are being used in diverse industries, including ever-increasing new applications in drug targeting and formulation. The exposure of these materials to workers in such industries, to nanomaterial researchers, and to a lesser extent to the general public, is evidently of some concern. This potential environmental distribution and increasing use of these materials may pose a health risk to humans, animals, and other species that come into contact with nanomaterials. Our laboratories have been systematically studying the biological and putative toxicological effects of a variety of nanomaterials on different types of mammalian cells, including both normal and neoplastic ones to not only determine such materials' putative toxic effects but also explore their therapeutic potentials. Results of our recent and ongoing studies revealed that several metallic oxide nanoparticles exert differential cytotoxic effects on both neural and non-neural cell types, including normal human fibroblasts, with titanium and zinc oxides nanoparticles being more potent and magnesium oxide nanoparticles being less potent. Our findings also implicate both apoptosis and necrosis in their cytotoxic mechanisms. We continue to investigate the cytotoxic effects of these nanoparticles by elucidating the underlying cell signaling mechanism(s). Furthermore, we are extending our systematic study to include other nanomaterials such as nanotubes. Consequently, our results as well as those from several other groups strongly suggest there is an urgent need to further elucidate the putative health hazards of exposure to such nanomaterials in the occupational and global environmental contexts.

Biological and Toxicological Impact of Nanomaterials – Urgent Needs for Health Hazard Assessments

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Biography:

Dr. James C.K. Lai is Professor of Pharmacology & Toxicology in the Biomedical & Pharmaceutical Sciences Department, College of Pharmacy and is also the Associate Director of ISU Biomedical Research Institute at Idaho State University. He is Visiting Scientist, Magnetic Resonance Research Center, Yale University School of Medicine. He received his B. Sc. (Honors) degree in Microbiology from Cardiff University, Wales, M. Sc. Degree in Neurocommunications from University of Birmingham, UK and Ph.D. degree in Biochemistry from University of London, UK. He had post-doctoral training from Liver Unit, King's College Hospital Medical School and Neurochemistry Department, Institute of Neurology, both of University of London, UK. He held faculty positions in Neurology, Neuroscience, and Biochemistry at Albert Einstein College of Medicine and Cornell University Medical College, New York prior to joining Idaho State University College of Pharmacy. He was on the Editorial Board of *NeuroToxicology* and *Neurochemical Research* and is currently on the Editorial Boards of *Metabolic Brain Disease* and. He is a member of American Society for Neuroscience, American Society for Pharmacology and Experimental Therapeutics, Snake River Association for Neuroscience and Rho Chi.

His research interests are:
1. Nanotoxicology;
2. Nanopore transport of biomolecules;
3. Neurotoxicity and metabolism of metals, ammonia, and fatty acids in relation to neurodegenerative, neurological and psychiatric diseases;
4. Anticancer drug discovery;
5. Cancer prevention;
6. Regulation and compartmentation of brain intermediary metabolism; 6. Glutathione transport and metabolism;
7. Environmental toxicity of metals, especially manganese, cadmium, and aluminum; and
8. Functional roles of glutathione and other antioxidants.

He has published extensively in the above-mentioned areas.

Current Environmental Law Issues in Nanotechnology

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Biography:

John Monica is a partner in the Washington, D.C. office of Porter Wright Morris & Arthur where he chairs the firm's nationally recognized multi-disciplinary Nanotechnology Practice Group. He has been named as one of the country's leading experts on environmental, health, and safety issues related to engineered nanomaterials by *Nanotechnology Law & Business* peer-reviewed journal, and has a strong track record of winning complicated cases and appeals for Fortune 500 clients in state and federal courts across the country. He is a much sought after speaker and author on nanotechnology issues and manages the topical legal news website and newsletter *Nanotechnology Law Report* where readers can learn about the latest legal and regulatory developments in nanotechnology. Mr. Monica received his law degree with honors from George Washington University and his undergraduate degree from Northwestern University.

Pharmaceutical Nanoexcipients – Balancing Toxicity and Safety

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Biography:

Dr. Marianna Foldvari is the Canada Research Chair in Bionanotechnology and Nanomedicine. She is also a professor of pharmaceutical sciences and the associate director of research and graduate studies at the University of Waterloo's School of Pharmacy. Dr. Foldvari received a pharmacy degree and a doctorate in pharmaceutical sciences, both from Semmelweis Medical University in Budapest, Hungary. She then obtained her PhD in pharmaceutical sciences (drug delivery) from Dalhousie University in Canada. Dr. Foldvari's research program focuses on the development of intelligent delivery systems for macromolecular drugs and design of biomolecular devices for individually responsive therapeutic systems. Dr. Foldvari has authored over 100 papers and presented at over 70 conferences. She is the inventor on 14 patents. She has founded two spin-off companies from her research that focus on nanomedicine product development to commercialize the technologies that she and her research team have developed. She is Associate Editor of the journal, *Nanomedicine: NBM*.

Abstract:

Many of the recently designed drug delivery systems are constructed from nano-sized components that serve as the carrier or targeting ligand for a therapeutic agent. Even though these biomaterials have been regarded in the past as inert or non-active components of dosage forms, they are now recognized as being sometimes even more important than the drug itself. Hence, it is becoming increasingly important that the pharmaceutically relevant properties, including toxicity, of these functional nano-excipients be fully characterized. The desirable and undesirable 'nano-effects' of carbon nanotubes, metallic and metal oxide nanoparticles, polymers, lipids, surfactants, peptides, carbohydrates, and dendrimers and their composites, used as pharmaceutical excipients on cellular function will be discussed. An initiative for the construction of a physicochemical database for functional nano-excipients that will assist in establishing correlation between their physical, chemical, morphological and intelligent properties and their biological effects *in vivo* will be described.