Nano Convergence:
Real Time Legal Risks & Opportunities

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International Association of Nanotechnology
Bridging the Next Frontier
San Francisco, California
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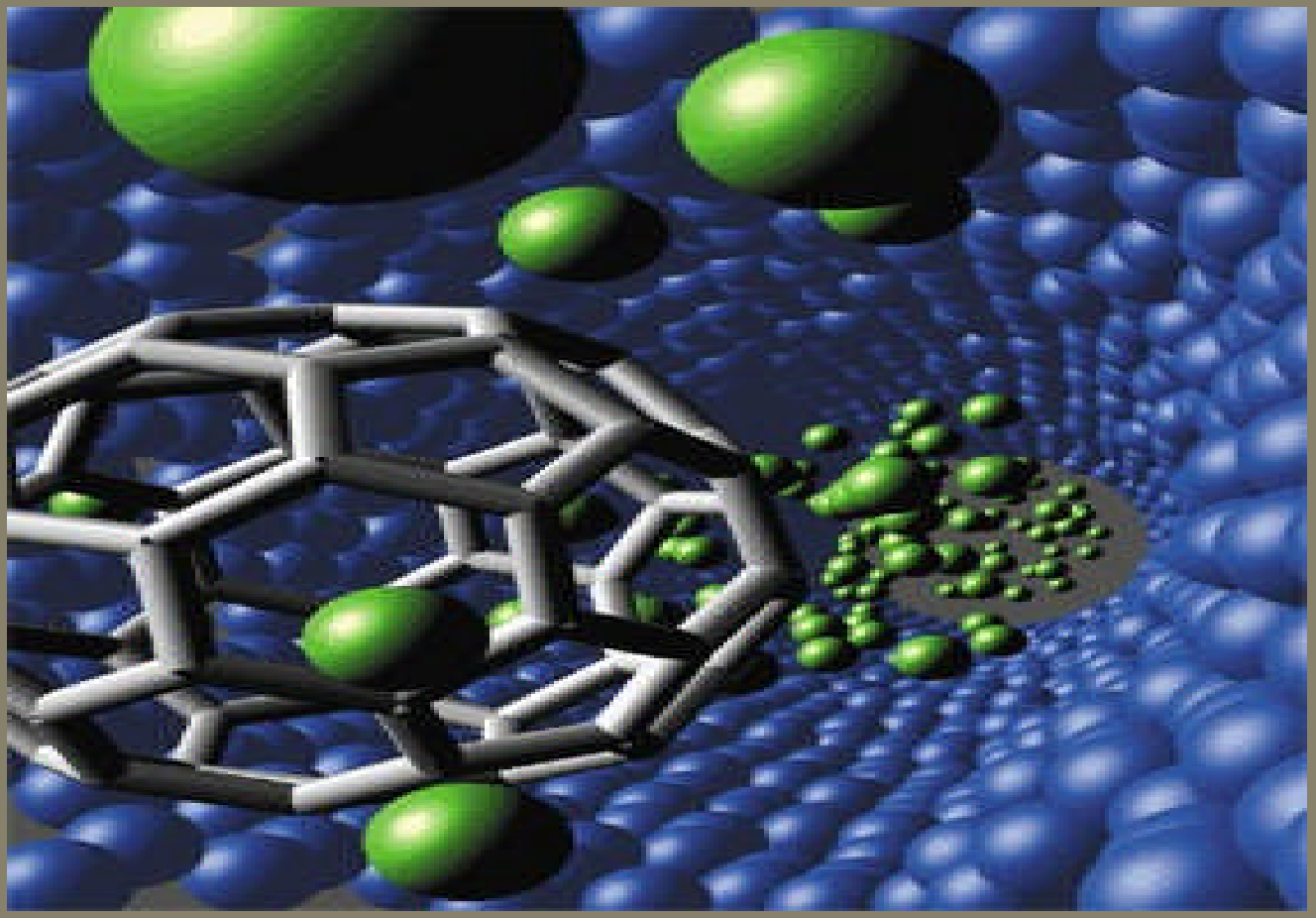
Atom by Atom



NSF & Nanotechnology

- Federal funding for R&D reached $961M in 2004.
- President George W. Bush's 2005 Budget calls for a $1 billion investment in NNI.
- Two million workers needed worldwide within 15 years to support nanotechnology industries.
- By 2015, the annual global market for nano-related products & services will exceed $1 trillion.

Nano Legislation

- December 03, 2003.
- 21st Century Nanotechnology Research & Development Act (Public Law 108-153).
- Places NNI supported programs & activities into law.
- A total of nearly $3.7 billion from 2005-2008 authorized for research across various federal agencies.

Program Activities

Establish:

American Nanotechnology Preparedness Center

a. conduct, coordinate, collect, & disseminate studies on the societal, ethical, environmental, educational, legal, & workforce implications of nanotechnology; &

b. identify anticipated issues related to the responsible research, development, & application of nanotechnology, as well as provide recommendations for preventing or addressing such issues.

Act Defines Nano

- "The science & technology that will enable one to understand, measure, manipulate, & manufacture at the atomic, molecular, & supramolecular levels, aimed at creating materials, devices, & systems with fundamentally new molecular organization, properties, & functions."

Organizations

- Responsible for implementing regulations & guidance regarding nano - materials & products:

1.	EPA	Environmental Protection Agency
2.	FDA	Food & Drug Administration
3.	NIOSH	National Institute of Occupational Safety & Health
4.	OSHA	Occupational Safety & Health Administration
5.	USDA	U.S. Department of Agriculture
6.	CPSC	Consumer Product Safety Commission
7.	USPTO	U.S. Patent & Trademark Office

USPTO

- Monday, October 18, 2004, USPTO announced a new registration category (Class 977) solely for nanotechnology inventions.
- USPTO definition requires that **at least one dimension of an invention be less than 100 nanometers**.
- The nanoscale element of the product or process must be essential to whatever properties make it novel.

USPTO Class 977

- Facilitate the searching of prior art related to nanotechnology.
- Help cut down on overlapping patent claims.
- Help cut down on the potential for patent litigation.

USPTO

Issues: What happens if -

- …an examiner trained in chemistry examines a nanotechnology patent claim that also touches on physics & biology, overlooking previous inventions or publications in those fields relevant to whether a new claim is patentable?
- …the same invention is called by different names in separate patent applications?
  - Carbon nanotube
  - Elongated cylinder made of carbon

USPTO

- … dealing with a nanotech drug-delivery mechanism?
  - pharmaceutical strategy
  - mechanical device strategy
- How do you patent inventions that are invisible without special technology & require an unprecedented intersection of disciplines?

USPTO

- Nanotechnology is multidisciplinary & interfaces with biology, physics, chemistry, engineering, & computer science.
- There is no specialized examining group with focused expertise across diverse disciplines.
- Worldwide patent classification systems lack sufficient definition or description to accommodate the unique properties found in nanotechnology.

Nano Legal Challenges

- Today, the law governing nanotechnology is where Internet Law was in 1995 – it fills only a pamphlet.
- Nano- products, materials, applications, & devices are governed today within the existing framework of statutes, laws, regulations, & policies.
- Government policies to deal with the ethical and social consequences of bioengineering do not exist.

Nano Legal Challenges

- There is no:
  a. globally recognized definition
  b. uniform nomenclature
  c. common language that enables shared global understanding
  d. internationally valid standardization for the huge variety of nanotechnological substances, materials, products, or applications
  e. universal assessment of nanotechnology opportunities, nor impact on the risk landscape in the future, particularly as it relates to toxicology and exposure
  f. common terminology for a comparative analysis of the risk assessments of different institutions or countries.

PCAST

- On March 30, 2004, PCAST members heard about current research on the health & environmental impacts of nanomaterials & the efforts of federal agencies to regulate them.
- Some of the comments –
  - (a) there is no consensus within the scientific community re: safety of purposely-engineered nanomaterials;
  - (b) little is known regarding the impact on biological systems;
  - (c) consistent terminology is nonexistent;
  - (d) it is still unclear as to what nanomaterials & nanotechnologies might require FDA or EPA approval before going to market.

PCAST

- Recommended needs:

  (a) develop terminology & standards;

  (b) establish global leadership to define risks as a basis for labeling & regulation;

  (c) learn from social scientists about how to communicate risk to the public;

  (d) protect the nation's innovation ecosystem (mix of research universities, R&D centers, government funded research, the VC industry, & the free enterprise system).

Nano Challenges - FDA

- Regulates products, not processes or materials, & relies on existing protocols to regulate new nanomaterials, while developing data on toxicology, environmental fate, & tissue accumulation.
- It is the job of the Office of Combination Products of the FDA to determine which of its centers will take the lead in approving a combination product, a decision based upon the primary mode of action of the unit (device or therapeutic).

Are Nanomaterials New Chemicals?

- Nanoscale particles behave differently than macro-size substances of similar chemical compositions.
- Do existing regulatory protocols for regulating new chemical substances apply to nanoparticles?
- The law governs certain chemicals but does not distinguish among size scales.
- Are nanomaterials new chemicals?
- If so, do they fit the definition of a chemical substance as provided in the Toxic Substances Control Act, 15 U.S.C. § 2601 et seq.?

TSCA

- EPA tracks & screens 75,000 industrial chemicals currently produced or imported in U.S.
- EPA can require reporting or testing of chemicals that may be an environmental or human-health hazard.
- EPA can ban the manufacture & import of chemicals posing an “unreasonable risk”.

Chemical Substance

- “Any organic or inorganic substances of a particular molecular identity including any combination of such substances occurring, in whole or in part, as a result of chemical reaction or occurring in nature & any element or uncombined radical – are properly identified & adequately addressed prior to production or transport.”

REACH

- EU Chemicals Policy.
- REACH – Registration, Evaluation, Authorization, & Restriction of Chemicals.
- November 1, 2004 EU began a first of its kind trial of a legislative proposal to determine if rules forcing companies to register 30,000 chemicals will work & if the chemical industry will follow the registration procedures & processes outlined in the proposal.

REACH

- Involves:
  - finding out how the chemical will be used
    - by manufacturer
    - by all the companies which use the chemical
  - compile a ‘registration file’ for submission to the appropriate member state & then the EU.

Nano Challenges continued…

- Lack of conclusive technical data is causing contradictory & sweeping conclusions about the safety of engineered nanoparticles and its effects in the environment & if inhaled.
- If nanotechnology is a material in a chemical system, does it pose an unreasonable risk?

Swiss Re - Risk

- "Nanotechnology, as an emerging risk, challenges the insurance industry because of the high level of uncertainty in terms of potential nanotoxicity or nanopollution, the ubiquitous presence of nano-products in the near future (across industry sectors, companies, and countries), and the possibility of long latent, unforeseen claims…

Swiss Re continued…

- The insurance industry is concerned because scientific evaluations of potential risks for human health and the environment are few and remain inconclusive. Nor are there regulatory guidelines that address potential risks in an adequate manner. The industry community has only begun to evaluate potential ‘nano-risks’ and there is no global approach towards finding a solution satisfactory to business, scientists and regulators alike.”

Britain's Royal Society

- In their July 29, 2004 report, Britain's Royal Society and Royal Academy of Engineering recommended that a precautionary approach to nanotechnology be taken alleging that manufactured nanoparticles should be treated as dangerous until proven harmless, requiring an overhaul of safety regulations both in and outside the laboratories.

Royal

- Calling for a law to recognize that substances safe in large quantities can be dangerous when reduced to particles at the nanoscale, because no one yet knows whether any particular nanoparticle can harm human or environmental health, in addition to proposing that any use of manufactured nanoparticles be assessed by dedicated scientific panels, operating alongside the regulatory bodies that currently assess the safety of chemicals, with the data collected being made public.

European Voice

Martin Livermore

- "The Best Things Come in Small Packages"

  October 28-November 3, 2004.

  "A further barrier to innovation is the precautionary principle, wheeled out on a frequent basis when environmental issues are perceived to be at stake. This is used by both politicians & interest groups to push for tighter & tighter regulation…Could commercial applications of nanotechnology suffer a similar fate? And what can be done to ensure they don't?"

Projects on Environment & Health Implications

- In 2004, agencies participating in NNI are funding approximately $106M in research on health & environmental aspects of nanoscale materials.
- DOD – approximately $25M over 5 years
  - Develop a computer model that predicts if nanostructures are toxic
  - Develop nanostructures that can detect & protect against radiation & biological agents

Projects

- NIOSH - $2.3M in FY2004
  - Understand occupationally relevant airborne nanoparticles
  - Learn whether carbon nanotubes are harmful to the lungs or heart

EPA - $4M in FY 2004

- Toxicity of nanomaterials & their reaction while in transport

Nano Legal Effects

- International trade law
- Torts
- Criminal law
- Intellectual property
- Employment law
- Elder Law
- Insurance law
- Environment law
- Treaties banning chemical & biological weapons
- Regulations governing medical diagnostics & therapy
- National security

Legal Issue

- "Legal institutions created many years ago weren't designed to handle the complex issues and burdensome caseloads we routinely see in our courtrooms… What is needed today is nothing short of a revolution in our administration of justice…there is no choice, when you consider the alternatives."

Roberta R. Katz

Justice Matters (1997)

Questions

- Rapid technological advances at the intersection of nano-, bio- and pharma- mean that if the mere tweaking of a molecule can create an entirely different cell line or useful or harmful biological agent, then how would one handle the intellectual property rights?
- Because we do not yet know how to make these convergent technology products, is it more appropriate and easier to show a greater sensitivity to risk and a willingness to intervene now to avoid serious long-term problems rather than allow the manufacture of something on an ad hoc basis and then attempt to deal with the development of these problems as they arise?

A Matter of Torts

- Tort liability - as it relates to the development, manufacturing, & sale of nanodevices, products, materials, & applications – without the intent to harm others.
- To minimize the risk for tort liability – whether in negligence or strict liability – develop & implement rigorous & systematic documented process of risk analysis, review, & management.

Product Liability

- Product liability law provides a means whereby parties injured as a result of defective products can see redress.
- Innovations developed from nanotechnology involve risk.
- Product liability requires that companies critically examine the possible risks associated with their products, with special attention to their design, manufacturing, and accompanied warnings.
- In product liability, it is the defendant's product that must not be unreasonably dangerous – without regard to the reasonableness of the conduct.

Negligence

- The law of negligence states that if precautionary measures can be taken, & it is reasonably foreseeable that failing to take those preventive measures would cause harm, liability will attach.
- Would a reasonable person have foreseen the harm in question?
- In negligence, it is the defendant's conduct that is judged by a standard of reasonableness.

Protecting Against Tort Liability

- Quality & safety measures, as well as industry & government standards must be incorporated into "defensive" product designs, exploring not only where failures may occur, but the implications of those failures.
- Greater precautions & proactive measures must be incorporated regarding nanomaterials and their entry into the marketplace.

U.S. Liability Laws, Innovation, & the Courts

- Issues regarding a new product or process development:
  - Professional judgments from design to end use can be introduced as evidence;
  - Liability can exist even when products are built according to accepted industry standards – the only proof required is that it was possible to produce a safer product, even if production costs were so prohibitive that the product became unmarketable;

Liability Laws & the Courts

- manufacturers are increasingly being held responsible for human error & poor judgment in product use;
- nonscientific juries are deciding highly complex science, engineering & technology issues; and
- sometimes the technology itself goes on trial - & the more unfamiliar & innovative it is – the harsher it is judged.

How do we Look to the Future?

- Look at the laws and issues of today.
- How we got here – *brief rewind* to the past.
- Reconcile the vision of the future, with existing laws and the legal paradigms and systems possibly needed to meet the scientific and technological advances of tomorrow – *cautious forward*.
- Or, we just tinker with the existing body of laws.

Questions to Consider

- Should the law vary according to the technology involved?
- Should patent strategy be aligned with business strategy?
- Do we need an international patent system?
- Do we need to establish a Court of Convergent Technologies or a specialized Part within an existing court system?
- Should we organize new courts, and a new court system, by the kinds of subjects they must consider - CORE Courts (Katz, 1997), arranged by technical area, industry, activity, or physical community?
- Should we establish a Federal Convergent Technologies Commission, along the lines of the FTC and FDA?

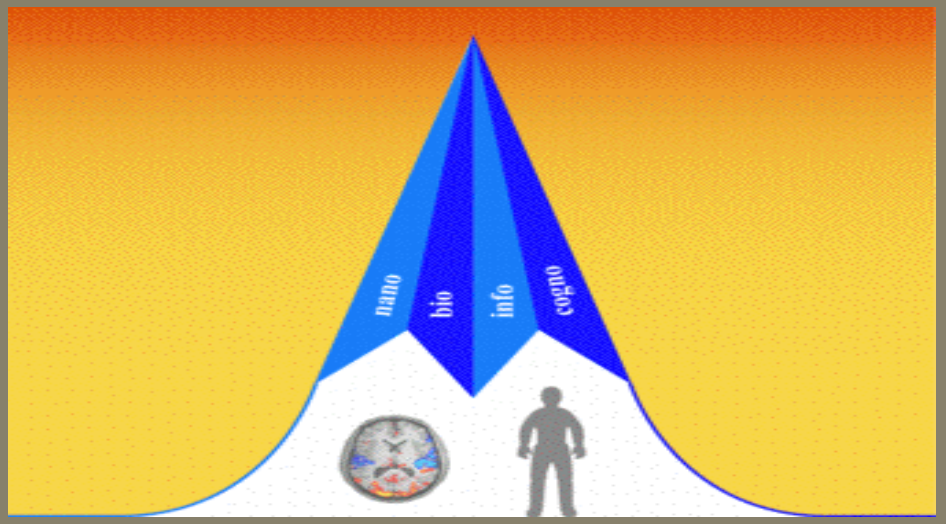
The New

- New paradigms will push existing public policy, legal regimes, and ethical models.
- Any new technology generates novel forms of human activity calling for evaluation, analysis, and assessment.
- Convergent Technologies have begun to dramatically alter life's landscape and infrastructures. We now must anticipate issues and implications and begin designing effective frameworks for new innovations.
- The Converging Technologies Bar Association (CTBA) has already begun to address the issues.

www.convergingtechnologies.org

Mission

- First professional association in the world dedicated to addressing the interrelated impact of the convergence of NBIC.



Purpose

- To foster interest, understanding, and collaboration among the legal, scientific, engineering, technology, and business communities centering on the convergence of NBIC, and other related sciences and technologies.

Initiatives

1. Facilitate solutions-based Dialogues.
2. Formulate and propose forward-looking measures within the legal system addressing broad implications of converging technologies.
3. Promote innovative educational programs.
4. Heighten public awareness of NBIC and serve as a clearinghouse of information.
5. Advocate, analyze, evaluate, and advise on laws, regulations, policies, and legislation.

Centers & Divisions

1. Center on Law, Ethics & Judicial Affairs.
2. International Law & Foreign Policy Center.
3. Education Center.
4. Communication Center.
5. Action Nerve Center.
6. Institute of Legal Convergence & Global Innovation.
7. New Renaissance Legal Laboratory.

The Unknown

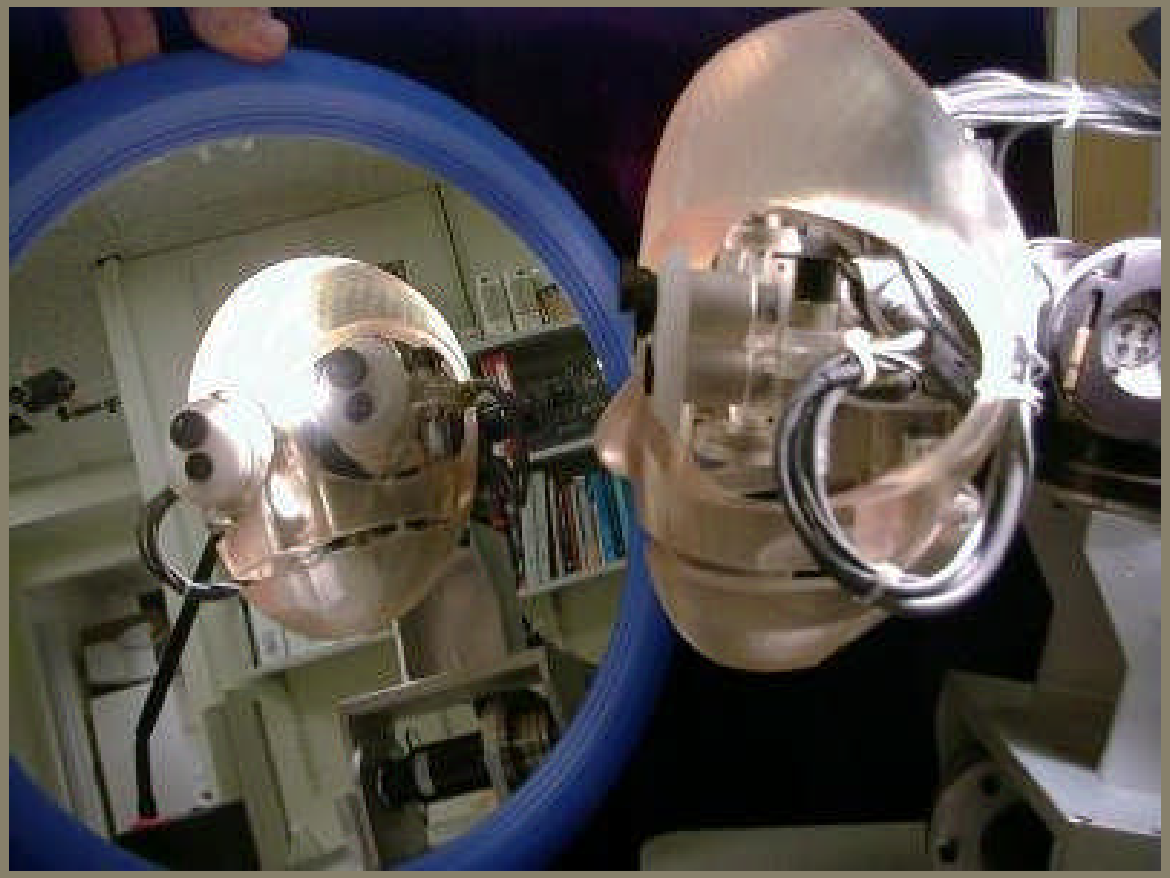
- "Life is … a process of development, expansion, exploration, achievement, and creation. The events of our lives are the wellspring of our social evolution, the key to the future of the human race … What is important is what is not yet known."

Geoffrey Raisman, M.D., Ph.D., FRS

The Idea That Scandalized Brain Science

Cerebrum, Volume 6, Number 1, Winter 2004

Peering Into the Future



Thank You

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