Minimizing Legal Exposure

Are you Ready for a Lawsuit by a Patent Troll or Tort Attorney?

Jack Hicks & John Sweeney
Womble Carlyle Sandridge & Rice, LLP
MINIMIZING LEGAL EXPOSURE

Are you Ready for a Lawsuit by a Patent Troll or Tort Attorney?

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NanoBusiness Commercialization Association

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Womble Carlyle Sandridge & Rice, LLP
Adjunct Professor, Elon University School of Law

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Womble Carlyle Sandridge & Rice, LLP
A licensed patent attorney with more than 25 years of legal experience, Jack Hicks counsels clients to craft the intellectual property position that meets their business goals. A substantial portion of his practice includes the preparation and prosecution of U.S. and foreign patent and trademark applications. Although Jack started his career as a successful trial lawyer, his practice currently focuses upon strategic counseling of clients in national and international intellectual property litigation, evaluation, protection and enforcement. Jack’s honors and awards include being ranked among the leading lawyers in his field by The Best Lawyers in America, North Carolina Super Lawyers and North Carolina Legal Elite.

Jack currently is working with numerous nanotechnology clients, helping them prepare and prosecute patents and other suitable intellectual property protection. One recent matter involved preparing and filing multiple U.S. and international patent applications for a leading aerospace manufacturer on the use of carbon nanotubes in coatings and complex composite structures. Other projects include nanofibers for drug delivery and filter technologies.
Class Actions and Mass Torts often involve “bet the company” risks. John Parker Sweeney’s more than 30 years of experience defending major Class Actions and Mass Torts involving Product Liability, Consumer Protection, Environmental, and Toxic Tort cases allows him to tailor an appropriate litigation response for any company to meet those types of high stakes risks. He regularly serves as national counsel, creating and supervising comprehensive defense strategies in Class Actions and Mass Tort cases across the country.

John’s effectiveness and national prominence as a defense lawyer for businesses in Class Actions and Mass Torts was recognized by his peers when he was elected as an officer of DRI—The Voice of the Defense Bar. John will serve as President of the 22,000 member association of corporate defense lawyers in 2014.

A nationally-recognized “Expert on Experts,” John relies on his relationships with internationally renowned technical, scientific, and medical experts, as well as his thorough understanding of the rules and procedures governing expert testimony in both Daubert and Frye jurisdictions to protect his clients from scientifically unfounded claims and unqualified plaintiffs’ experts, securing precedent-setting decisions excluding junk science from the courtroom.

John has many years of experience in Government Investigation work beginning with his years at the U.S. Securities Exchange Commission. Since then, in addition to responding to SEC investigations, he has been involved in investigations and other compliance actions involving a number of federal and state law enforcement agencies. He is particularly experienced in handling Consumer Product Safety reporting, recalls and corrective actions before the U.S. Consumer Product Safety Commission, and in advising clients on compliance with the far-reaching new requirements of the Consumer Product Safety Improvement Act of 2008 and the Consumer Product Safety Information Database.
Minimizing Legal Exposure

Patent Litigation
EXPANDED ROLE OF PATENTS

Patent is a tool to encourage innovation and prevent trespass on your invention.

Patent is a commoditized asset, aggregated for profit.
EXPANDED ROLE OF PATENTS

Patent is a tool to encourage innovation and prevent trespass on your invention.

Patent is a commoditized asset, aggregated for profit.
What is a Non-practicing Entity?

Troll?

Is a University a Troll?
• Patent troll claims rights to an invention without commercializing

• Non-practicing entity (NPE) who engages in “stick” licensing
  • Patent holding & licensing entities
  • “Invention research organization”
  • University Tech Transfer Office
  • Government Research Organization
Assertion:

• You are using our patented technology
• Take a license or face litigation

• Legal fees for infringement study: $5,000-$20,000 per patent
• Legal fees for patent litigation: $1.5M-$5.0M
• Settle: $10,000 - $150,000
## NPEs with Largest Patent Holdings

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Intellectual Ventures</td>
<td>10-15k (Est)</td>
<td>-</td>
</tr>
<tr>
<td>Round Rock Research LLC</td>
<td>3652</td>
<td>1300</td>
</tr>
<tr>
<td>Rockstar Consortium LLC</td>
<td>3428</td>
<td>2867</td>
</tr>
<tr>
<td>Interdigital</td>
<td>2955</td>
<td>1463</td>
</tr>
<tr>
<td>Wisconsin Alumni Research Foundation (WARF)</td>
<td>2556</td>
<td>1896</td>
</tr>
<tr>
<td>Mosaid Technologies Inc</td>
<td>2011</td>
<td>1219</td>
</tr>
<tr>
<td>Rambus</td>
<td>1696</td>
<td>727</td>
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<tr>
<td>Tessera Technologies Inc</td>
<td>1375</td>
<td>683</td>
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<tr>
<td>Acacia Technologies</td>
<td>1316</td>
<td>575</td>
</tr>
<tr>
<td>Commonwealth Scientific and Industrial Research Organisation (CSIRO)</td>
<td>1160</td>
<td>935</td>
</tr>
<tr>
<td>IPG Healthcare 501 Limited</td>
<td>1141</td>
<td>1074</td>
</tr>
<tr>
<td>Walker Digital LLC</td>
<td>896</td>
<td>222</td>
</tr>
<tr>
<td>Wi-Lan</td>
<td>888</td>
<td>716</td>
</tr>
<tr>
<td>Jerome H Lemelson</td>
<td>470</td>
<td>227</td>
</tr>
</tbody>
</table>

Public NPE firms

- Acacia Technologies
- Asure Software
- Burst.com Inc
- Decisioning.com Inc
- Interdigital
- Intertrust Technologies Corp
- LecTec Corp
- Mosaid Technologies Inc
- Network-1 Security Solutions Inc
- OPTi Inc
- Rambus
- Tessera Technologies Inc
- VirnetX Inc
- Wi-Lan
## NPE Patent Litigation Statistics by Industry


<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Electronics</td>
<td>3198</td>
<td>549</td>
<td>328</td>
<td>1646</td>
<td>1434</td>
</tr>
<tr>
<td>Retail</td>
<td>3116</td>
<td>912</td>
<td>289</td>
<td>1259</td>
<td>901</td>
</tr>
<tr>
<td>Media/Telecom</td>
<td>2591</td>
<td>708</td>
<td>274</td>
<td>1345</td>
<td>993</td>
</tr>
<tr>
<td>Computer Software/Services</td>
<td>2476</td>
<td>966</td>
<td>316</td>
<td>1401</td>
<td>1253</td>
</tr>
<tr>
<td>Computer Hardware</td>
<td>2262</td>
<td>334</td>
<td>324</td>
<td>1278</td>
<td>1362</td>
</tr>
<tr>
<td>Financial Services</td>
<td>1681</td>
<td>596</td>
<td>170</td>
<td>730</td>
<td>512</td>
</tr>
<tr>
<td>Automotive &amp; Transport</td>
<td>1599</td>
<td>525</td>
<td>145</td>
<td>685</td>
<td>492</td>
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<tr>
<td>Consumer Products</td>
<td>1032</td>
<td>446</td>
<td>178</td>
<td>549</td>
<td>413</td>
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<tr>
<td>Semiconductor</td>
<td>872</td>
<td>142</td>
<td>133</td>
<td>467</td>
<td>527</td>
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<tr>
<td>Industrial Manufacturing</td>
<td>681</td>
<td>338</td>
<td>193</td>
<td>465</td>
<td>552</td>
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<tr>
<td>Healthcare &amp; Pharma</td>
<td>603</td>
<td>363</td>
<td>83</td>
<td>284</td>
<td>210</td>
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<tr>
<td>Energy/Utilities</td>
<td>536</td>
<td>282</td>
<td>140</td>
<td>383</td>
<td>344</td>
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<tr>
<td>Other (Hotels, Services, Agriculture etc.)</td>
<td>1638</td>
<td>823</td>
<td>267</td>
<td>944</td>
<td>763</td>
</tr>
</tbody>
</table>
Litigations Over Time

Patent lawsuits involving NPEs have increased dramatically over the last decade. In 2011, another record setting year, there were more than 5,000 occasions when a company found itself in litigation with an NPE, a number that has increased by an average of over 35% *per year* since 2004.

*Operating Company Parties in NPE Lawsuits*

Litigations Over Time

*Patent Lawsuits Involving NPEs*

Nano and Patents?
What’s Special?

Universities owning patents

- Basic research centered in Universities & spin-outs
- Universities/tech transfer offices push patents
- Bayh-Dole Act (1980) permits University ownership of federally funded research
### Is There “Room at the Bottom”?

<table>
<thead>
<tr>
<th>U.S. Patent Number</th>
<th>Date of Issue</th>
<th>Owner</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>6,683,783</td>
<td>January 27, 2004</td>
<td>William Marsh Rice University Houston, TX</td>
<td>Carbon fibers formed from single-wall carbon nanotubes</td>
</tr>
<tr>
<td>5,747,161</td>
<td>May 5, 1998</td>
<td>NEC Corporation</td>
<td>Graphite filaments having tubular structure and method of forming the same</td>
</tr>
<tr>
<td>5,424,054</td>
<td>June 13, 1995</td>
<td>International Business Machines Corporation</td>
<td>Carbon fibers and method for their production</td>
</tr>
<tr>
<td>5,505,928</td>
<td>April 9, 1996</td>
<td>The Regents of University of California</td>
<td>Preparation of iii-v semiconductor nanocrystals</td>
</tr>
<tr>
<td>6,268,041</td>
<td>July 31, 2001</td>
<td>Starfire Electric Development and Marketing, Inc.</td>
<td>Narrow size distribution silicon and germanium nanocrystals</td>
</tr>
<tr>
<td>6,322,901</td>
<td>November 27, 2001</td>
<td>Massachusetts Institute of Technology</td>
<td>Highly luminescent color-selective nanocrystalline materials</td>
</tr>
<tr>
<td>5,897,945</td>
<td>April 27, 1999</td>
<td>President and Fellows of Harvard College</td>
<td>Metal oxide nanorods</td>
</tr>
<tr>
<td>5,833,705</td>
<td>November 10, 1998</td>
<td>Target Therapeutics, Inc.</td>
<td>Stretch resistant vaso-occlusive coils</td>
</tr>
<tr>
<td>4,724,318</td>
<td>February 9, 1998</td>
<td>International Business Machines Corporation</td>
<td>Atomic force microscope and method for imaging surfaces with atomic resolution</td>
</tr>
<tr>
<td>5,286,571</td>
<td>February 15, 1994</td>
<td>Northwestern University</td>
<td>Molecular modification reagent and method to functionalize oxide surfaces</td>
</tr>
<tr>
<td>6,346,189</td>
<td>February 12, 2002</td>
<td>The Board of Trustees of the Leland Stanford Junior University</td>
<td>Carbon nanotube structures made using catalyst islands</td>
</tr>
</tbody>
</table>
Carbon Fibers Formed From Single-Wall Carbon Nanotubes

US 6,683,789
Filed: 3/6/1998
Issued: 1/27/2004

“semiconducting nanocrystals”
William Marsh
Rice University

Carbon Fibers Formed From Single-Wall Carbon Nanotubes
US 6,683,789
Filed: 3/6/1998
Issued: 1/27/2004

(19 claims)

A composition of matter comprising at least about 99% by weight of single-wall carbon molecules.
Can you prepare? How?

• Core Products - Prior Art Searching
  • Obtaining patents for trade
  • Patentability … AND
  • Freedom to Operate to identify licensors/predators
  • Build license royalty into business plan
  • Join patent pool organization

• Ancillary Businesses
  • Use solvent contractors / suppliers who indemnify
  • Insurance … ?
What to do when you receive a demand letter?

- Gather information on NPE’s patterns & strategies
- Assess strength of claim, underlying IP, exposure and indemnity
- Defenses
  - Prior Commercial Use; laches
Fight or Settle?

- File preemptive declaratory judgment lawsuit in home district; early claim construction and summary judgment ($$)
- File post-grant review ($$)
- Joint defense groups
- Crowd sourcing for invalidating prior art (Article One Partners)
- Defensive Patent Aggregation (RPX; Allied Security Trust)
Is “help” on the way? What can Congress do?

- Transferability of Patents and Non-working Requirement are Hallmarks of US Patent System

- America Invents Act
  - Joinder rules
  - Post-grant review proceeding for covered business method patents.
Is “help” on the way? What can Congress do?

• Recent legislation – **HR 6245** Saving High-Tech Innovators from Egregious Legal Disputes Act (Shield Act)
  
  ✓ Fee-shifting / “loser pays” for computer hardware & software patent litigation where no “reasonable likelihood of succeeding”
Minimizing Legal Exposure

CLASS ACTIONS AND MASS TORTS

Nanomanufacturing Summit 2012 & 11th Annual NanoBusiness Conference
Nanotechnology Is in the News

WHAT IS A NANO TUBE?

Carbon nanotubes are atom-thick sheets of graphite formed into cylinders. They may be formed from a single layer of graphite (called graphene), or they may consist of multiple concentric layers of graphite, resulting in Multi Walled Carbon NanoTubes (MWCNTs). While the diameter of a nanotube can vary from a few nanometers up to tens of nanometers, they can be hundreds or even thousands of nanometers long. Carbon nanotubes come in many forms, with different shapes, different atomic arrangements, and varying amounts and types of added chemicals—all of which affect their properties, and might influence their impact on human health and the environment. Japanese researcher Sumio Iijima is generally credited with discovering carbon nanotubes in 1991.

Nanotechnology is the ability to measure, see, manipulate and manufacture things usually between 1 and 100 nanometers at the scale of atoms and molecules. A nanometer is one billionth of a meter; a dollar bill is roughly 100,000 nanometers thick. Nanotechnology is a new technology, and it is expected to have broad applications in the coming decades in fields as diverse as, medicine, energy, computing, manufacturing, space travel, and sporting goods—to name a few. According to manufacturer claims, nanotechnology is already used in over 600 consumer products on the market today, ranging from sporting goods to cosmetics to food packaging. By 2014, Lux Research projects that $2.6 trillion in global manufactured goods will incorporate nanotechnology, or about 15 percent of total global output.

Nanomaniufacturing Summit 2012 & 11th Annual NanoBusiness Conference
BUT NOT ALL THE NEWS IS GOOD
Ken Donaldson, professor of respiratory toxicology at the University of Edinburgh, said: "Concern has been expressed that new kinds of nanofibers being made by nanotechnology industries might pose a risk because they have a similar shape to asbestos."
“Nanofibers 'may pose health risk'”

“Inhaling tiny fibers made by the nanotechnology industry could cause similar health problems to asbestos,” say researchers.

1,000 times smaller than a human hair
Earlier Studies Made the Same Comparison... results in asbestos-like, length-dependent, pathogenic behaviour.
Carcinogenicity Is Assumed

"We knew that long fibres, compared with shorter fibres, could cause tumours, but until now we did not know the cut-off length at which this happened."

"This research is particularly interesting as it gives us an indication of the size of fibre that might lead to mesothelioma if inhaled."

"If confirmed by subsequent studies, this minimum fibre length can be cited in industry guidelines to help ensure people are not exposed to the sorts of fibres that may lead to such deadly diseases."
What About Asbestos Litigation?
Rumors of Its Death Are Premature, but . . .
Everyone Is Looking for the Next Asbestos
Research Continues...
Will Nanomaterials Be Tarred with the Asbestos Brush?
Carbon nanotubes, how distinct characteristics, but their needle-like fibres have been compared to asbestos-like characteristics that widespread use of carbon nanotubes may lead to mesothelioma. Cancer of the lining of the lungs caused by exposure to asbestos. We show that exposing the mesothelial lining of the body cavity of mice, as a surrogate for the mesothelial lining of the pleural cavity, to long nanotubes results in asbestos-like, length-dependent, pathogenic behaviour. This includes inflammation and the formation of nodules known as granulomas. This is of considerable importance, because, research and business communities continue to invest heavily in carbon nanotubes for a wide range of materials, including the assumption that they are not as hazardous as graphite. Our results suggest the need for further research and get carcinogenic before introducing such products into the market. The question of how to use carbon nanotubes is a complex issue.

Carbon nanotubes (CNTs) are often considered to be key components of the field of nanotechnology—a diverse collection of nanoscale materials used for various purposes such as manipulation of nanoscale objects and drug delivery. Carbon nanotubes (CNTs) are typically classified as single-walled nanotubes (SWNTs) or multi-walled nanotubes (MWNSTs). They are composed of carbon atoms arranged in a hexagonal lattice, forming a cylindrical structure that can be either single-walled or multi-walled.

The unique nanoscale structure of CNTs on a cell's surface makes them particularly interesting for biomedical applications. However, the potential health risks associated with their use in nanomedicine need to be carefully evaluated. The integration of CNTs into living systems requires a deep understanding of their safety and biocompatibility. Future research should focus on the development of CNT-based materials that are optimized for specific applications, such as drug delivery or diagnostics, while minimizing potential health risks.
The Literature Stacks Up

• Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma.

Safety Concerns Abound

Risk perception and risk communication with regard to nanomaterials in the workplace

Soybean susceptibility to manufactured nanomaterials with evidence for food quality and soil fertility interruption

ISO Preparing Labeling Guidance for Manufactured Nano-Objects and Products Containing Manufactured Nano-Objects

SCCS Calls for Experts on the Safety Assessment of Nanomaterials in Cosmetic Products

SCENIHR Issues Call for Information and Experts on Health Effects of Nanomaterials Used in Medical Devices
FDA Directed to Study Nanomaterials

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act became law, charging the Secretary of Health and Human Services to “intensify and expand activities related to enhancing scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated” by FDA.
Regulation is Coming Slowly
Industry Safety Assurances Get Little Media Attention
The 2011 Nanodermatology Society Position Statement on Sunscreens

Introduction

The harmful effects of both short-term and long-term sun exposure have been well described and range from accelerated skin aging to skin cancer, a potentially fatal condition. One of the most common approaches to prevent this damage or harm is with the application of sunscreens, which contain a variety of chemicals and minerals that act to block or reflect ultraviolet (UV) radiation, the component of sunlight that is responsible for many of its harmful effects. For years, titanium dioxide (TiO₂) and zinc oxide (ZnO) have been used in sunscreens since they serve as a physical barrier to both short (UVB) and long-wave (UVA) UV radiation and thus decrease the amount of radiation to which the skin is exposed. However, these ingredients in their native state are not water soluble, but are opaque and coat the skin when applied with an oily and cosmetically displeasing white residue, resulting in limited consumer use. In recent years, there has been a revival of TiO₂ and ZnO use in sunscreens as the science of nanotechnology has allowed for improved versions of these products.

Nanotechnology involves the design, production, and application of materials that are extremely small, (1 nanometer = one billionth of a meter). When this technology is applied to sunscreens, specifically nanosized TiO₂ and ZnO, these products do not have the thick feel or unsightly chalky film as compared to their predecessors. Even more importantly, sunscreens with these nanomaterials offer superior UV protection when compared to conventional formulations. However, many organizations and regulatory bodies have raised concerns regarding the safety of nanoparticle sunscreens.

These concerns are based on the unique properties of materials at the “nano” level, which include increased surface area to weight ratio (provides more surface to interact with the environment) and enhanced skin and organ penetration capabilities. As such, agencies wonder if these nanoparticles are toxic to living cells and if they are capable of being absorbed through the skin into the bloodstream. Regulatory agencies have reviewed studies that have focused on the safety of nanoparticle formulations. These results have been presented by the Environmental Protection Agency (EPA), Environmental Working Group (EWG), European Union (EU) and Australia’s Therapeutic Goods Administration (TGA), among other groups. This paper reviews results regarding titanium and zinc nanoparticles and sunscreen safety.

Are TiO₂ and ZnO nanoparticles toxic to cells?

Recently, it was discovered that ROS (reactive oxygen species) are produced when skin cells are exposed to UV radiation. ROS are chemically-reactive molecules that have the potential to significantly damage proteins, DNA, RNA, and fats within cells. The actual amount of ROS produced depends on a variety of factors including their size, structure, surface properties, toxicity, and ability to aggregate. For example, several crystal forms of nanosized TiO₂ exist, and differ in the amount of damage they exert on cells. In addition, coating with manganese⁶ or other materials⁷ has been shown to limit the formation of free radicals.

Damage associated with free radical formation is dependent on their ability to interact with living cells. Two barriers must be surmounted for nanoparticle toxicity to occur: penetration in the body via the skin, and host defenses against ROS by neutralizing enzymes and other molecules. It is important to remember that the...
Potential Areas of Liability Concern

• “Occupational” Claims

• “Consumer” Claims

• “Environmental” Claims
Worker Exposure Is a Concern

Health scare: Labor unions claim that workers in the nanotechnology sector might be facing a health “time bomb”

The July 3, 2012 National Institute for Occupational Safety and Health (NIOSH) eNews nanotechnology update states that the critical question to address is whether nanomaterials pose health or safety risks to workers employed in their manufacture and industrial use.
Consumer Health Concerns

NEWS AND ANALYSIS

Nanotechnology risks ignored

MEDIA
Press focus on positives of new technology

A US study has found scant media coverage of the potential risks posed by nanotechnology, with many more articles extolling its future benefits.

In their longitudinal study spanning coverage from 2000 to 2005 — in 50 US, nine UK newspapers and two wire services — the US researchers looked for articles that could alert readers to nanotechnology’s risks.

Sharon Friedman and Brenda Egolf, from Lehigh University in Bethlehem, found the number of stories that mentioned risks averaged around just 37 per year in each country. Three main narratives prevailed — runaway technology, science-based studies and regulation — and journalists most often covered health risks, followed by environmental and societal risks. Regular coverage was less frequent but increased over time.

The report concludes that given the many articles describing nanotechnology’s benefits and the average person’s minimal knowledge about this topic, we may be setting the stage for public distrust of nanotechnology in the event that a dangerous event should occur.

Friedman tells Chemistry World that there has been a great deal of “cherry-picking” by the US and UK governments, universities, companies and scientists about nanotechnology. “The number of news releases with ‘good news’ about nanotechnology has been overwhelming,” she says. “Almost every study in the US and most European countries has found that the dominant narrative or frame for nanotechnology media articles has been positive.”

Positive coverage has focused on the health, energy and computer technology benefits of nanotechnology.

Friedman says that editors think readers want to read this. “With very few risk incidents occurring and many scientists providing either balanced or very positive information about nanotechnology, reporters have had little incentive to follow up on scientific risk messages,” she adds.

Friedman suggests other reasons for example, positive stories predominating include cutbacks at mainstream US newspapers. “When the departure of most science writers from a newspaper’s staff, it is much easier to write an article based on a news release,” she says.

Robb Williams, director of the Institute for the Study of Science, Technology and Innovation at the University of Edinburgh, UK, says that there is no proof that a greater discussion of the assumed risks in the media today will lead to nanotechnology being better accepted and understood in future. Efforts to outline nanotechnology’s potential risks or benefits ahead of time are based by pitfalls and will not necessarily avert public controversy, he argues.

Attempts have been made to anticipate the outcome by extrapolating from previous technologies, such as the recent debate over genetically modified foods. However, studies of historical experiences show that the initial conception of the implications of a technology are often far removed from ultimate outcomes as to be uninformative,” he explains.

“Indoctrination pathways are often deviated from their initially expected trajectory,” Helen Carnichael.
Despite FDA Denials, Nano-Food Is Here

According to a USDA scientist, some Latin American packers spray U.S.-bound produce with a wax-like nanocoating to extend shelf-life. "We found no indication that the nanocoating ... has ever been tested for health effects,"
A Cautionary Tale

1960s
The first silicone breast implants are developed by two plastic surgeons from Texas.

1976
FDA now has the authority to approve new medical devices. But since silicone breast implants have been on the market for almost 15 years, they are "grandfathered."

1980s
Ralph Nader's Public Citizen Health Research Group, Washington, D.C. sends out warning signals that silicone breast implants cause cancer.

January 1982
FDA proposes to classify silicone breast implants into a Class III category which would require manufacturers to prove their safety in order to keep them on the market.

December 1990
Program on the dangers of silicone breast implants airs on "Face to Face with Connie Chung."
December 1991
The largest tort award yet, $7.3 million, is given to Mariann Hopkins whose mixed connective-tissue disease is linked to her ruptured silicone breast implants. To date, 137 individual lawsuits have been filed against Dow Corning.

January 1992
FDA Commissioner, David Kessler, calls for a voluntary moratorium on silicone breast implants until the FDA and the advisory panel have an opportunity to consider newly available information. The manufacturers agree.

March 1992
Dow Corning leaves the silicone breast implant business

December 1992
Pamela Jean Johnson wins $25 million tort award in Houston. To date 3,558 individual lawsuits have been filed against Dow Corning.

March 1994
A class action settlement is reached with Dow Corning being the largest contributor. Manufacturers claim there is no scientific evidence linking silicone breast implants with autoimmune diseases.
**September 1997**
The Journal of the National Cancer Institute publishes a review of scores of medical studies that concludes breast implants do not cause breast cancer. The researchers described the evidence for linking implants to any other disease as "borderline."

**November 1998**
Dow Corning files for bankruptcy reorganization, which includes the $3.2 billion previously agreed-to settlement and offers claimants several payout options.

**December 1998**
A panel of four independent experts appointed by Judge Sam C. Pointer, overseer of implant lawsuits in the Federal courts, concludes that scientific evidence so far has failed to show that silicone breast implants cause disease.

**June 1999**
The Institute of Medicine releases a 400-page report concluding that silicone breast implants do not cause any major diseases such as lupus or rheumatoid arthritis.
Due Diligence

• Is the company’s IP solid?

• What are the potential regulatory hurdles?

• What are the potential liabilities?
LOOK BEFORE YOU LEAP
Questions, Comments and Concerns

Thank you