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Regulating Tiny Technology:
Preparing for Big Impacts on Innovation and Commercialization

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Navigating the Regulatory Maze

Fern P. O'Brian

September 26, 2011

Overview of Legislative and Regulatory Landscape

FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CONSUMER PRODUCT SAFETY COMMISSION · UNITED STATES OF AMERICA

NSF

Nano.gov National Nanotechnology Initiative

USDA

DEPARTMENT OF COMMERCE · UNITED STATES OF AMERICA

National Institute for Occupational Safety and Health NIOSH

NIST

NATIONAL INSTITUTES OF HEALTH

U.S. DEPARTMENT OF HOMELAND SECURITY

DEPARTMENT OF TRANSPORTATION · UNITED STATES OF AMERICA

DEPARTMENT OF DEFENSE · UNITED STATES OF AMERICA

Statutory & Regulatory Landscape at Federal and State Levels

- EPA, TSCA & FIFRA
  - "plugged in" both internationally (e.g., ISO; OECD) and domestically (e.g., California DTSC activities)
  - CNT and Nano Initiatives
  - EPA Nanotechnology White Paper
  - Nanosilver and recent CNT SNUR
- FDA
- NIOSH
- USDA

TSCA – Chemical Substances

- §5 – “New Chemicals”
  (“R&D” important to note)
- §4 – Testing
- §8 – Information gathering
  - Reports
  - Records
  - Information and data call-In
- §6 – Regulatory actions/restrictions
- §12/13 – Export/Imports
- Other §§ – Addressing other areas, notably, enforcement and §15(2)

Evolution of EPA and Congressional Action – TSCA

- **CNT SNURs**
- **Safe Chemicals Act of 2011 - Introduced 4/14/11**
  - Burden of proof on manufacturer to prove chemical meets safety standard before chemicals allowed to reach the market
    - "The Administration shall . . . find that a chemical substance meets the safety standard only if the Administrator finds that there is a **reasonable certainty that no harm will result** to human health or the environment from aggregate exposure to the chemical substance."
  - Safety testing "as a condition" for allowing distribution of the chemical
  - EPA to prioritize chemicals based on risk
  - Expedited risk management of persistent, bioaccumulative and toxic chemicals
  - Public database

FIFRA – Pesticides

- Includes: Insecticides, Fungicides, Herbicides, Rodenticides, and Antimicrobials
- § 3–Registration
- § 5–Experimental Uses
- §17–Exports and Imports

FIFRA – Pesticides

- EPA's Office of Pesticide Programs intends to confirm that nanoscale versions of existing registered active ingredients are "new" pesticides that require registration under FIFRA section 3.
  - Regardless of whether a non-nanoscale form of the same active or inert ingredient is already registered under FIFRA
  - Nanosilver considered a new pesticide, even though silver is already registered as a pesticide.

FIFRA – Pesticides

- Rumored revisions to interpretation of FIFRA Section 6(a)(2) (“adverse effects” section) – no formal proposed revisions yet
  - Currently requires pesticide product registrants to submit adverse effects information about their products to the EPA
  - EPA: new interpretation would likely:
    - Require pesticide manufacturers to report the deliberate inclusion of intentionally produced nanomaterials in their products
    - Emphasize data collection, while also including adverse effects
    - Reach substances other than nanomaterials

FDA: Proposed Legislation

- H.R. 5786, Safe Cosmetics Act of 2010 – died in committee, but could be reintroduced
  - Phase-out of ingredients linked to cancer, birth defects and developmental harm;
  - Elimination of labeling loopholes by requiring full ingredient disclosure on product labels and company web sites;
  - Worker access to information about unsafe chemicals in personal care products;
  - Data-sharing to avoid duplicative testing and encourage the development of alternatives to animal testing
  - Safety standard similar to the standard purposed in Toxic Chemicals Safety Act of 2010:

    "With respect to an ingredient when the route of exposure directly relates to a particular cosmetic use, a standard that— **provides a reasonable certainty that no harm will result** from aggregate exposure to the cosmetic or ingredient, including impacts on vulnerable populations, taking into account possible harmful effects from low dose exposures to the cosmetic or ingredient or from additive effects, where such evidence exists…"

NIOSH

- National Institute for Occupational Safety and Health set Recommended Exposure Limits (RELs) for fine and ultrafine **titanium dioxide**
  - exposure limit for ultrafine titanium dioxide is the first REL applied to nanoparticles
  - REL imposed because of *in vitro* and *in vivo* studies in animals (rodent inhalation and ingestion studies) suggesting the genotoxicity of titanium dioxide is related to particle surface area rather than the compound itself
    - More regulation of nanomaterials, based on particle size, likely soon

OEHHA Recommendations

University of California
San Francisco
UCSF
National Center of Excellence
in Women's Health

- May 4, 2011: “Recommendations for Addressing Potential Health Risks from Nanomaterials in California,” Commissioned by California's Office of Environmental Health Hazard Assessment (OEHHA)
  - Recommendations to address health risks from nanomaterials for OEHHA that can be achieved under the existing regulatory structure (*e.g.*, develop a definition of nanomaterials; define, identify and collect information regarding priority properties for risk characterization, fate and transport of nanomaterials; etc.)
  - Recommendations to support successful approaches to address potential health risks from nanomaterials that are currently outside the scope of OEHHA (*e.g.*, require disclosure of where and what nanomaterials are manufactured, in what quantities, and for what new or existing products; reporting and disclosure requirements; testing requirements; etc.)
    - http://www.prhe.ucsf.edu/prhe/nanodocument.html

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Leahy-Smith American Invents Act

The day everything changed

Troy S. Prince

September 26, 2011

Leahy-Smith American Invents Act
Enacted 16 Sept. 2011

President Barack Obama signs the America Invents Act, Friday September 16 2011, at Thomas Jefferson High School for Science and Technology in Alexandria, VA

What People Are Saying

- This much-needed reform will speed up the patent process so that innovators and entrepreneurs can turn a new invention into a business as quickly as possible"

  - *President Obama*

- The America Invents Act brings the U.S. patent system into the 21st century and will help speed and expand the innovation capacity of the American economy, creating new technologies, products and jobs.

  - *Ellen Kullman, CEO DuPont*

- [AIA] actually represents an effort by multinational and foreign corporations to crush America's vital culture of independent inventors.

  - *Robert Zubrin, Washington Times*

- "The America Invents Act is a true jobs bill at a time when we need it the most."

  - *Senator Leahy*

First Take Aways

- First-to-file (sort of)
  - Derivative Actions and Procedural Loophole
- Tiered Implementation stretching over 18 months
  - Effectively creates a dual system stretching into the 2030's
- Fees – 15% surcharge today
  - Micro-entity status / Universities and most non-profits
- Patent marking – Qui Tam essentially dead
- No joinder of multiple defendants in infringement action

Timeline for Enactment

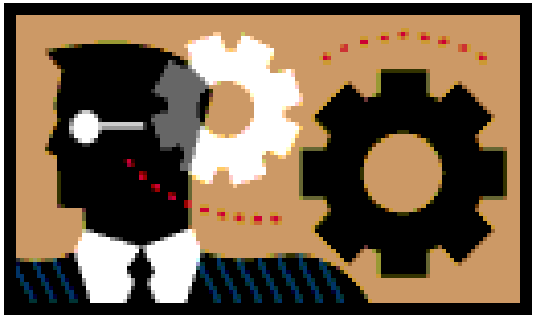
+0 days Sept. 16, 2011	+10 days Sept. 26, 2011	+60 days Nov. 15, 2011	+12 months Sept 16, 2012	+18 months March 16, 2012
Re-examination threshold – higher – Reasonable likelihood Tax strategies – verboten Best mode invalidity – gone Virtual marking – allowed via web False marking – Qui Tam suites are gone	Prioritized Examination – 10k cases maximum $4800 fee limited claims Answer in 12 months 15% surcharge is effective	Electronic filing incentive - $400 penalty for filing on paper	Inventor's Oath/Declaration – easier for company to file if inventor is MIA 3rd Party submission of prior art for patent application Supplemental Examination Citation of prior art in patent file Priority examination for important technologies Post-grant review Transitional post-grant review program	First Inventor to File – the flood gates open Derivation proceedings – Modified first-to-file system

Rule making has started – USPTO requests early feedback.

Zeroth Day

- Re-examination – higher threshold
  - *Reasonable likelihood that requester would prevail*

    vs
  - OLD *substantial new question of patentability*
- Best mode invalidity
  - Gone* – *But see* 35 USC 112,¶1
- Virtual marking
  - Allowed via website
- False marking
  - Qui Tam suites are gone
- Tax strategies are automatically within the prior art



Ten to Sixty Days

- Prioritized examination today
  - 10,000 cases maximum
  - $4800 fee
  - limited claims (4 ind / 30 total)
  - Answer in 12 months
- 15% surcharge is effective today
  - Fee diversion is “gone”*
- Stop paper filing by November 15, 2011
  - $400 fee for filing by paper
  - EFS filing is easy and fast (now stable too)

12 Months

- Inventor's Oath/Declaration
  - Easier for company to file if inventor is missing or unwilling to comply with obligations as inventor
- Pre-grant submission of prior art for patent application
  - Allowed to submit prior art along with explanations
- Priority examination for important technologies
  - Extend USPTO's Green Tech program to other technologies – Class 977 Nano?

12 Months Continued

Yes there is more

- Post-grant opposition and review period
  - Post Grant Review - within 9 months after issuance – very broad scope
    - Threshold – “more likely than not that 1 or more claims invalid”
  - Inter Partes Review – >9 months – prior art patents and printed publications
    - Threshold – “reasonable likelihood would prevail”
  - Relationship to civil actions – bars Post and Inter Partes Review if previously filed civil action challenging validity (not counterclaim) and automatically stays civil actions filed after request filed
  - Ex Parte Reexamination – anytime after patent grant for prior art patents and printed publications
- Supplemental Examination
  - Allows submission of prior art to USPTO to determine if prior art raises a significant new question of patentability
- Transitional post-grant review program for business methods

18 Months
Beware the Ides of March 2013

- First Inventor to File
  - Transition to first-inventor-to-file patent system while maintaining 1 year grace for inventor disclosures
  - File on March 15, 2013 – New Applications; Continuations-in-Part; Continuations with new claims disclosed but not claimed?
- Derivation proceedings – Modified first-to-file system
  - Allows inventor who files later to challenge an earlier filed patent application because it is “derived” from the inventor’s work

- Prior Art – changed but similar
  - Patented
  - Described in printed publication
  - On sale
  - Otherwise available to the public
  - Also new 102(e) standards

Leahy-Smith America Invents Act

There is a lot more…

But not for today

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Nanotechnology Litigation In The Future

Steps to Protect Your Company

John R. Mitchell

September 26, 2011

Steps to Protect Your Company

1. Recognize that one size does not fit all
2. Be (or employ) an expert
3. Be aware of existing and future regulations
4. Consider voluntary disclosure
5. Know the details of your insurance coverage
6. Participate in organizations
7. Take precautions

1. One Size Does Not Fit All

- As we know, nanomaterials can vary tremendously in size, shape, structure, reactivity, etc.
- The toxicology studies involve varying sizes of particles, levels of exposure, duration of exposure, types of laboratory animals, and results
- Plaintiffs often try to group diverse products under one umbrella to take advantage of existing studies or negative publicity
- Distinguish your products and prepare a course of action specific to your products and your company

2. Be (or Employ) an Expert

- Two key factors of product liability law:

  a. Manufacturers are responsible for warning of dangers they know or have reason to know

  b. Manufacturers are held to have the level of knowledge of an expert in their field

- It is **critical** to have knowledgeable and adequately trained people to monitor the state-of-the-art

- You will not get the benefit of the doubt later

3. Be Aware of Regulations

- Federal, state, and foreign governments are all regulating products containing nanomaterials
- As seen above, no clear cut consensus exists with regard to the manner in which nanomaterials will be regulated in the United States, Europe, or elsewhere

4. Consider Voluntary Disclosure

Question:: If a company is not under any legal obligation to disclose information about its use of nanomaterials, why should it consider voluntary disclosure?

Answer:: Courts and juries looking in hindsight may decide that companies should have provided warnings despite absence of mandatory disclosures.

4. Consider Voluntary Disclosure

- Deciding *whether* to disclose information or warn is a VERY difficult question
  - False Alarms - Past epidemiology and toxicology studies can be proven wrong as science develops
  - Providing warnings under such circumstances could promote unnecessary fear and anxiety in workforce

4. Consider Voluntary Disclosure

- Deciding *what* information to provide is a VERY difficult question
  - Effective warning typically provides:
    - Warning language ("DANGER," "HAZARD")
    - Instruction on what to avoid
    - Potential consequences

  - Creating an effective warning becomes difficult when the state-of-the-art is constantly changing and so little is known

5. Understand Your Insurance Coverage

- The insurance industry is paying attention
- Several attempts to exclude coverage for anything related to nanotechnology (as opposed to raising deductibles or setting coverage limits)
- Review your insurance polices and consult an expert to make sure you are covered

6. Participation in Organizations

- ANSI Nanotechnology Standards Panel advocates for uniform nanotechnology standards
- ACC Nanotechnology Panel shares information and supports health and safety research
- Benefits - Keep abreast of state-of-the-art; contribute to policy-making discussions
- Risks - Cost; potential civil conspiracy claims in future mass tort litigation

ANSI
American National Standards Institute

American Chemistry Council℠

7. Take Precautions

- Use industrial hygiene practices proven to be effective for fine particles (ventilation systems, respirators, other protective clothing, etc.)
- Document the reasons behind your decisions to take (or not take) certain precautionary actions
- Helps avoid punitive damage claims and prevent plaintiff's lawyers and juries from speculating as to your motives
- Consulting attorneys on these issues creates attorney-client privilege

Conclusion

- Stay abreast of current developments, research, and the ever-changing regulations
- Be or employ toxicology, epidemiology, industrial hygiene, and warnings experts so that you can best protect your employees and customers
- Consult with attorneys to develop strategies that are specific to **YOUR** products and processes

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