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Intellectual Property Law Issues in Nanotechnology:

What can the "Nanotech Revolution" learn from the "Biotech Revolution"?

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September 5, 2012

“Those who do not learn from history are doomed to repeat it”- George Santayana

- Already thousands of nanotech patents, the rate patent applications filings is accelerating
- Lots of investment money, potentially great financial & social returns
- In many ways, similar to the Biotech boom of the 90s.

Cutting Edge Technology = Cutting Edge IP Issues

- Cutting edge companies and industries rely on patent protection
- The law consistently lags behind innovation in science, technology, and medicine.
- “New” technologies create learning curves at the United States Patent and Trademark Office and in the Courts

Where have we heard this before?

- U.S. patent examiners lack focused expertise on the technology.
- Minimal technology specific training.
- The PTO is understaffed and plagued by high attrition rates.

Problems created by the “lag”

- Extended patent pendency.
- Inconsistencies in claim language.
- Overbroad claims that may block other innovators.
- Claims that don’t reflect the actual invention.
- Overlapping claims
- Inconsistency in the courts

Lessons from the “Biotech Revolution.”

- Understand the technology and the context.
- Not all patent claims are created equal.
- Who are the other players, understanding of the “lay of the land.”
- Adaptability.
- Hidden value.

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Protecting Your Company's Value : Steps to Mitigate Risk

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11th Annual NanoBusiness/Nanomanufacturing
September 5, 2012

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. Participate in Industry Organizations
5. Consider voluntary disclosure
6. Know the details of your insurance coverage
7. Take precautions

1. One Size Does Not Fit All

- As we know, nanomaterials can vary tremendously in size, shape, structure, reactivity, etc. and are used in many different types of products
- The toxicology studies involve varying sizes of particles, levels of exposure, duration of exposure, types of laboratory animals, and results
- 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
- No clear cut consensus exists with regard to the manner in which nanomaterials will be regulated in the United States, Europe, or elsewhere

4. 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℠

5. 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.

5. 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

5. 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

6. 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

7. Take Precautions

- Use industrial hygiene practices proven to be effective for fine particles (ventilation systems, respirators, other protective clothing, etc.)
- Create a risk committee to continually understand new regulations and industry practices and to implement changes in safety-related processes and to create improved products
- Conduct an audit of current practices
- Document the reasons behind your decisions to take (or not take) certain precautionary actions to 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 and industry practice
- 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