Toxic Torts

Andrews Litigation Reporter

VOLUME 27 ★ ISSUE 4 ★ APRIL 8, 2009

Expert Analysis

Nanotechnology: Understanding And Managing the New Frontier

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Nanotechnology is a long-awaited panacea, its ardent champions swear. Advocates of nanotechnology claim that it has the potential to simultaneously solve the energy crisis and cure cancer. It promises to usher in an age of vastly improved consumer products and make formerly impossible things possible. Indeed, one graduate student's nano-research promises to make grafting human veins "as easy as soldering wire."[1] If these predictions are true, soon nano-products will be as ubiquitous in our everyday lives as plastic, and the future for any 21st-century Benjamin Braddock will best be summed up in a single word: nano.

But does the reality of nanotechnology live up to its advance billing, and at what cost? And when and how will the inevitable governmental response affect this brave new frontier, if at all? These and other questions about the future of nanotechnology are addressed in this article.

The Promise of Nanotechnology

The term "nanotechnology," which first was used in the 1970s, is so called because it pertains to the development and application of atomic, molecular and macromolecular materials.[2] Definitions vary, but nanotechnology generally is regarded as the manipulation of "nanoparticles" that are less than 100 nanometers in any one dimension.

A nanometer (nm) is one-thousand-millionth of a meter. A human hair, by comparison, is about 60,000 nm wide, a red blood cell is about 7,000 nm in diameter and a human DNA helix is about 2 nm in diameter.

Nanotechnology, however, is not distinguished merely by the minute scale on which it operates. Rather, nanomaterials differ from macro-materials in at least two significant ways. First, they have larger surface areas compared to their mass and, therefore, are more chemically reactive. Second, nanomaterials exhibit quantum properties, which means they can have different magnetic, electrical and optical characteristics than larger scale materials.

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Opaque materials, such as copper, can become transparent at the nano-level; relatively soft materials, such as graphite, can become stronger than steel; solids, such as gold, can turn liquid at room temperature; and relatively stable materials, such as aluminum, can become highly combustible.

The industrial application of nanotechnology is not new. Evidence of the use of carbon nanotubes in the production of steel swords manufactured more than 400 years ago has been reported.[3] Ceramicists and stained-glass makers have exploited the properties of nano-gold, which can appear red or blue in color, for centuries.[4] Particles of carbon black or soot, the by-product of long-standing industrial processes and one of the principal components of modern automobile tires, tend to range in size from 1 to 100 nm.

Widespread interest in, and use of, nanotechnology, on the other hand, is a relatively new phenomenon. An online inventory of consumer products that use nanotechnology lists more than 800 items, nearly four times as many as in 2006,[5] and the market for such products is expected to be $1 trillion by 2015.[6]

Some areas in which nanotechnology is believed to offer particular promise include fuel cells, batteries, pollution control and cleanup, medical implants, semiconductors and electronic memory storage, optics, aerospace, and textiles. But for the current recession, 2008 likely would have seen a wave of nanotechnology IPOs.[7] Humanity, it seems, is poised at the dawn of a golden age of nanotechnology research and application.

The Risks of Nanotechnology

As the list of actual and potential applications for nanotechnology grows, however, so does concern about the hazards — both known and unknown — potentially posed by such products. Titanium dioxide and zinc oxide, for example, are transparent in their nano-dimensional form, but they also are able to absorb and reflect light, which makes them popular ingredients in various sunscreens and sunblocks.

There is concern, however, regarding what happens to the titanium dioxide and zinc oxide nanoparticles once they are absorbed into the body. Logically they either enter the lymphatic or circulatory systems, where they may be able to permeate cellular barriers that are effective at filtering out only larger toxins, or else accumulate in the skin.[8] Either result is troubling to some scientists because the long-term effects of the presence of nanoparticles in the body currently are unknown.

Other products that contain nanoparticles present the risk of releasing those particles into the environment with unforeseen consequences. Nano-silver is an increasingly popular antibacterial and odor-fighting additive to everything from socks to bandages to baby clothes.

A recent study of socks that are treated with nano-silver, however, indicates that nano-silver particles can be released from the socks when they are washed in an ordinary washing machine. The nano-silver then can pass through wastewater treatment plants and find its way into the environment,[9] where it is potentially harmful to fish and other forms of aquatic life. "Nano-socks" are just one illustration of the hazards that nanotechnology products can present throughout their lifecycle, including after they are discarded.

Possible adverse effects resulting from exposure to nanoparticles in the workplace are another area of concern. Potential avenues of exposure include inhalation, dermal absorption and ingestion.[10] There is limited exposure data because the field is still nascent, but animal studies suggest that exposure to nanoparticles may result in both respiratory and brain injuries, possibly even after short-term exposure.[11] Inhalation of particulate matter has long been a concern; the increased reactivity of nanomaterials that results from their higher surface-area-to-mass ratio may only compound the problem.

Just as nanoparticles may expose workers and consumers to new health risks, they eventually may expose manufacturers and distributors to new waves of litigation and liability. Some members of the scientific community and the legal bar believe that nanoparticles may represent the next asbestos and are gearing up accordingly.[12] While there have not yet been any reported lawsuits for personal injuries allegedly caused by the presence of nanotechnology in consumer products, the potential for such litigation looms large.

Current Oversight of Nanotechnology

Because nanotechnology itself still is not fully understood, its risks also are not fully understood. These unknowns make the regulation of nanotechnology all the more difficult. On the one hand, nanotechnology covers so many disciplines — physics, chemistry, biology and engineering, among others — and is present in so many types of products that it cannot be controlled by a single agency or set of rules.

On the other hand, many existing products that incorporate nanotechnology already are subject to various forms of regulation. It therefore makes sense to understand the extent to which nanotechnology currently is regulated and to inquire into what additional forms of regulation can be expected.

At present, nanotechnology is not regulated separate and apart from other types of technology. No manufacturer that uses nanomaterials is required to report such usage to the government or to comply with an independent set of product guidelines as a consequence of that usage. Consistent with this reality, the word "nanotechnology" appears only once in the current Code of Federal Regulations.[13]

The lack of regulations specific to nanotechnology, however, does not mean that products incorporating nanotechnology are not regulated. The prevailing regulatory attitude in this field is typified by the Consumer Product Safety Commission, which maintains that "[t]he potential safety and health risks of nanomaterials, as with other compounds that are incorporated into consumer products, can be assessed under existing CPSC statutes, regulations and guidelines."[14]

The United States is not alone in this approach; the regulatory systems of the United Kingdom and the European Union also address nanotechnology risks under existing regulations.[15] This means that producers of nanotechnology do not have to behave differently because their products contain nanotechnology. They only have to comply with the existing regulations specific to the type of industry or product.

An example of the application of existing regulations to a nanotechnology product can be seen in the Environmental Protection Agency's recent action against a maker of computer keyboards and mice coated with an anti-microbial nano-silver coating. The manufacturer claimed that the nano-silver coating helped to protect users from germs. The EPA took the position that the sale of such anti-microbial products, without registering them beforehand with the agency, constituted the distribution of unregistered pesticides in violation of the Federal Insecticide, Fungicide and Rodenticide Act.[16]

In February 2008 the manufacturer entered into a consent agreement with EPA and paid a six-figure fine. The EPA has not assessed any similar fines since that time, but its regulations still require the registration of products containing pesticides prior to sale in the United States.

Existing regulations may not be sufficient, however, to address the risks posed by the unique properties of nanomaterials. Otherwise innocuous materials that receive little or no regulatory attention in their macro form can be toxic at the nano level. The challenge lies in determining when a substance becomes dangerously small.

For instance, the Federal Hazardous Substances Act includes in its definition of "hazardous substances" materials that are combustible[17] and imposes certain labeling requirements on all hazardous substances.

The degree to which aluminum should be considered a hazardous substance for purposes of the FHSA is unclear; it usually is not combustible, but reduced to its nano form, aluminum can become highly combustible. The FHSA makes no accommodation, however, for determining or addressing relative hazards based on the presence, or absence, of nanoparticles.

A similar problem arises under the federal Toxic Substances Control Act. Pursuant to the TSCA, the EPA maintains an inventory of all chemical substances currently used in the United States. Anyone who wishes to use a "new chemical substance" that is not listed on the TSCA inventory or to put a listed substance to a "significant new use" must notify the EPA before importing or manufacturing that substance. But a chemical substance is not considered "new" under the TSCA if it is merely the nano form of a material that already is listed on the TSCA inventory, and the statutory definition of a "significant new use" is not dependent on the size of the particle being used.

To be sure, some substances are chemically distinct in their nano forms; carbon nanotubes, for instance, generally are considered chemically distinct from other forms of carbon, such as graphite, that are listed on the TSCA inventory.[18] Nonetheless, product manufacturers in the United States are, for the most part, not currently required to alert the EPA before creating or using known materials in nano form regardless of their actual or potential hazards.[19]

Future Oversight of Nanotechnology

Although products incorporating or containing nanotechnology are not presently subject to separate regulation in the United States and elsewhere, that may soon change. Mounting concern about the potential health and environmental effects of nanomaterials is focusing attention on new ways to measure and control the use of nanotechnology. Evidence of this heightened awareness can be found in the fact that peer-reviewed research of the toxicity of nanomaterials has increased nearly 600 percent since 2000.[20]

The first logical step in the increased regulation of nanotechnology is the development of a better understanding of its various risks and benefits. In January 2008 the EPA launched its Nanoscale Materials Stewardship Program. The goal of the program is to develop the scientific information that is needed for the EPA to make sound regulatory decisions concerning nanotechnology issues, especially under the TSCA. The EPA has said its primary objectives are to come up with ways to identify hazardous properties before they enter the environment and to determine which nanomaterials pose an unreasonable risk after they enter the environment.

As of December almost 30 major companies had voluntarily provided data to the EPA concerning their present use of nanomaterials under the auspices of the Nanoscale Materials Stewardship Program.[21]

The EPA, along with the CPSC, the Food and Drug Administration, the National Institutes of Health, and more than 20 other federal agencies and administrative entities also are participants in the National Nanotechnology Initiative, a federal program established in 2001 to coordinate the individual and cooperative activities of the participating governmental entities in the research, development and regulation of nanotechnology.[22]

A report by the National Research Council of the National Academy of Sciences issued late last year, however, was highly critical of the NNI's efforts to date to assess the health and environmental safety of nanomaterials. In describing its findings to the public, the NRC said the NNI's current health and environmental research plan "does not provide a clear picture of the current understanding of these risks or where it should be in 10 years" and does not "include research goals to help ensure that nanotechnologies are developed and used as safely as possible."[23] The NRC recommended that a "new national strategic plan is needed that goes beyond federal research to incorporate research from academia, industry, consumer and environmental groups, and other stakeholders."[24]

If history is a guide, the new administration in Washington is likely to be a proactive supporter of regulatory reform for nanotechnology. President Obama clearly appreciates the promise, as well as the possible risks, of nanotechnology. His energy secretary, Steven Chu, is a Nobel Prize laureate in physics who has spent portions of his career exploring the use of nanotechnology in the development of alternative renewable energy sources. The new White House chief of staff, Rahm Emanuel, has been an outspoken advocate for increased government investment in nanotechnology research.

The president himself recently met at the White House with the CEO of a leading nanotech company, and he is expected to soon sign into law the National Nanotechnology Initiative Amendments Act of 2009, which provides, in part, for the appointment of a federal coordinator to oversee research on the health, safety and environmental risks of nanomaterials and to help advise on potential new regulations focused on nanotechnology.

The creation and implementation of a cohesive regulatory scheme for nanotechnology, like the construction of Rome, will not take place overnight. Although pressure for action is building, the private and public sectors are still in the information-gathering phase and are likely to remain there through at least 2009.

One indication of when the federal government may be prepared to put a tentative toe in the waters of nanotechnology regulation is the scheduled expiration of the EPA's Nanoscale Materials Stewardship Program in 2010. At that time, the agency should be well-situated to assess what it has learned from the program and to begin overhauling its regulatory programs to address the particular risks that have been identified.

Whether the EPA actually does so, or whether regulatory action must await the development of a broader scientific and governmental consensus on the hazards posed by nanomaterials and the protections that are required, remains to be seen.

Conclusion

Nanotechnology is a burgeoning field that holds tremendous promise but also poses considerable risk. Industrialists, scientists and government officials alike still are attempting to understand how nanomaterials operate, how they can be used and controlled, and what ramifications their use may have for human health and the environment. Because of the many unknowns that currently exist, government regulation of nanotechnology is still in the formative stages and is likely to remain so for the foreseeable future.

One thing is certain: As with all other emerging technologies both before and after, there undoubtedly will be some form of regulatory response to nanotechnology — and, just as likely, lawsuits, plenty of lawsuits.

Notes

1 Jennifer Kahn, *Welcome to the World of Nanotechnology*, Nat'l Geographic, June 2006, at 98.

2 The Royal Soc'y & The Royal Acad. of Eng'g, Nanoscience & Nanotechnologies: Opportunities and Uncertainties (2004), at viii. This report provides an excellent overview of the history, science and applications of nanotechnology.

3 M. Reibold, P. Paufler, A.A. Levin, W. Kochmann, N. Pätzke, & D.C. Meyer, *Materials: Carbon Nanotubes in Ancient Damascus Sabre*, 444 Nature 286, 286 (2006).

4 Opportunities and Uncertainties, *supra* note 2, at 5.

5 The inventory, available at http://www.nanotechproject.org/inventories/consumer/analysis_draft/, is published by the Project on Emerging Nanotechnologies, which is perhaps the most comprehensive online source of information regarding the uses, risks and regulation of nanotechnology.

6 James Flanigan, Nanotechnology Near the Point When It's Time to Go Public, N.Y. Times, Dec. 20, 2007, at C7.

7 *Id.*

8 Christina Buzea, Ivan I. Pacheco & Kevin Robbie, *Nanomaterials and Nanoparticles: Sources and Toxicity*, Biointerphases, December 2007, at MR17, MR21. This article provides a detailed exploration of the potential adverse effects of nanotechnology.

9 Paul Westerhoff & Troy M. Benn, Nanoparticle Silver Released into Water from Commercially Available Sock Fabrics, 42 Envt'l Sci. & Tech. 1315 (2008).

10 Paul A. Schulte & Fabio Salamanca-Buentello, *Ethical and Scientific Issues of Nanotechnology in the Workplace*, Envt'l Health Perspectives, January 2007, at 5, 6.

11 *Id.*

12 Craig A. Poland, Rodger Duffin, Ian Kinloch, Andrew Maynard, William A. H. Wallace, Anthony Seaton, Vicki Stone, Simon Brown, William MacNee & Ken Donaldson, *Carbon Nanotubes Introduced Into the Abdominal Cavity of Mice Show Asbestos-Like Pathogenicity in a Pilot Study,* 3 Nature Nanotechnology 423, 423-428 (2008).

13 In a section titled "Nanotechnology Safety," the Department of Energy regulations provide, "The department has chosen to reserve this section since policy and procedures for nanotechnology are currently being developed." 10 C.F.R. pt. 851, app. A(11).

14 Consumer Product Safety Commission, CPSC Nanomaterial Statement (Oct. 27, 2005), *available at* http://www.cpsc.gov/LIBRARY/CPSCNanoStatement.pdf.

15 Opportunities and Uncertainties, *supra* note 2, at 69-70.

16 In the matter of ATEN Tech. Inc. d/b/a IOGEAR Inc., No. FIFRA-09-2008-0003, consent agreement and final order pursuant to Sections 22.13 and 22.18, ¶¶ 1, 2, 7-10 (E.P.A. Feb. 27, 2008).

17 15 U.S.C. § 1261(f)(1)(A).

18 73 Fed. Reg. 64,946 (Oct. 31, 2008).

19 *See* EPA, Nanotechnology White Paper § 4.2.1, EPA 100/B-07/001 (February 2007), *available at* http://es.epa.gov/ncer/nano/publications/whitepaper12022005.pdf.

20 Alexis D. Ostrowski, Tyronne Martin, Joseph Conti, Indy Hurt & Barbara Herr Harthorn, *Nanotoxicology: Characterizing the Scientific Literature, 2000-2007*, 11 J. Nanopart. Res. 251, 252 (2009).

21 EPA, Nanoscale Materials Stewardship Program, Interim Report 1, 3 (January 2009), *available at* http://www.epa.gov/opptintr/nano/nmsp-interim-report-final.pdf.

22 *See* http://www.nano.gov/html/about/nniparticipants.html.

23 Press Release, The National Academies, Federal Research Plan Inadequate to Shed Light on Health and Environmental Risks Posed by Nanomaterials (Dec. 10, 2008), *available at* http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12559.

24 *Id.*

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