
PRODUCT LIABILITY
IMPLICATIONS OF
NANOTECHNOLOGY

by Robin L. Juni

Nanotechnology is currently being utilized in hundreds of products, with more coming on the market every day. However, few companies have comprehensively evaluated the risks that nanomaterials may present, and even fewer have addressed the potential for litigation surrounding alleged harms from products containing nanomaterials. Significant litigation risk exists for companies not prepared to challenge the underlying science and law of alleged harms stemming from nanomaterials. This article describes recent developments and discusses potential strategies to defeat or minimize claims.

THE SCIENCE IS LEADING THE REGULATIONS

Nanomaterials are particles of less than 100 nanometers in diameter specifically engineered to take advantage of size-related characteristics, compared with larger particles of the same material. A nanometer is one-billionth of a meter; in comparison, a human hair is approximately 80,000 nanometers wide, while a red blood cell is 7,000 nanometers in diameter. Nanomaterials are currently used in hundreds of products, including paints, varnishes, insulation, electronic diodes, clothing, cosmetics, and sunscreens. New products are constantly being evaluated. For example, researchers are developing "bio-reactive plastics"—infection-fighting plastics embedded with nanoscale antibodies and enzymes that begin decontamination as soon as pathogens or toxins touch the surface. Pursuant to its authority under the Federal Insecticide, Fungicide, and Rodenticide Act, the United States Environmental Protection Agency ("EPA") recently regulated as an antimicrobial device a washing machine using silver nanoparticles.

Although limited research has been done to date, nanomaterials are alleged to have discrete human health risks. These risks include:

Increased mobility. Due to size, nanomaterials may be more easily taken up by the body and transported across biological membranes.

Increased reactivity. Because of the increased surface area, more biological tissues may interact with nanomaterials.

Increased persistence. Again, because of size, some fate and transport mechanisms that might otherwise remove toxins may operate less effectively against nanomaterials.[1]

Government agencies have just begun to grapple with these issues. In particular, in February 2007, EPA issued a long-awaited Nanotechnology White Paper ("White Paper"). This White Paper provides some useful guidance on potential nanotechnology regulation but, not surprisingly, does little to clarify any litigation issues.

First, the White Paper explains that EPA believes current environmental statutes provide authority for the agency to regulate nanomaterials. While this statement is not surprising, left unanswered is the more difficult question of how statutes that delineate specific triggers for EPA action—a Maximum Contaminant Level under the Clean Water Act, for example—will apply to nanomaterials that are present in much smaller amounts than traditional toxicants.[2]

Second, the White Paper addresses—but does little to resolve—the critical issue of risk assessment. EPA specifically identifies "research needs for risk assessment" in the areas of chemical identification and characterization, environmental fate and transport, environmental detection and analysis, human exposures, human health effects, and ecological effects. White Paper at 72–80. Each of these areas is tremendously complex; years of study will likely be needed even to make a real start on many of these issues.

Industry groups have recognized the need for similar actions, including the need to: (1) assess the human health and environmental risks posed by nanomaterials; (2) determine exposure potentials; and (3) establish handling guidelines for operations involving nanomaterials.[3] And some initial steps have been taken. On June 21, 2007, for example, DuPont and the environmental advocacy group Environmental Defense—in conjunction with the Woodrow Wilson International Center for Scholars—announced the launch of their jointly developed Nano Risk Framework, "a tool for evaluating and addressing the potential risks of nanoscale materials." *See* http://www.wilsoncenter.org/nano (last visited on October 8, 2007).

Academic groups have likewise called for further research. In particular, the National Research Council released *A Matter of Size*: *Triennial Review of the National Nanotechnology Initiative*, which describes federal research and development efforts regarding nanotechnology. That document explains that the National Nanotechnology Initiative ("NNI") was created in 2000 to coordinate research activities in order "to accelerate responsible development and deployment of nanotechnology for economic benefit and national security." *See A Matter of Size*: *Triennial Review of the National Nanotechnology Initiative (Report in Brief)* at 1. With respect to risk assessment, the report states:

> Although some evidence exists that engineered nanomaterials have adverse effects on laboratory animals, NNI environmental, health, and safety (EHS) research to date has been inconclusive. Research on environmental, health, and safety effects of nanotechnology needs to be expanded.

A Matter of Size: *Triennial Review of the National Nanotechnology Initiative (Report in Brief)* at 3. But government statements regarding the potential for risk and the need for further research do little to help a company seeking to evaluate its risk today.

DEFENDING PRODUCT LIABILITY CLAIMS IN A CLIMATE OF UNKNOWNS

Product liability lawsuits focused on alleged harms from nanomaterials are likely to pose difficulties for unprepared companies because of the substantial unknowns in the science, the huge number of potential claimants, and the long latency periods between exposure to a nanomaterial and the onset of disease alleged to be related to that exposure.

Although defective-design and defective-manufacture cases will undoubtedly be brought, perhaps the most difficult class of cases for companies to defend will be allegations regarding failure to warn (and related claims for failure to test). This is so because "state of the art" and "no alternative design" are likely to be colorable defensive arguments in many defective-design and defective-manufacture cases, and those defenses have strong applicability to products containing nanomaterials. However, nanotechnology has so many unknowns that even beginning to draft adequate warnings is fraught with uncertainty.

Generally speaking, a product may be found defective on the basis of inadequate instructions or warnings when foresee-

able risks of harm posed by the product could have been reduced or avoided if reasonable instructions or warnings had been provided by the manufacturer, seller, or other entity in the chain of distribution, and when omission of the instructions or warnings rendered the product not reasonably safe.

A manufacturer or seller generally need not warn about small or inconsequential risks that a reasonable person would not deem material to his or her decision to use the product, or about obvious and generally known risks. Rather, the law expects warnings to be provided for all inherent risks that anticipated product users would reasonably deem material or significant in deciding whether to use the product. But this is where nanomaterials become difficult; there are many unknowns, and more research is constantly being done.[4]

Moreover, manufacturers may face additional risks because of a duty to research all "reasonably foreseeable or scientifically discoverable" risks before putting a product on the market. A decision in Texas reinforces this view:

> Dangers that a seller "should know" include those that are reasonably foreseeable or scientifically discoverable at the time the product is sold. . . . A manufacturer also has a duty to instruct users on the safe use of its product. . . . In this regard, a manufacturer is held to the knowledge and skill of an expert. . . . This means that it must not only keep abreast of scientific knowledge, discoveries, and advances, but, more importantly, test and inspect its product. . . . This duty to research and experiment is commensurate with the dangers involved. . . . A manufacturer may not rely unquestioningly on others to raise concerns about its product, but must instead show that its own conduct was proportionate to the scope of its duty.

Wood v. Phillips Petroleum Co., 119 S.W.3d 870, 873 (Tex. App. 2003) (citations omitted).

REDUCING LITIGATION RISK

Faced with this level of uncertainty from the scientific community, as well as from regulators, companies with nanotechnology-based products in development have several potential courses of action to protect themselves from litigation risk and should ask themselves the following questions:

Comprehensive Evaluation of Product Risks. Is an alternative design—one with better risk-assessment knowledge—available? Is our manufacturing process well controlled? Have we crafted warnings as skillfully as possible? Have we fully researched the risks of the materials used, including nanomaterials?

Use of Outside Scientific Experts. Can outside experts provide insight into potential product risks and help to define appropriate warnings? Can outside experts help to show that our research was unbiased and comprehensive? Are we confident that we are in touch with the most recent developments?

Control of Documents. Are memoranda carefully worded? Are e-mails, especially those transmitted by BlackBerry®, utilized properly? Are risks fairly described and studies appropriately documented? Have speculation and hyperbole been avoided? Are document retention policies consistently implemented?[5]

Utilization of these strategies, along with early analysis of relevant issues, can help to ensure that nanotechnology-related claims do not provide a basis for unwarranted discovery and potential relief. ■

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[1] *See* Günter Oberdörster, Eva Oberdörster, and Jan Oberdörster, "Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles," 113 *Envtl. Health Perspectives* 823 (July 2005).

[2] *See also* Linda K. Breggin and Leslie Carothers, "Governing Uncertainty: The Nanotechnology Environmental, Health, and Safety Challenge," 31 *Col. J. Envtl. L.* 285, 292–98 (2006) (summarizing the federal government's regulatory initiatives on nanotechnology).

[3] Katherine A. Dunphy Guzmán, Margaret R. Taylor, and Jillian F. Banfield, "Environmental Risks of Nanotechnology: National Nanotechnology Initiative Funding 2000–2004," 40 *Envtl. Science & Technology* 1401, 1402 (Mar. 1, 2006) (citing views of Chemical Industry Vision2020 Technology Partnership).

[4] The learned-intermediary rule should provide additional protection for manufacturers of pharmaceutical drugs and medical devices using nanomaterials.

[5] *See* Robin L. Juni, J.C. McElveen, and Nathan C. Doty, "Document Retention Issues in Environmental Law," in *Environmental Law Practice Guide: State and Federal Law* (Matthew Bender & Co. 2005).