Midwest IN-HOUSE
A Quarterly Publication of Lawyers Weekly, Inc.

Nanotechnology:
Innovations, potential risks and government scrutiny

By Cary Silverman and Judith L. O'Grady

There is a new industrial revolution underway involving the manipulation of materials at a molecular level, and it comes with the futuristic Star Trek-sounding name of nanotechnology.

Nanotechnology is generally characterized by control of particles that are 1 to 100 nanometers, a nanometer being one-billionth of a meter, too small to be viewed with even a conventional laboratory microscope.

A human hair, for example, is 80,000 nanometers. A red blood cell is approximately 7,000 nanometers wide.

Nanotechnology is not a single technology with a defined use. It has numerous and widely varying applications in which the size of the particles is the defining characteristic.

Today, over 380 products containing nanotechnology are reportedly already on the market. The use of nanotechnology spans the gamut of consumer and commercial uses.

Possibly the most common use of nanotechnology is its incorporation in many popular sunscreens, which provides transparency and better coverage, rather than the traditional white coating.

Nanotechnology is used by Eddie Bauer to make clothing stain resistant and by Wilson to make bouncier tennis balls. It is incorporated into products ranging from disinfectants to skin creams. Nanotechnology is employed to fight counterfeiting and allow for accurate product identification through its incorporation into materials such as paint, cosmetics, cement, concrete, glass, and explosives, as well as barcodes and labeling.

Use of nanotechnology is expected to explode in the future. In 2003, the United States awarded over five thousand nanotechnology patents, more than double that of Japan, Germany, Canada, and France combined. Hewlett Packard, Intel, and IBM are developing larger and faster memory chips for computers and cell phones based on the technology.

Nanotechnology has enormous promise in the healthcare field, whether it is in providing more effective drug delivery systems or more durable medical devices. In fact, nanotechnology is viewed as having the potential to improve access to clean water for billions of people in developing countries.

By 2014, sales of products incorporating nanotechnology are projected to account for $2.6 trillion. If these estimates are accurate, such products would represent 15 percent of the global manufacturing output.

Protecting your client's nanotechnology interests

The new world of nanotechnology poses challenges for in-house counsel.

You should begin by asking: Does your organization incorporate nanotechnology into any of its products or utilize nanotechnologies in their manufacturing processes? Are there any potential uses of nanotechnology in development?

If so, you should carefully follow scientific developments and periodically assess environmental health and safety implications of the technology. It is also important to closely monitor the actions of federal, state, and local regulators and weigh in to educate them as to the benefits of your products and the potential impact of any proposed regulations.

Does size matter?

Nanotechnology may involve more than just the ability to manufacture innovative products at a molecular level. What makes nanotechnology most attractive to some – and raises concern among others – is that what we know about ordinary-sized materials may not hold true at the nanoscale.

Nanoparticles may exhibit different magnetic, electrical, optical, or chemical properties. For example, a UNESCO report notes that nanoparticles of gold appear red to the human eye, and that nanotubes increase the electrical conductivity of carbon.

A variety of organizations have questioned whether the small size, increased surface area, and distinct reactivity of nanoparticles could have implications for human health and the environment.

For example, Friends of the Earth has called for a ban on the use of nanoparticles in sunscreens, personal care products, and cosmetics, based on a concern that nanoparticles applied directly to the skin might permeate the bloodstream and access cells, tissues, and organs than ordinary sized particles cannot reach.

A coalition of organizations, including the International Center for Technology Assessment and Greenpeace, among others, filed a petition in 2006 with the Food and Drug Administration requesting that it recognize products including nanoparticles as "new substances," which would require manufacturers to obtain additional regulatory approval before incorporating nanoparticles in drugs, cosmetics, and sunscreens.

The Woodrow Wilson International Center for Scholars has funded monographs advocating for increased research into potential risks of nanotechnology by such federal agencies as the FDA, National Institute for Occupational Safety and Health, and the Environmental Protection Agency.

It suggests there are gaps where current laws do not provide sufficient legal authority to effectively monitor and regulate applications incorporating nanotechnology to protect public health and safety.

In addition, the American Bar Association's Section on Environment, Energy, and Resources recently completed a comprehensive review of each of the core federal environmental statutes to assess their suitability for addressing issues pertinent to human health and the environment arising from applications of nanotechnology.

Encouraging innovation, considering risks

Given the spotlight on nanotechnology, government agencies are grappling with how to encourage innovation and development of beneficial products, while protecting human health and safeguarding the environment.

In 2001, Congress established the National Nanotechnology Initiative (NNI), an interagency workgroup aimed at expediting the discovery, development, and deployment of nanotechnology in order to achieve responsible and sustainable economic benefits, enhance the quality of life, and promote national security.

NNI coordinates nanotechnology initiatives throughout the federal government with participation from 26 federal agencies. In addition to focusing on innovation and development, NNI is also considering the potential risks of nanotechnology.

To that end, a September 2006 NNI report identifies research and information needs related to understanding potential risks in commercial or consumer products, medical treatments, environmental applications, research or elsewhere. The report, which focuses on federal needs, notes that it could also assist businesses by informing their own research, risk assessment, and risk management activities.

The federal government funded $38 million in research on nanotechnology health and safety in 2006, an amount expected to grow to at least $46 million this year. President Bush's 2008 budget – which proposes to create a network of academic centers to study the topic and disseminate their findings – would further boost this spending to $59 million.

This amount relates to federal spending on nanotechnology health and safety risk assessment. The overall federal budget for nanotechnology is far greater.

Greater regulation on the horizon?

To date, no government has developed a nanotechnology-specific regulatory framework. Governments around the world are examining whether existing regulations are sufficient, or if entirely new regulations are necessary for products containing nanotechnology. As a result, products containing nanotechnology are subject to regulation and oversight to the same extent as products that do not incorporate the new technology.

That does not mean agencies have their hands tied in considering potential risks or examining concerns. For instance, last year, the EPA required companies using nanosilver to provide evidence that its use did not harm waterways or public health.

The FDA has approved numerous nanotechnology-containing products through its ordinary procedures.

As a result of the increasing presence and use of nanomaterials, several federal agencies are assessing the potential risks posed by nanomaterials and considering whether new regulations are needed to evaluate the potential impact of such particles on public health and the environment.

FDA. In August 2006, the FDA formed the Nanotechnology Interest Group (NTIG) to determine "regulatory approaches that encourage the continued development of innovative, safe and effective FDA-regulated products that use nanotechnology materials."

As part of NTIG's efforts, the FDA hosted a public meeting on nanotechnology in October 2006 to gather information related to nanotechnology products under development, and any scientific or safety issues related to the use of nanomaterials in FDA-regulated products.

With respect to pharmaceuticals, the FDA's current position is that "the existing battery of pharmacotoxicity tests is probably adequate for most nanotechnology products they (sic) will regulate." As it becomes aware of new risks, the FDA has indicated that new tests may be necessary.

With respect to other products that fall under its jurisdiction, such as cosmetics, the FDA has limited authority to regulate. These products are not subject to a pre-market approval process, and are often not regulated until they have been shown to have adverse health effects with use.

NIOSH. NIOSH, the federal agency charged with research and development of workplace safety standards, published "Approaches to Safe Nanotechnology" in 2005. This document offers interim guidelines for working with nanomaterials that NIOSH believes are consistent with the best scientific knowledge available.

NIOSH plans to periodically update these recommendations and encourages the public to provide input.

In February, NIOSH issued a thorough review of the progress of the NIOSH Nanotechnology Research Center (NNRC) from its inception in 2004 through 2006 in a report entitled "Progress Towards Safe Nanotechnology in the Workplace."

This report provides a process for managing the potential risks nanotechnologies may pose to workers. The process includes hazard identification, hazard characterization, exposure assessment, risk characterization, and risk management.

EPA. The EPA issued a Nanotechnology White Paper in February that emphasizes the need to balance the potential benefits of nanotechnology against the risks. The paper indicates the agency envisions taking an active role in the regulation of nanotechnology in the future.

Congress. Congress also plays a role in these efforts. In every year since 2001, Congressional budget approvals for research on the environmental, health, and safety impacts of nanotechnology have topped the President's requests.

In addition, Sen. Mark Pryor (D-AR), chairman of the Commerce Committee's subcommittee with jurisdiction over consumer affairs, product safety, and insurance industry issues, is reportedly considering approaches to limit liability for accidental release of nanoparticles into the environment.

State and local governments. According to the National Conference of State Legislatures, at least 22 states have enacted legislation to support nanotechnology through economic development initiatives, such as

grant funding and building of research facilities. States have largely not addressed health and safety issues related to nanotechnology.

In the absence of any federal or state nanotechnology-specific regulatory frameworks, a few local governments have stepped in.

For example, in December 2006, Berkeley, Calif. became the first governmental entity to enact a law regulating nanotechnology. Berkeley's ordinance requires all entities using or manufacturing nanomaterials to file a report disclosing how they will work with and dispose of them. The Cambridge, Mass. City Council recently announced that it is considering following suit.

Cary Silverman is an attorney in the public policy group of the Washington, D.C. office of Shook, Hardy & Bacon. Judith L. O'Grady is an attorney in the firm's pharmaceutical and medical device litigation practice group. Founded in 1889, SHB is an international law firm that has grown to nine offices with more than 500 attorneys and 262 research analysts and paraprofessionals, many of which hold advanced science and engineering degrees.