Litigation Risks Related to Nanoproducts

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Corporations must be ever vigilant of the next wave of tort-related litigation. One area being watched with increasing interest is the "nanotort"—an action related to the purported health and safety impacts of manipulating matter smaller than 100 nanometers and incorporating these materials into a wide array of products, ranging from fabrics and pharmaceuticals to bicycles and baseball bats. Lawsuits could take the form of personal injury claims by employees working with nanomaterials, product liability actions by consumers, or demands for medical monitoring by individuals who may have been exposed to nanomaterials but have not contracted a disease. While nanotorts remain only a potential legal risk for now, companies that utilize nanomaterials should keep abreast of developments that will no doubt impact the ultimate viability of these types of lawsuits in the future. This article discusses three relevant areas—research into the health and safety effects of nanomaterials, regulatory and standardization efforts related to nanotechnology, and factual and legal issues that any corporation will inevitably encounter in a nanotort action.

Health and Safety Effects of Nanotechnology

According to a 2009 report by the National Institute for Occupational Safety and Health ("NIOSH"), little is known about the impact that nanomaterials may have on human health. Based on the limited amount of information available regarding nanomaterials, NIOSH concluded that, until further research proves that these substances do not pose a health risk, "precautionary measures are warranted."

Notwithstanding this state of uncertainty, one recent study on the health and safety effects of nanomaterials has caused great alarm among the general public. On May 20, 2008, the "Poland Study" was published and received widespread media attention. The Study suggested that carbon nanotubes, which physically resemble harmful asbestos fibers can, like asbestos fibers, cause inflammation and granulomas in the lungs of laboratory mice, raising concerns that carbon nanotubes could cause mesothelioma. While the Poland Study has been roundly criticized, and mesothelioma did not actually present in any of the mice, the criticism has received far less media attention than the actual Study, with the media widely reporting that nanotechnology could be the "next asbestos."

Past experience indicates that inflammatory reports are invariably followed by the onset of mass tort and class action litigation. Plaintiffs could argue that nanoparticles exhibit greater toxicity than larger particles of the same substance, are more volatile, and, at least in the case of carbon nanotubes, that their unique shape bears similarities to asbestos. Plaintiffs would likely assert counts sounding in negligence, defective design, defective manufacture, and failure to warn. Plaintiffs that already have a disease would assert that it was caused or exacerbated by their exposure; those without disease would assert a need for medical monitoring.

monitoring. And as is the case in mass tort actions generally, plaintiffs would no doubt be able to locate "experts" who would provide the testimony required to reach a jury.

**Regulation and Standardization of Nanotechnology**

In response to the growth of the nanotechnology industry, as well as to the notoriety nanotechnology has achieved, governmental agencies and standard-setting organizations at all levels have begun to propose and adopt regulations and standards governing the production and use of nanomaterials. When filing nanotort claims, plaintiffs will undoubtedly point to alleged violations of such rules when attempting to prove liability.

Specifically, regulations may be used by courts to define the standard of care that must be met by companies when manufacturing materials, incorporating hazardous substances into intermediate and finished products, or selling these items to the consuming public. In some states, violating a regulation constitutes negligence *per se*. Where the plaintiff falls within the class of individuals that the regulation was intended to protect, the company may be found liable where the violation actually caused the alleged injury. In other states, while a violation does not lead to a presumption of negligence, it may at least constitute evidence of a breach of duty. Similarly, some courts may permit the introduction into evidence of industry-wide standards as bearing on whether a company’s conduct complied with the requisite standard of care. And in product liability cases, regulations and industry-wide standards are often cited by plaintiffs as evidence that the defendant defectively designed or manufactured a product, or that it failed to warn employees or consumers of any risks.

Although there is no comprehensive federal regulatory scheme specifically addressing nanotechnology, efforts are underway at all levels of government to regulate specific aspects and potential risks associated with the nanotech industry. The most notable steps in this area have been taken by the EPA under the Toxic Substances Control Act ("TSCA").

To date, EPA has used TSCA to regulate several types of nanomaterials. There is every indication that EPA’s regulation of nanomaterials will continue to grow both in focus and in breadth. For example, EPA recently finalized rules that impose restrictions on manufacturers and importers of carbon nanotubes, including requirements that employees use gloves, wear chemical protective clothing, and employ full-face respirators while exposed to nanoparticles in the work area. EPA has finalized similar rules applicable to manufacturers and importers of siloxane modified silica and siloxane modified alumina nanoparticles, and it has proposed rules addressing certain multi-walled carbon nanotubes.

In the next three months alone, EPA intends to propose two additional rules addressing nanomaterials. The first would address nanoscale versions of existing chemical substances (e.g., nanoscale silver), allowing EPA to limit their production and to impose workplace safety measures. The second would require manufacturers and importers of nanomaterials to provide information on production volume, methods of manufacture and processing, exposure and release, and available environmental, health, and safety studies.

Other federal agencies, including the FDA, OSHA, and the Consumer Product Safety Commission are becoming more involved in the oversight and regulation of nanotech materials as well. All three agencies participate in the National Nanotechnology Initiative, which coordinates federal nanotechnology research and development across government agencies, including research into environmental, health, and safety issues related to nanotechnology. Plaintiffs’ lawyers will no doubt look to these and other agencies for standards and research that could be used to support nanotort claims.
State and local legislators also have begun addressing nanotech issues. Some states have considered legislation supporting research into the potential risks associated with nanotechnology. In 2009, the State of California took a first step toward regulating nanomaterials by sending notices to over two dozen companies and public facilities who were manufacturing or importing carbon nanotubes. These notices required noticed entities to submit toxicity data, to describe how they were monitoring exposure in the workplace, and to identify safeguards used to protect workers. In September 2010, California identified six other nanoscale materials that the State intends to target. California also announced that it will seek additional information from manufacturers and importers of carbon nanotubes. The collected Information will be used to assess the potential impacts of nanomaterials and to support the development of regulatory programs. At the local level, cities, including Berkeley, California, and Cambridge, Massachusetts, have established ordinances requiring the registration and disclosure of the production or use of nanoscale materials.

Finally, industry standard-setting organizations have also turned their attention to nanotechnology issues. Groups like the American National Standards Institute ("ANSI") and the International Standards Organization ("ISO") are working on standards in numerous fields, including health, safety, and the environment. Once finalized, regulators may use these standards as a basis for promulgating manufacturing and use requirements, as well as by companies to adopt industry-wide practices. NIOSH has issued guidelines for companies wishing to develop risk management systems aimed at establishing engineering controls (e.g., ventilation systems) to reduce exposure, selecting and using personal protective equipment, and training workers in the proper handling of nanomaterials. NIOSH has also proposed a recommended exposure limit of 7 micrograms per cubic meter of air for carbon nanotubes and nanofibers based on observed pulmonary inflammation and fibrosis in animals exposed to certain nanoparticles. All of these standards could become benchmarks by which a defendant’s conduct is judged.

Defending Against Nanotort Claims

As nanotechnology becomes more prevalent, plaintiffs’ lawyers can be expected to aggressively pursue nanotort claims. But as is the case in other toxic tort actions brought by the Plaintiffs’ bar, numerous defenses will be available against the nanotort. These defenses include:

(1) **Product identification.** Was the plaintiff potentially exposed to the defendant’s product? If the plaintiff is unable to establish that the defendant’s product was near the plaintiff or in the plaintiff’s vicinity, a court may dispose of the action at an early stage.

(2) **General causation.** Is the product in question inherently capable of causing the disease in question and, if so, at what dose? If the product is not able to cause the disease in question, or if it is only able to do so at doses far above the dose at issue, the plaintiff will be unable to meet its burden on causation.

(3) **Timing of exposure.** When was the plaintiff exposed to the defendant’s product? To the extent the exposure occurs after the disease process has manifested (or if before, after an insufficient time to provide for the latency period), it follows that the exposure could not have caused the disease.

(4) **Specific causation.** Did the product and dose in question actually cause the disease at issue in the case? If the product, in the dose actually present, did not cause the disease, an essential element of the plaintiff’s case will be absent.
(5) **Quantitative risk.** Was the plaintiff exposed to a dose associated with a material risk? If the dose at issue is *de minimis* (i.e., well below any regulatory threshold) it is reasonable to conclude—perhaps even as a matter of law—that it did not cause the disease at issue.

(6) **Comparative risk.** Was any risk associated with the exposure at issue dwarfed by other every day risks and exposures? Many daily activities and exposures present risks far beyond those presented by the products at issue, and it is helpful for the jury to appreciate these in order to fully grasp the *de minimis* nature of any risk presented.

(7) **Alternative causation.** If not the defendant’s product, what caused the plaintiff’s disease? All too often the jury will look to the defendant to answer this question. In many instances, risk factors in the individual’s history may be present, whether in a genetic or other setting. Often, however, the most typical cause of a disease is "idiosyncratic" (i.e., modern medicine does not have an explanation at the present time).

Perhaps most importantly, while not a defense *per se*, there is the issue of credibility. Typical jury instructions provide that where a juror concludes that a witness has intentionally told a falsehood, the juror may disbelieve that portion of the witness’s testimony or all of the testimony. As a seasoned trial attorney well knows, a juror that reaches such a conclusion with respect to a plaintiff is unlikely to look kindly upon that plaintiff’s claims.

There will be substantial debate concerning the admissibility of regulatory standards. In developing standards designed to protect public health, regulators tend to make numerous assumptions—many of which err on the side of over-protecting the public. For example, they routinely reduce permissible exposure levels by several orders of magnitude. While these may be appropriate measures to protect the public, they do not shed light on whether any given chemical, in the dose present, actually caused a specific plaintiff’s disease. When an apparently black and white regulatory number is weighed against its potential prejudice and the opportunity for confusion, a court may choose in favor of excluding this evidence.

In light of the questionable nature of the scientific theory underlying potential nanotechnology-related claims, defendants can be expected to take steps at the earliest stages in the case to test the viability of a plaintiff’s claims. Where permitted, defendants will file what has become known as a "Lone Pine" order. In *Lone Pine*, shortly after the complaint was filed, the court ordered plaintiffs’ counsel to detail the facts of each plaintiff’s claims including: (1) exposure to alleged toxic substances, including reports of treating physicians and medical or other experts supporting causation; (2) specific information concerning the property allegedly damaged; and (3) reports of real estate or other experts regarding property damage/diminution claims. The order was designed to require plaintiffs to make an objective showing—early in the litigation—that there was sufficient evidentiary basis to warrant continued litigation. Plaintiffs were unable to establish a *prima facie* case and the case was dismissed. "Lone Pine" is consistent with Federal Rule 16(c)(2). Since its development, the "Lone Pine" order has been widely accepted and used in federal and state courts throughout the nation.

Defendants can also be expected to mount challenges to the admissibility of plaintiffs’ causation evidence under the federal *Daubert* standard or state equivalents. In *Daubert v. Merrell Dow Pharmaceuticals*, the United States Supreme Court addressed the admissibility of testimony from expert witnesses. In holding that federal judges are the "gatekeepers" of scientific evidence, the Court explained that the Federal Rules of Evidence, particularly Rule 702, assign to the trial judge the
task of ensuring that expert testimony rests on a reliable foundation and is relevant to the task at hand.\textsuperscript{17} In assessing the reliability of proffered evidence, the \textit{Daubert} Court noted that courts could consider: (1) whether the scientific theory or technique "can be (and has been) tested"; (2) whether the scientific theory or technique "has been subjected to peer review and publication"; (3) in respect to a particular scientific technique, whether there is a high "known or potential rate of error" and whether there are "standards controlling the technique's operation"; and (4) whether the theory or technique enjoys "general acceptance" within a "relevant scientific community."\textsuperscript{18} In sum, according to the \textit{Daubert} Court, the "overarching subject" of the evidentiary inquiry envisioned by Rule 702 is the "scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie a proposed [evidentiary] submission."\textsuperscript{19}

As the Supreme Court explained several years later in \textit{Kuhmo Tire Co., Ltd., v. Carmichael},\textsuperscript{20} the objective of the \textit{Daubert} standard "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Accordingly, in the case of a nanotort, were a court to hold, as others have already suggested, that the design and execution of the "Poland Study" (and other studies that may be conducted) are not generally accepted in the scientific community, that the Study fails to account for alternative explanations, that it presents other flaws that call its reliability into question, or that anyone attempting to use it to argue a causal link to human disease improperly extrapolates from accepted premise to unfounded conclusion, plaintiffs' experts may be stricken and their claims dismissed.

\textit{Minimizing Future Nanotort Litigation Risks}

Companies can engage in various activities in order to minimize future nanotort litigation risks. In doing so, they may wish to adhere to the old adage that a best defense is a good defense. It is true that there exist today many obstacles to reducing legal exposures. There are scientific uncertainties, a large number of potential claimants, and potentially long latency periods between exposure to nanomaterials and the onset of any disease. But companies should focus on what they can control, such as product and manufacturing processes and warning labels. Companies should: (1) determine whether an alternative design is available; (2) ensure that the potential hazards of the nanomaterials being used have been fully researched; (3) take affirmative steps to implement recommended controls and best practices to reduce worker and consumer exposure; and (4) craft product warnings as skillfully as possible.

Companies also should develop and implement adequate risk minimization strategies, such as: (1) keeping abreast of the most recent scientific and regulatory developments related to nanomaterials; (2) identifying experts to help evaluate existing data on nanomaterials and developments in nanotechnology; (3) establishing a process of regular evaluation, management, and communication of potential risks to employees; (4) engaging regulatory agencies as appropriate; and (5) evaluating existing insurance coverage and considering whether additional coverages are necessary to insure against nanotort claims.

\textit{Conclusion}

As has been true with other new technologies, jurisprudence can get ahead of science. Plaintiffs will likely press ahead despite significant questions concerning whether nanomaterials pose any adverse health effects. It will be up to the courts, therefore, to determine whether to aggressively use vehicles like \textit{Lone Pine} and \textit{Daubert} to assess the scientific reliability of these possible nanotort claims at an early stage in the litigation process, or whether to permit these sorts of cases to impact the judicial system as cases involving asbestos have done. But one thing is certain. Nanotech companies
can begin taking actions now to protect themselves and substantially reduce their litigation risks.


2 Craig A. Poland et al., Carbon Nanotubes Introduced Into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study, 3 NATURE NANOTECHNOLOGY 423 (May 2008).
3 Id.
8 See NIOSH, Occupational Exposure to Carbon Nanotubes and Nanofibers (December 2010).
11 Id.
12 See id.
13 Id.