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Nanotechnology: Law and Business at One-Billionth of a Meter

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For those scanning the horizon in search of emerging legal trends — particularly in regard to product liability law, a relatively solid bet is nanotechnology. Like "genetically modified," "nanotechnology" is certain to become a voguish word not only for various public interest groups, but also for the plaintiff's bar as well.

Nanotechnology is officially defined by the federal government's National Nanotechnology Initiative as the science of engineering and manipulating matter at the level of approximately 1 to 100 nanometers, with a nanometer equaling one-billionth of a meter. NATIONAL SCIENCE AND TECHNOLOGY COUNCIL, Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials at iii (Sept. 2006). More generally, nanotechnology refers to the creation and use of structures, devices, and systems at the molecular and atomic level — with novel properties and functions owing to their incredibly small size. Like prior enabling technologies — the steam engine, the telephone, the computer chip, and plastics all come to mind — nanotechnology is expected to transform human experience, cutting deeply across all sectors of the global economy, including, *inter alia*, pharmaceutical, medical device, transportation, communications, energy, and food products. *See generally,* Nanotechnology: The Plastics of the 21st Century? (Guy Carpenter & Co., Inc. 2006).

Nanotechnology represents a vast frontier for science, business, and law. Already governments and corporations are sinking an estimated $10 billion annually into nanotechnology R&D, and economic forecasters are predicting that nanotechnology will account for some 15% of all global manufacturing output by 2014 — commerce valued at some $2.6 trillion. *See, e.g.,* Evan Michelson, Nanotechnology and the World: Point of View, PROJECT ON EMERGING TECHNOLOGIES: WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS (May 2007).

The plaintiff's bar, mass torts, and class actions cannot be too far behind such words.

WHAT IS NANO?

In late 1959, in remarks delivered to the American Physical Society at the California Institute of Technology, theoretical physicist Richard P. Feynman wondered aloud about the scientific possibilities of the future — and then proceeded to sketch a broad futuristic vision of scientific engineering at the atomic and molecular levels.

That evening, at the outset of the Space Age, Feynman hypothesized the ability in the not-too-distant future to print the entire Encyclopedia Britannica — all 24 volumes — on the head of a pin. As remarkable as such a proposition might seem all by itself, his calculations left still "plenty of room at the bottom" to fit still more information in small places. *See* R. Feynman, There's Plenty of Room at the Bottom: An Invitation to Enter a New Field of Physics, ENGINEERING & SCIENCE (Caltech Feb. 1960).

The notion that Feynman seemed to spin so effortlessly almost a half-century ago, today encompasses the field of nanotechnology. The "technology" part of the word is easily enough understood; it is the "nano" prefix that gives pause. What exactly is a nano? For starters, it refers to an incredibly small unit of measure — a nanometer equaling one-billionth of a meter — which is not all that helpful actually to the layman (especially in the United States, which has long resisted metric conversion).

Breaking things down further, the word "nanoid" — from the Latin word "nanus" — means "dwarf-like," which begins to illuminate dimly the nature and significance of nanotechnology. Prefixion of the word "nano" to "the names of units to form the names of units 10^9 times smaller, *i.e.,* one thousand-millionth part of them (symbol n)," by contrast, would not appear for another 100 years — in 1949, with the published proceedings of the 14th Conference of the International Union of Chemists. *Id.* (citing Compt. Rend. de la 14me Conf., Union Internat. de Chimie at 115). Continuing along this line, the piece of paper on which these words are printed is 100,000 nanometers thick.

Again, however, except to conjure the notion of something incredibly small, this explanation is still wanting — certainly for non-scientists seeking a more familiar frame of reference for purposes of understanding the concept of nanotechnology. One of the better nano-equivalency

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statements was floated almost 45 years ago — just a few years after Feynman started the nano-ball rolling in his post-prandial remarks at Caltech. In 1964, General David Sarnoff — an American radio pioneer, who rose from telegraph operator for the American Marconi Company in the early 1900s to head RCA from 1947 to 1971 — cast nanotechnology in a much more familiar light with these words:

> A nanosecond is to a second as a second is to 30 years. C. Wordsmith, VERBIVORE'S FEAST: A BANQUET OF WORDS & PHRASE ORIGINS 234 (Farcountry Press 2004).

On this relativity scale, in roughly the time it has taken the reader to get to this point, some 5,400 years (give or take) have passed in nano equivalence. At the same time, if it is true — as some are suggesting — that nanotechnology holds the promise of a second Industrial Revolution, then the 250 years that have passed since the first one began (around 1750) has taken about 8.3 seconds. From a more visual perspective, there is this description of a nanometer:

> If a nanometer were somehow magnified to appear as long as the nose on your face, then a blood cell would appear the size of the Empire State Building, a human hair would be about two or three miles wide, one of your fingers would span the continental United States, and a normal person would be about as tall as six or seven planet Earths piled atop one another. Adam Keiper, The Nanotechnology Revolution, THE NEW ATLANTIS: A JOURNAL OF TECHNOLOGY AND SOCIETY 2 (Summer 2003).

These words strike at the heart of nanotechnology's magnitude. Finally, with these more familiar extrapolations, the transformative lines, scale, and scope of this emerging technology — nanoscale science and engineering — become sharper, clearer. In brief, through nanotechnology, man takes known materials with well-established physical properties (conforming to known laws of nature) and fundamentally transforms and transmutes them into opposites and unknowns at frontier levels of science that are inherently difficult to grasp, study, quantify, and predict — much less to regulate.

LESSONS FROM THE PAST

While, throughout history, emerging technologies have been harnessed to generate the promise of revolutionary quality-of-life advancements, progress of this variety has traditionally traveled in the company of challenge — chiefly in the form of uncertainty and risk.

In the early 1900s, for example, radioactive materials were widely marketed in such diverse products as medical devices to treat skin conditions, watch faces (and hands) that glowed in the dark because they were treated with radium, and dinnerware given beautifully decorative hues by uranium-oxide glazing. One by one, these products were subsequently withdrawn from the market. Closer in time, asbestos building products, PCB electrical insulators, and lead paint were also once widely heralded technologies, the risks of which were fully appreciated only decades after their widespread commercialization. More recently still, biotechnology — specifically, the risks to health and safety associated with genetically modified agricultural products — has generated public alarm and economic uncertainty, raising the ante for innovation players. *See, e.g.,* Drew L. Kershen, Legal Liability Issues in Agricultural Biotechnology, 44 CROP SCIENCE 456-463 (March-April 2004).

Among the health and safety concerns attributed to nanotechnology is recognition that familiar substances — known to be nontoxic as currently used — may be transformed into new, potentially dangerous compounds through nanoscale engineering. Gold, for example, is biologically inert as routinely used in various medical devices, but is dramatically transformed by nanoscale manipulation. "Its color changes to a striking red" — it is "no longer the inert metal used in home and biological appliances. ... [As a consequence,] gold nanoparticles may be very reactive, may penetrate the blood/brain barrier, or may enter into cells." *See* Research on Environmental and Safety Impacts of Nanotechnology: What Are the Federal Agencies Doing? Before the House Comm. on Science, 109th Cong., 2nd Sess. (2006) (statement of Dr. Arden Bement, Jr.); *Id.* (statement of Dr. Andrew D. Maynard: "Make no mistake, nanotechnology is different and there will be some materials and products developed under this banner that have the potential to cause harm.")

Authorities generally agree that an enormous amount of work is required in regard to the commercialization of nanotechnology — first, to identify and characterize the risks inherent in nanotechnology, and second, to establish a regulatory framework for its use in the marketplace. At the same time, while awaiting further progress on this front, widespread press coverage of possible nanotechnology health and safety risks will likely generate public alarm not unlike that associated with genetically modified food products, not to mention other recent emerging technologies. This is true notwithstanding the results of early social-science fieldwork indicating that human perceptions of nanotechnology risks are still largely unformed — representing both a potential problem and an opportunity. *See, e.g.,* D. Kahan, et al., Nanotechnology Risk Perceptions: The Influence of Affect and Values, The Cultural Cognition Project at Yale Law School (March 2007).

In short, nanotechnology is unfamiliar enough at this juncture that law and commerce still have the opportunity to shape and respond to its acceptance by consumers — before, for instance, the cart (law) gets put ahead of the horse (science) in the court system. This phenomenon has been a common thread running through public response to the commercialization of most new technologies since the latter half of the 1900s (typically spun by the popular media). It leads, in turn, to the courtroom ritual of "death by a thousand cuts" (in the United States, at least), where claims are serially aggregated against commercial interests in response to media accounts of published scientific reports linking a product or technology to human health risks. (Oftentimes, a single scientific study is sufficient to produce this reaction.)

Proceeding in this fashion, in the rush to judgment (and money damages), law and public policy end up nonsensically leading science — increasing the challenge and cost associated with emerging technologies in ways that reverberate throughout the economy. This needs changing. As Judge Richard A. Posner has observed, "the courtroom is not the place for scientific guesswork even of the inspired sort. Law lags science; it does not lead it." *See, e.g., Rosen v. Ciba-Geigy Corp.,* 78 F.3d 316, 319 (7th Cir. 1996).

THE ROAD FORWARD: STILL 'PLENTY OF ROOM AT THE BOTTOM'

Touching medicine, pharmaceuticals and medical devices (life sciences generally), cosmetics, manufacturing, communications, transportation, and energy, among other commercial applications, nanotechnology offers profound potential as an enabling technology.

To be sure, commercial interests continue to beat a nanotechnology path to the marketplace. The first challenge will be the establishment of stable capital and insurance markets to support and protect the advancement of innovative nanotechnologies. Thereafter lies the

gauntlet of public policy, politics, and litigation — law and society basically. As a general matter, though, however novel nanoscale science may be, however much its sheer scale might boggle the mind, the legal issues it raises are likely to be more familiar than not, based primarily on prior experience with emerging technologies — biotechnology, for instance.

Among other things, recent experience in American product liability litigation suggests the overriding importance of dialogue — between industry, government, and the public at large — and new perspectives on liability issues, beginning with regulation. Lessons learned from such liability case studies as asbestos, nuclear power, and biotechnology would, in some respects, seem a good starting point for the development of a new medico-socio-legal paradigm: balancing, on one hand, the need to promote sound investment and trade in nanotechnology, against (and accounting for) the distributive social costs of wider trade in that emerging technology, on the other. More than 40 years on, for instance, does strict liability require rethinking? Is reinvigoration of the state-of-the-art (or developmental) defense necessary? Would initiatives along these lines, or the adoption of statutory liability caps — perhaps a limited "loser pays" rule — better balance the (wealth redistribution) scales in respect of certain "protected" emerging technologies? *See, e.g.,* 42 U.S.C. §2210 (codifying the Price-Anderson Act to limit liability in regard to nuclear power plants).

Most commercial factors (the cost of money in the main) being ultimately subservient to formal regulation, one of the key factors in the development of nanotechnology law and commerce — a first principle — will be governmental response to this emerging technology: basically, the pith and substance of regulation. A potentially complicating factor, however, is that the nanotechnology landscape is likely to change quickly and dramatically in response to widely published scientific reports of risk, or recalls — as evidenced by the recent example of "Magic-Nano," an aerosol tile sealant of German manufacture (in the first reported recall of a nanotechnology-based product). *See, e.g.,* Has All the Magic Gone? THE ECONOMIST (April 12, 2006); Press Release, German Federal Institute for Risk Assessment (Dec. 12, 2006).

To this end, both the U.S. Food and Drug Administration and the European Union have recently issued reports concerning nanotechnology and product safety. *See generally,* Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force (July 25, 2007) *and* Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009: First Implementation Report 2005-2007 (Sept. 6, 2007). Both bodies largely conclude that private industry must account for any risks unique to nanotechnology in complying with existing regulatory requirements — suggesting that nanotechnology-specific regulatory regimes are still very much on the drawing board.

The FDA Nanotechnology Task Force specifically declined to recommend adoption of any new labeling rules requiring identification of nanoscale materials in FDA-regulated products:

> *[b]ecause the current science does not support a finding that classes of products with nanoscale materials necessarily present greater safety concerns than classes of products without nanoscale materials,* the Task Force does not believe there is a basis for saying that, as a general matter, a product containing nanoscale materials must be labeled as such. *Therefore the Task Force is not recommending that the agency require such labeling at this time.* FDA Task Force Report at 35 (emphasis added).

More generally, it recognized that greater study is required before nanotechnology-specific regulatory regimes can be formulated — a view essentially echoed by the EU report. EU Report at 9.

Summing up, for now, both the FDA and the EU clearly fix industry with the immediate burden of identifying and describing nanotechnology health and safety issues within the context of existing regulatory schemes — as a corollary of the standard duty of care that is otherwise the norm. This probably means, unfortunately, that until clear regulatory guidelines for nanotechnology are forthcoming, innovative business (traveling at nano speed and depth) is likely to face the force and the need, like never before, to minimize and control the cost of uncertainty and regulation by litigation.

CONCLUSION: FOR NOW ...

In the present circumstances, given how little is actually known about nanotechnology, it is difficult to find fault with retreat to and reliance upon the legislative and regulatory status quo as a safe harbor — at least until more is known about nanotechnology. Nano business, however, is more likely than not to rapidly outpace the ability of known regulatory and liability paradigms to keep pace. *See, e.g.,* Patrick Linn, Nanotechnology Bound: Evaluating the Case for More Regulation, in 2 NANOETHICS: ETHICS FOR TECHNOLOGIES THAT CONVERGE AT THE NANOSCALE at 105-122 (Springer Aug. 2007).

Moreover, until any regulatory void is filled, it likely will be occupied by the default of civil litigation — and its ripple effect on capital, insurance, and all other markets critical to navigation of the "Valley of Death" through which every pioneering scientific idea must pass on the road to commercialization. In many ways, passage of these waters is every bit as treacherous and fearful to commercial interests of our time as was Cape Horn for whalers and shipping interests from the 1700s to the early 1900s. As then, what is needed most is a reasonably true map, preparation and planning, a favorable wind, and — as ever — a bit of luck.

Returning to the beginning, and Feynman's prescient observations nearly 50 years ago, "there is [still] plenty of room at the bottom" in the field of nanotechnology, and much work that must be done to address the profound commercio-legal uncertainty associated with this revolutionary emerging technology. It is a subject calling for legal and business thinking every bit as transcendent as the scientific variety that has delivered us nanotechnology.

In the 1960s, in the infancy of today's highly commercialized, mass consumption and Web-driven society, the California Supreme Court began the modernization of American tort law with the invention of strict liability. Half a century on, one can only wonder what reforms, if any, the unique promise and challenge of nanotechnology will produce in regard to product liability law. Time will tell.

In the meanwhile, law and society must keep pace with the reality of business at one-billionth of a meter.

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