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LEGAL AND REGULATORY CONCERNS FACING NANOTECHNOLOGY

By
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On December 29th, 1959, Richard P. Feynman, the Nobel price-winning physicist who was to serve on the commission investigating the Challenger disaster, presented his famous lecture titled "There's Plenty of Room at the Bottom" during the annual meeting of the American Physical Society hosted by the California Institute of Technology. In his lecture, Feyman discussed a wide range of novel ideas, included among them were the ability to rearrange atoms for information storage, duplicating how biological systems write and execute information stored at the molecular level, and the creation of tiny, self-replicating "hands" that were capable of simultaneously manufacturing very small devices (for full text go to www.zyvex.com/nanotech/feynman.html).

However, while Feynman's talk was clearly visionary, it could not foresee the advances that would make possible what was later become the field of "nanotechnology." It was not until several decades later, when K. Eric Drexler envisioned the creation of molecular machines in his seminal book Engines of Creation: The Coming Era of Nanotechnology (1st ed., Anchor Books 1986), that the field of nanotechnology began its formal existence. Since Feynman's talk in 1959, enormous technological and scientific advances have brought us closer to this "nano" world, so close indeed, that many of the prophetic ideas expressed first by Feynman and then by Drexler are now leaving academic, industrial, and government research laboratories and are becoming commercial realities (for additional information on emerging technological issues on nanotechnology go to the Foresight Institute's website at www.foresight.org).

The staggering speed at which nanotechnology seems to permeate many commercially important industries around the world, especially semiconductor manufacturing and biotechnology, has raised some concerns among regulatory and legal

experts as to their current ability to foresee the commercial and social effects of such a rapidly evolving field.

WHAT IS NANOTECHNOLOGY?

Nanotechnology encompasses many different concepts but it is more generally associated with the "manipulat[ion] [of] matter on an atom-by-atom or molecule-by-molecule basis" to construct or build a certain atomic or molecular configuration. Frederick Fiedler & Glenn Reynolds, Legal Problems of Nanotechnology: An Overview, 3 S. Cal. Interdisc. L.J. 593, 595 (1994). Rather than following traditional manufacturing, nanotechnology borrows from living organisms its goal of constructing machines, such as cells and organelles, by organizing atoms and molecules into particular configurations able to create works of great complexity by performing operations in parallel. Id. at 596. The scale and complexity of this effort will likely remove boundaries that have long existed between various scientific and engineering disciplines and between various technological fields, for example, solid-state devices and biochemistry. While many of these ideas seemed to be more the product of fantastic science fiction than reality, the race to develop commercial products has been well on its way for some time now. Barry Newberger, Intellectual Property and Nanotechnology, 11 Tex. Intell. Prop. L.J. 649, 649 (2003).

GENERAL CONCERNS

Problems facing nanotechnology will be different at various stages of development, that is, the concerns that arise will vary from those of an emerging technology to those of a mature technology with an established market. Fiedler et al., 3 S. Cal. Interdisc. L.J. at 602. At first, "it will probably be necessary to base future law concerning [nanotechnology] on prior law concerning analogous prior products or processes." Id. at 602-603. One such analogous field from which guidance can be obtained is biotechnology. As the unification of scientific disciplines continues in the 21st century, the efforts of biotechnologists and those of nanotechnologists are likely to come together, which would require biotechnologists and public policy makers to understand the social and ethical impact of such a merger. Until regulation is able to

account for the novelty of "products and processes created by nanotechnology, reasoning by analogy may be the best that can be done." Id. at 603. Later on, as the technology becomes more established, some of the problems facing nanotechnology will be particular to it and may therefore be "addressable only through the creation of entirely new rules." Fiedler et al., 3 S. Cal. Interdisc. L.J. at 603.

Nanotechnology is likely to produce a great deal of debate for government regulation; the goal of this debate would be to achieve a balance between comprehensive regulation, focused regulation, and, in some instances, no regulation. Joel Rothstein Wolfson, Social and Ethical Issues in Nanotechnology: Lessons from Biotechnology and Other High Technologies, 22 Biotechnology L. Rep. 376, 384 (2003). Any regulatory extreme may present a risk; on one end, very little regulation may make investors reluctant to support development, on the other hand, too much regulation may lead to undesirable, and avoidable, consequences. Fiedler et al., 3 S. Cal. Interdisc. L.J. at 603. The vast range of devices and products that will likely be produced by nanotechnology companies may require many agencies, such as the Food and Drug Administration, the Environmental Protection Agency, the National Institute of Health, or the Department of Health and Human Services, to either have their own regulatory approach or to develop a coordinated regulatory approach. Wolfson, 22 Biotechnology L. Rep. at 384.

In addition to legal and regulatory concerns, there are several socio-political issues that will likely arise from the development of nanotechnology. In a peaceful and stable world, the benefits of new medical treatments or better consumer goods are likely to be welcomed; in a world in conflict, nanotechnology it is likely to find military applications with potentially grave consequences. Fiedler et al., 3 S. Cal. Interdisc. L.J. at 604. Socio-political problems may also raise concerns regarding class distinction between wealthier societies and countries that can develop or gain access to the benefits of nanotechnology and those who cannot. Wolfson, 22 Biotechnology L. Rep. at 377. Other concerns may be the inadvertent release or spread of nanotechnology-based devices or the use of nanotechnology as a terrorist weapon. Id. at 381-382.

REGULATION

One question to ask is whether nanotechnology regulation should be different whether "the activity at issue is research and development or commercial deployment." Id. at 382. Regulatory concerns at the early stages of nanotechnology development will likely be minor, as was the case with biotechnology. Fiedler et al., 3 S. Cal. Interdisc. L.J. at 605. Unfounded and exaggerated fears that were first associated with biotechnology may once again appear in nanotechnology as possible obstacles for its development. The fear that self-replicating organisms would escape and attack everything they encounter, the "gray goo problem," which arose during biotechnology's early stages, is also feared to happen as a result of uncontrolled self-replicating nanodevices. Id. As with biotechnology, researchers and government regulators will likely develop simple and straightforward rules to prevent any far-fetched catastrophe from happening. Such steps may include reasonable containment precautions, limits on research of particularly dangerous nanodevices, limits on the creation of self-replicating devices that can survive outside the lab, and limits on the research into military applications of nanotechnology. Id. at 606.

A real concern regarding regulation is the ability or competence of regulators to keep up with the industries and technologies they regulate. Id. at 617. The question then arises as to whether regulation should be governmental or self-regulation, or a combination of the two. Wolfson, 22 Biotechnology L. Rep. at 386. Examples of government oversight of self-regulation include the securities industry and the certification of aircraft manufacturing. Because of the commercial and social importance of nanotechnology, it is likely that such an approach may be used in those applications where nanotechnology appears to be potentially dangerous. Fiedler et al., 3 S. Cal. Interdisc. L.J. at 618. However, with limited resources and rapidly evolving technology, it is more likely that a self-regulating approach may be followed, "perhaps backed up by powerful incentives in the form of tort liability or criminal statutes." Id.

PROPERTY RIGHTS

In 2001, approximately 800 patents existed that had "nanotechnology" somewhere in the description or the title of the patent, indicating that intellectual property protection is

important to those entities that are currently working on the field. Newberger, 11 Tex. Intell. Prop. L.J. at 650. "As an emerging technology, the opportunity for pioneering patents" is clearly available. Id. "The absence of prior art affords the opportunity for broad patent protection," but it is also likely that it complicates the patent examining process Id. at 654.

It is important to look at the kinds of problems that may arise in legal structures and doctrines because of the revolutionary nature of nanotechnology. Fiedler et al., 3 S. Cal. Interdisc. L.J. at 618. For example, the generally accepted assumption that a particular configuration of matter is an important property interest may no longer be valid in a world where nanotechnology can assemble nearly any object. Id. at 619. In other words, while the object can be constructed from inexpensive materials almost anywhere, the instructions for making the object will remain very valuable. Id. at 619.

Traditional intellectual property protection regimes - trade secrets, patents, copyrights, and trademarks - may not all be affected by this disruptive technology. There may not be anything particular about trademarks, copyrights or trade secrets with regard to nanotechnology. Newberger, 11 Tex. Intell. Prop. L.J. at 653. Patents will remain the primary regime to provide strong protection for nanotechnology, although it remains far more costly than trade secrets. Id. at 653. While no doctrinal issues may need to be addressed at this point for nanotechnology, other aspects of intellectual property protection may require consideration. For example, fundamental questions arise as to how to categorize certain products that will result from nanotechnology manufacturing, will they be mechanical or biological. Traditional distinctions will likely be of no use and categories may need to be differentiated based on whether the use is process-oriented or functional. Fiedler et al., 3 S. Cal. Interdisc. L.J. at 615-616.

Another important aspect in nanotechnology protection is the role that the federal government plays as the major sponsor of research and development money. Issues of public disclosure and experimental use of patent technology may make the participation of the federal government less desirable for small companies whose sole or primary asset is their patent portfolio. Newberger, 11 Tex. Intell. Prop. L.J. at 655.

CURRENT EFFORTS

As part of its leadership in this field, the federal government has authorized the 21st Century Nanotechnology Research and Development Act ("Act"), 15 U.S.C.A. §7501-§7509 which provides $4.7 billion in funding between 2004 through 2008 for the National Nanotechnology Initiative, a nanotechnology initiative comprised of nine agencies: the National Science Foundation, Department of Energy, National Aeronautics and Space Administration, National Institutes of Heath, National Institute of Standards and Technology, Environmental Protection Agency, Department of Justice, Department of Homeland Security, and the Department of Agriculture. Programs under these agencies will be overseen by both external and intergovernmental committees, while the Office of Science and Technology Policy is responsible for coordination and management of the National Nanotechnology Initiative (for additional information go to www.nano.gov). One of the main goals of the Act is to provide a joint government-industry effort to develop and commercialize nanotechnology in a coordinated and efficient manner.

Another organization which is currently looking into the impact of nanotechnology is the American Bar Association. The Science and Technology Law Section's Standing Committee on Nanotechnology is currently organizing a forum where it may attempt to understand the potential risks and dangers associated with nanotechnology, and where scientists, attorneys, and legislators may discuss the ethical and social implications of nanotechnology (for additional information go to www.abanet.org/scitech/specomm.html).

CONCLUSION

At this point, it is likely that one or more decades may pass before any of the potential problems associated with nanotechnology become a reality. At first, it is important to think about the "impact that nanotechnology is likely to have and about the social institutions and rules that will be necessary to shape that impact in positive ways." Fiedler et al., 3 S. Cal. Interdisc. L.J. at 626. In the medium term, the best approach is to

evolve any regulation or any changes in protection in a rather tempered manner and based on the experience that results from dealing with problems, expected or not, that revealed them. Id. For the long term, after nanotechnology has matured and it becomes a well established industry, it is likely that the circumstances would be so different than those in today's world, that any of the current "suggestions must necessarily be wide of the mark." Id. at 627.