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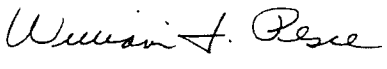

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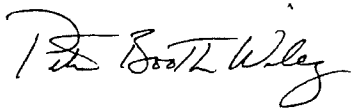

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NANOSCALE

ISSUES AND PERSPECTIVES FOR THE NANO CENTURY

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"Now nanotechnology had made nearly everything possible, and so the cultural role in deciding what should be done with it had become far more important than imagining what could be done with it."

—Neal Stephenson, *The Diamond Age or a Young Lady's Primer* (1995)

"Each new power won *by* man is a power *over* man as well. Each advance leaves him weaker as well as stronger. In every victory, besides the general who triumphs, he is a prisoner who follows the triumphal car . . . *Human* nature will be the last part of Nature to surrender to Man. The battle will then be won. We shall have "taken the thread out of the hands of Clotho" and be free henceforth to make of our species whatever we wish it to be. The battle will indeed be won. But who, precisely, will have won it?"

—C. S. Lewis, *The Abolition of Man* (1943)

"[T]he discoverer of an art is not the best judge of the good or harm which will accrue to those who practice it."

—Plato, *Phaedrus* (c. 370 BC)

"Science Finds, Industry Applies, Man Conforms"

—Motto of Chicago World's Fair, 1933–34 (Century of Progress Exposition)

Thus, even if only a small portion of nanotechnology's predicted promise comes to pass, as a long-term solution, it is obvious that current laws are not equipped to regulate such fundamentally different products and processes. Traditional regulatory frameworks, benchmarks, and distinctions will be less—not more—useful as applied to nanotechnology's processes and applications over time. A new nano-specific law will be needed; it is only a matter of when.

It is worth reiterating that this is not the first "wonder" material or technology that the world has seen. History is strewn with once-thought miraculous substances that turned out to be deadly or harmful to the environment. Asbestos was once considered an ideal material for clothing, buildings, and other goods; today, it kills 10,000 people annually. Similarly, for more than 50 years, chlorofluorocarbons (CFCs) were thought to be a miracle substance, used in innumerable household appliances and consumer products; scientists today know that CFCs are a catalytic agent in ozone destruction, leading to less protection from the sun's UVB rays, increasing the risk of skin cancer, and eventually leading to international and national bans on their release. As illustrated by asbestos, CFCs, DDT, leaded gasoline, PCBs, mercury, and numerous other former "wonder" substances and technologies, some nanomaterials will undoubtedly have significant and unintended negative consequences on human health and the environment; whether our policymakers and regulators wait until that occurs or adapt pre-emptively in an attempt to avoid such an accident remains to be seen.

CHAPTER 14

Nanotechnology and the Intellectual Property Landscape[1]

JULIE A. BURGER, MARIANNE R. TIMM, and LORI B. ANDREWS

INTRODUCTION

Advocates of nanotechnology offer many promises for the future—cleaner, more efficient energy sources, drugs that will fight cancer, computer chips that can be implanted in the brain to help the blind see and the disabled walk, and devices that can detect biowarfare agents and fight terrorism. The federal government has invested heavily in this promise of nanotechnology, with spending reaching an estimated $1.3 billion in 2006.[2] The National Cancer Institute alone has implemented a 5-year, $144.3 million program to use nanotechnology to improve options for the prevention, diagnosis and treatment of cancer.[3] Numerous individual states have enacted statutes designed to promote nanotechnology through direct funding, tax incentives, educational grants, or otherwise encouraging nanotechnology research and development.[4]

The National Nanotechnology Initiative (NNI), a U.S. multi-agency endeavor that coordinates nanotechnology research and development, defines nanotechnology

[1]This material is based upon work supported by the National Science Foundation (NSF) under grant SES-0508321 and the Office of Science, U.S. Department of Energy (DOE) under Award Number DE-FG02-06ER64276.

[2]National Nanotechnology Initiative. Available at http://www.nano.gov/html/about/funding.html (last visited October 8, 2006).

[3]M. Sherman, "Exploring the World of Nano Medical Devices," Medical Device and Diagnostic Industry, May 2006. Available at http://www.devicelink.com/mddi/archive/06/05/008.html (last visited October 8, 2006).

[4]For example, Arkansas, ARK. CODE ANN. § 15-4-2104 (West 2006); California, CAL. EDUC. CODE § 88500 (Deering 2006); Connecticut, CONN. GEN. STAT. § 4-124hh (West Supp. 2006); Illinois, 2005 ILL. LAWS 094-079; Indiana, IND. CODE ANN. § 5-28-10-1 *et seq.* (West 2005); Michigan, MICH. COMP. LAWS ANN. §§ 125.2088 *et seq.* (West 2005) and 206.30 (West 2006).

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as: "[T]he understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale."[5] The NNI recognizes that the physical, chemical, and biological differences in properties of materials at the nanoscale have the potential to be harnessed in valuable applications.[5] Other definitions exist, however. The State of Michigan, in a statute designed to promote nanotechnology, defines nanotechnology as "materials, devices, or systems at the atomic, molecular, or macromolecular level, with a scale measured in nanometers."[6] This definition does not require any new property or function for a material or product to be labeled as nanotechnology.

Development of nanotechnology, and the impact it has on our health, economy, environment, security, and society will be influenced extensively by the application of the U.S. intellectual property laws. The intellectual property system is designed to provide incentives for innovation—a concept that is important in an emerging field, such as nanotechnology. When people know that their innovation will be rewarded, they have more of an incentive to invent. Yet, when intellectual property laws are improperly applied, patents may be granted that are overbroad, stifling innovation, or patents may be granted that are overly narrow, and do not provide sufficient incentive to continue to invent.

The differences in definitions for nanotechnology in the marketplace, combined with the existing mechanisms of review of nanotechnology patents at the United States Patent and Trademark Office (USPTO), make it problematic to determine exactly how prevalent patents covering nanotechnology are in the United States. Electronic word-based searches designed to locate patents claiming nanotechnologies can be performed on patents that have been issued by the USPTO since 1976, leading some researchers to attempt to analyze the number of nanotechnology patents that have been granted in the past three decades. But applicants can claim that their technology is "nano," even if it does not meet any of several definitions for nanotechnology. Depending on search terms used, such patents might be counted as referring to nanotechnology, though they really do not meet a definition such as that used by the NNI. For similar reasons, it is difficult to pinpoint the exact number of nanotechnology patent applications are currently pending. Not all patent applications are published. The application will remain confidential if the applicant promises not to file for patent protection outside the United States. With respect to published applications, they are only searchable since 2001, when the American Inventors Protection Act[7] went into effect, and are generally published 18 months after their filing date. Therefore, it is also difficult to estimate how many nanopatents applications might be pending.

A brief review of studies of the prevalence of nanotechnology patents illustrates the problems with estimating the incidence of nanopatents. One study undertaking a

[5]National Nanotechnology Initiative, "What is Nanotechnology." Available at http://www.nano.gov/html/facts/whatIsNano.html (last visited October 8, 2006).

[6]MICH. COMP. LAWS ANN. §§ 125.2088A(2) (West 2005) and 206.30(1)(bb)(i)(B) (West 2006).

[7]American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 1000(a)(9), 113 Stat. 1536 (1999).

search of all patent descriptions (the portion of the patent describing the new invention) using the prefix "nano" identified more than 96,000 patents.[8] However, this is an overinclusive search because it includes patents that merely reference "nanoseconds," but do not relate to nanotechnology. Search results may also vary depending on whether just the title of the patent is searched, whether portions of the patent are searched, or whether the entire patent is searched. For studies that conducted searches of titles and claims (the portion that sets forth the legal boundaries of the patent) to include derivations of terms, such as "quantum dot" or "self-assembling," the number of patents found was in excess of 11,000.[9] Other studies reported the number of nanopatents drops to approximately 2000 when only the title is searched for the limited term "nano."[10]

Whatever search terms are used, however, there is evidence that nanotechnology patents are on the rise and that there are more nanotechnology patents than there were biotechnology patents at this stage of the latter technology's development.[11] An understanding of the patent system can help predict future stumbling blocks to innovation and potential costly litigation.

This chapter highlights the importance of the intellectual property system in the development of the new field of nanotechnology, briefly explains laws and principles governing intellectual property, examines how the application of patent law will shape nanotechnology research, development, and progress, and then discusses unique issues that may be raised when intellectual property laws are applied in the nanotechnology field.

PATENT LAW AND NANOINVENTION

The patent system is designed to provide incentive to inventors—people who use their ingenuity to create something truly new. In exchange for disclosing the details of their invention, inventors are given exclusive rights to their invention for a period of 20 years. Patent rights can spur development of technologies. For example, imagine a university develops a nanoparticle-containing coating that can be used as an antimicrobial material for use in hospitals. It receives a patent on this new material it has developed. One day researchers at the National Aeronautics and Space Administration (NASA) read about this material and, after obtaining a license from the university, experiment with the material, and develop heat-shielding tiles for spacecraft and patent that use. Two industries have benefited from this technology.

[8]T. K. Tullis, Comment, "Application of the Government License Defense to Federally Funded Nanotechnology Research: The Case for a Limited Patent Compulsory Licensing Regime," 53 UCLA Law Review 279, 282, 282 n.11 (2005).

[9]Z. Huang et al., "International Nanotechnology Development in 2003: Country, Institution and Technology Field Analysis Based on USPTO Patent Database," 6 Journal of Nanoparticle Research 325–354, 327 (2004).

[10]T. K. Tullis, Comment, "Application of the Government License Defense to Federally Funded Nanotechnology Research: The Case for a Limited Patent Compulsory Licensing Regime," 53 UCLA Law Review 279, 282 (2005).

[11]See Chapter 15.

Yet, inappropriate patent policies can have detrimental effects on the development of new technologies, such as nanotechnology, preventing society from reaping the benefits of the new field.

What if the nanoparticle coating was found unpatentable as "obvious" merely because someone had patented an antibacterial paint, with none of the key, unique properties of the nanoparticles? Or what if the first university were to patent all uses of the nanoparticle coating? There would be no incentive for other entities, like NASA, to develop other uses.

The USPTO is the agency charged with granting or refusing to grant patent rights on inventions it examines. If USPTO examiners are too stringent in their analysis of the first patent applications in a new or emerging field of study, they will improperly reject valid patent applications. The lack of adequate property rights and protection will deter future research and investment, delay knowledge of advances to other researchers, create more overlapping and unnecessary research, and consume judicial resources, time, and money. Improper rejections could be extremely costly, either through inventors making use of the appeals process within the USPTO or litigating against the USPTO in the courts.[12] This increase in cost, time, and energy to obtain patent protection could deter some companies from investing in nanotechnology for fear that their investment will not be protected or recouped.[13]

As an example, consider a company that spends 2 years developing a new method of making Buckminster-fullerenes (buckyballs), the famous soccerball-shaped carbon configuration, C_{60}. The method is completely new, unanticipated by other work in the area. When the company applies for a patent on the method, the examiner, who is unfamiliar with nanotechnology, rejects it, which allows other companies to use the new method without compensating the company who invented it. Now the company has lost its incentive to invest in research and development in the future because it may not be able to recoup its costs or profit from the investment. Or, the company may continue to research new methods, but might choose to keep its results a trade secret. Then the technology is not available for sale or license to others who might go on to develop new products or technologies from it.

On the other hand, if patents are granted that are too broad, developments in nanotechnology might be stifled. Overly broad patents could prevent other researchers and developers of technology from working in that area.[14] If examiners issue overly broad patents, then conflicting property rights will be created, which will

[12]S. J. Ainsworth, "Nanotech IP: As Nanometer-Scale Materials Start Making Money, Intellectual Property Issues are Heating Up," 82 Chemical and Engineering News 17–22 (April 12, 2004).

[13]A. Regalado, "Nanotechnology Patents Surge as Companies Vie to Stake Claim," Wall Street Journal, June 18, 2004, at A1; S. J. Ainsworth, "Nanotech IP: As Nanometer-Scale Materials Start Making Money, Intellectual Property Issues are Heating Up," 82 Chemical and Engineering News 17–22 (April 12, 2004); R. A. Bleeker et al., "Patenting Nanotechnology," Materials Today, 44–48, 46 (February 2004).

[14]R. A. Bleeker et al., "Patenting Nanotechnology," Materials Today 44–48, 47 (February 2004). For example, in the field of gene therapy, W. French Anderson and his collaborators at the National Institutes of Health were granted a patent on all human gene therapy that involved the removal, alteration, and reinjection of a patient's cells. That broad patent, covering an entire field, was later criticized as potentially thwarting innovation. Lori Andrews and Dorothy Nelkin, Body Bazaar: The Market for Human Tissue in the Biotechnology Age, 62–63 (Crown Publishers: New York 2001).

also waste public resources through the cost and time of litigation. In addition, research will be discouraged, end products for consumers will increase in cost,[15] and a high-tech bubble could form and burst. Improperly granted claims may have a chilling effect on other researchers' use of the technology because they may not realize that the patent is legally deficient or may not be able to afford to challenge the patent in court.[16]

The Constitutional and Statutory Foundation of the U.S. Patent System

The patent system is designed to provide an incentive for inventors to create and disclose new products and inventions—discoveries that will be beneficial to the public. Nanotechnology offers many promises that would be beneficial, but the success of nanotechnology might depend on how the laws of intellectual property are applied. The U.S. Constitution grants Congress the power "[t]o promote the progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[17] Congress executed its power by enacting the Patent Act.[18] Under the Patent Act, inventors are essentially granted a monopoly—the exclusive rights for 20 years to make, use, sell, and import their invention.[19] If anyone makes, uses, sells, or imports the patented invention without the patent owner's permission, that individual has infringed the patent owner's rights[20] and is liable for damages.[21] The patent holder may also seek an injunction in federal court against the infringer and stop him or her from using the invention.[22] But there is a check to this system—not all inventions and discoveries may be patented.

An inventor may receive a patent on "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement on these things."[23] The applicant must demonstrate that the invention is novel,

[15]A. Regalado "Nanotechnology Patents Surge as Companies Vie to Stake Claim," Wall Street Journal, June 18, 2004, at A1.

[16]The litigation process to challenge a patent's validity has been estimated to cost between $650,000 and $4.5 million. American Intellectual Property Law Association, Report of the Economic Survey 102 (2005).

[17]U.S. Constitution, Article I, Section 8, Clause 8.

[18]35 U.S.C.A. § 101 *et seq.* (2001 and West Supp. 2006).

[19]35 U.S.C. § 154 (2001 and West Supp. 2006).

[20]35 U.S.C.A. § 271 (2001 and West Supp. 2006).

[21]35 U.S.C. § 284 (2000).

[22]35 U.S.C. § 283 (2000). Courts, following Federal Circuit precedent, routinely awarded injunctions as a matter of course when a patent holder demonstrated the existence of a valid patent and infringement. In 2006, the U.S. Supreme Court ruled that in patent cases, courts must consider the traditional four factors to determine if an injunction should issue. *eBay Inc. v. MercExchange, L.L.C*, No. 05-130, 126 S. Ct. 1837, 547 U.S. _, 2006 U.S. Lexis 3872 at *2–3 (2006). One factor the courts must consider is whether the public interest weighs in favor of enjoining the infringer from future infringement. In nanotechnology, where it is probable that developed technologies will have an impact on the public interest (such as life-saving nanodrugs or devices necessary for national security), the public interest may weigh against granting a permanent, or even preliminary, injunction.

[23]35 U.S.C. § 101 (2000).

nonobvious, and useful.[24] The inventor must also provide a written description of the invention sufficient to "enable" someone skilled in that field to make and use the invention.[25] In exchange for revealing and describing the invention, the inventor receives the exclusive rights described above. The system is designed to benefit the public and to provide incentives to the inventor.

The patent system has become a three-way give-and-take among Congress, the USPTO, and the courts. All three have active roles in ensuring that the goals of the patent system are met and that the monopoly granted is not too broad. Most often, this means that the courts and Congress winnow back patents granted by the USPTO. When Samuel Morse convinced the USPTO to grant him a patent on the use of electromagnetic waves to write at a distance, the Supreme Court ruled the patent was overbroad; Morse could only patent his invention—the telegraph.[26] In another example, in the mid-1990s surgeons began to patent their surgical methods in larger numbers. The American Medical Association took its case to Congress and said this practice was not good for medicine or for research. Congress amended the law and now, while surgical methods can be patented, under the medical use exemption doctors can use patented medical procedures and cannot be compelled to pay a royalty.[27]

Nanotechnology could raise concerns similar to both of these situations—where overbroad patents harm business and innovation, and where patents create risks to the public health. Nanomedicine holds great promise in the detection and treatment of disease and the improvement of the human condition. However, as with the patenting of surgical methods, improper patent policies can impede the advance of medical research and the availability of technologies to patients.

The incentive a patent promises has driven the development of products in other fields (e.g., as pharmaceuticals) for years. Yet, just as there may be problems in the scientific development of a technology, there may be problems in the legal system's response to that technology. Some of the problems at the intersection of nanotechnology and intellectual property may be analogous to those encountered by any new technology for which patent protection is sought. Other problems, however, are likely to be unique because of the extraordinary characteristics of nanotechnology.

[24]35 U.S.C.A. §§ 101–103 (2001 and West Supp. 2006).

[25]35 U.S.C. § 112 (2000). The disclosure provisions require that an applicant satisfy four basic requirements in patent specification: written description, enablement, best mode, and definiteness. 35 U.S.C. § 112 (2000). Specifically, the law requires that the patent application "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112 (2000). Written description relates to whether the invention as claimed has been sufficiently disclosed in the specification. Definiteness relates to the way the claim is written; the claim must "particularly point out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 (2000).

[26]*O'Reilly v. Morse*, 56 U.S. 62, 113 (1853).

[27]35 U.S.C. 287(c) (2000).

Patents May Only Be Granted on Eligible Subject Matter

The area of patentable subject matter has certain boundaries, outside of which no patents should be granted. For more than 150 years, the U.S. Supreme Court has held that patents are not allowed on laws and products of nature.[26] Basic laws of science are not patentable. The Supreme Court has emphasized:

> The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."[28]

If this were not so, future innovations could not be based on basic scientific ideas.

One way that overbroad nanopatents could be granted would be if nanopatents were granted on laws or products of nature. An example of overly broad patents may be in the area of nanotube technology. Nanotubes are cylinders made up of a layer of carbon atoms, either a single tube (single-wall carbon nanotubes) or multiple tubes within each other (multiwall carbon nanotubes). Credit for the discovery of nanotubes was asserted as early as 1991.[29] Two years after the discovery of the carbon nanotube was reported, IBM filed a patent application that included a claim for "[a] hollow carbon fiber having a wall consisting essentially of a single layer of carbon atoms."[30] This language is broad enough that it could encompass a single-wall carbon nanotube.[31] Obviously, the timing of the patent application raises questions as to whether it was truly novel when such a compound was discussed in scientific literature several years earlier. But just as importantly, nanotubes exist in nature.[32] Carbon occurs naturally in this form, and thus, as a product of nature, might be appropriately considered to be unpatentable subject matter.

Even methods of producing naturally occurring nanocompounds might mimic naturally occurring processes, resulting in overbroad patents if the processes are allowed to be patented. There are numerous patents for methods of producing buckyballs, for example. Yet, as with nanotubes, buckyballs are found in exhaust from vehicles, soot,[33] and even after lighting strikes sand. The heating of a substance to increase the presence of C_{60} is a fundamental principle of chemistry and a process that occurs naturally in nature.

Thus, in the nanotechnology sphere, questions arise as to whether certain nanoprocesses are actually fundamental principles of biology, chemistry, and physics,

[28]*Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

[29]Sumio Iijima, "Helical Microtubules of Graphitic Carbon," 354 Nature 56–58 (Nov. 7, 1991).

[30]Carbon fibers and method for their production, U.S. Patent No. 5,424,054 cl. 3 (filed May 21, 1993).

[31]J. C. Miller et al., The Handbook of Nanotechnology, 70 (John Wiley & Sons, Inc.: New Jersey 2004).

[32]S. Iijima, "Helical Microtubules of Graphitic Carbon," 354 Nature 56–58 (Nov. 7, 1991).

[33]L. E. Murr et al., "Carbon Nanotubes, Nanocrystal Forms, and Complex Nanoparticle Aggregates in Common Fuel-gas Combustion Sources and Ambient Air," 6 Journal of Nanoparticle Research 241–251 (2004).

and should not be patented. If the first patent on a nanoinvention improperly includes a claim stating a law of nature or improperly encompasses a product of nature, it may impede future and better inventions. It could also result in time-consuming and costly patent litigation. For a startup company, these costs could be oppressive, leading it to avoid entering the market. Or money may be diverted into litigation or into licensing fees that could be better spent on research and development.

The Supreme Court has consistently invalidated patents that claimed laws of nature. However, the Federal Circuit (which reviews all patent cases that are appealed after the trial court's decision and before appeal to the Supreme Court) has taken the contrary position that a product of nature or law of nature may be patented if it produces a useful and tangible result or has a real-world function.[34] Yet, laws and products of nature inherently produce useful results and have real functions. A carbon nanotube filled with a metal may act as a semiconductor, but might also exist on its own in nature. While "anything under the sun that is made by man" may be patentable,[35] laws of nature are basic facts and processes that pre-existed human intervention. It is likely that, if the Federal Circuit upheld a patent on a nanotechnology that was a mere product of nature or a bare application of a law of nature were patented, and upheld by the U.S. Supreme Court would reverse it. In a case dealing with similar issues that was dismissed on jurisdictional grounds, Justice Breyer stated that regardless of whether research is difficult or costly, laws of nature should not be patented because sometimes "*too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts.'"[36]

Novelty and Nonobviousness

Under the patent statute, inventions must be both novel and nonobvious.[37] But it appears that the U.S. Food and Drug Administration (FDA) is making findings that certain nanoproducts are not novel, which could impede their patentability if the USPTO were to follow the FDA ruling. Patents are to be truly new innovations (novel). But they must be more than just new. They cannot be inventions that can be easily created by combining existing technologies and they must represent an advance over earlier technology, that is, they must be "nonobvious." Existing technology and information in a field that are examined to determine whether the invention is novel and nonobvious are called "prior art."

Nanotechnology takes advantage of the fact that smaller size alone may give substances unique properties. Yet, for the past several years, the FDA has determined that it will treat nanotechnology products the same as any other product falling under its regulation.[38] Its policy has been that a nanotechnology product that has an

[34]*State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).
[35]*Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quotation omitted).
[36]*Laboratory Corporation of America v. Metabolite Laboratories, Inc.*, No. 04-607, 548 U.S. _, 126 S. Ct. 2921, 2006 U.S. Lexis 4893 at *4 (2006) (Breyer J. dissent) (quoting U.S. Const., Art. I, § 8, cl. 8).
[37]35 U.S.C.A. §§ 102–103 (West 2006).
[38]J. Miller, Note, "Beyond Biotechnology: FDA Regulation of Nanomedicine," 4 Columbia Science & Technology Law Review 1 at *9 (2002–2003). While the FDA has recently set up a task force to make recommendations about its nanotechnology policies, the results and the FDA's ultimate decision will not be known for many months, if not longer. Regardless, the FDA's determination in the past that products utilizing nanotechnology will be treated the same as their larger counterparts is an interesting comparison to the USPTO's nanopolicies.

identical composition to its larger common version would be considered to be equivalent under the FDA approval process. Accordingly, these smaller products might require no new premarket approval testing or might be eligible for an abbreviated approval process.[39]

The FDA has approved numerous drugs and devices that employ nanotechnology, such as particles for imaging, wound dressings, bone implants, drugs, makeup and cosmetics, dental implants, and sunscreens. It has determined that these drugs and devices are substantially equivalent to products that do not use nanotechnology. Several years ago, for example, the FDA determined that nanosized particles of titanium dioxide and zinc oxide, ingredients commonly found in sunscreen, are to be regulated the same as their larger sized counterparts.[40] The small size of the nanosized particles gives the sunscreen what seems to be a novel property—better absorbability that reduces the white skin appearance that otherwise results from these compounds. The small size might also allow the particles to cross the blood–brain barrier, thus raising health concerns.[41]

The product NanOss™ is another such device that capitalizes on nanotechnology and has benefited from expedited approval by the FDA. NanOss™ is a bone implant that uses nanocrystals of calcium phosphate created from a patented precipitation process.[42] The manufacturer claims that the nanocrystals, which will be reabsorbed by living bone, are very strong and resist cracking as compared to larger particles.[43] It advertises the nanocrystals as duplicating "the microstructure, composition and performance of human bone."[44] The FDA determined NanOss™ is "substantially equivalent" to other resorbable calcium phosphate bone void filler devices because its intended use, design, and functional characteristics are substantially the same as previously approved devices, each of which was intended to fill gaps in bone, was not intended to be load-bearing, and consisted of calcium compounds.[45] Yet, the USPTO has also granted a patent on NanOss™ covering both the nanocrystals and the method of producing them.[46] If NanOss™ is substantially equivalent to larger versions of bone implants, as the FDA has found, it might not be novel and nonobvious, as the USPTO has determined.

[39]R. Monastersky, "The Dark Side of Small," Chronicle of Higher Education, September 10, 2004.
[40]Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph, 64 Fed. Reg. 27666 (May 21, 1999).
[41]A. Nel et al., "Toxic Potential of Materials at the Nanolevel," 311 Science 622-627 (February 3, 2006).
[42]Nanocrystalline Apatites and Composites, Prostheses Incorporating Them, and Method for Their Production, U.S. Patent No. 6,013,591 (filed January 16, 1998).
[43]A. Baluch, "Angstom Medica: Securing FDA Approval and Commercializing a Nanomedical Device," 2 Nanotechnology Law and Business 168, 169 (2005). This article can be found on the "Press Releases" page of Angstrom Medica's website. Available at http://www.angstrommedica.com/images/Nanotech%20L&B.htm (last visited October 8, 2006).
[44]Angstrom Medica, "Technology." Available at http://www.angstrommedica.com/technology/default.htm (last visited October 8, 2006).
[45]501(k) Summary for Angstrom Medica NanOss™ Bone Void Filler, K050025, February 3, 2005.
[46]Nanocrystalline Apatites and Composites, Prostheses Incorporating Them, and Method for Their Production, U.S. Patent No. 6,013,591 (filed January 16, 1998).

Antimicrobial silver wound dressings are another device that employ nanotechnology, have FDA approval, and have been patented. NUCRYST Pharmaceuticals uses a patented process to isolate silver-containing nanoparticles, which are then placed on a substrate of polyethylene mesh as atomically disordered nanocrystals. The substrate is used in wound and burn care devices. The FDA determined that the dressings are "substantially equivalent" to prior silver coated dressings that release silver ions into wound sites to provide an antimicrobial effect.[47] Yet the company holds numerous patents that cover the manufacturing process, as well as compositions of matter (including coatings, powders, and flakes) and uses that incorporate the technology.

The USPTO thus treats various products as "novel" and "nonobvious," while another U.S. government agency determines that the same product is "substantially equivalent" to already-existing technologies. This indicates either that the USPTO may have granted patents on nanotechnologies that do not meet the statutory requirements[48] or that the FDA is allowing products to be put on the market whose novel properties have not been adequately investigated.

THE USPTO'S RESPONSE TO NANOTECHNOLOGY

Ensuring that patents are properly granted pursuant to the Patent Act requires, in part, looking at patents that have been granted in the past and at technology and literature in the field. Yet in the field of nanotechnology, it may be difficult to find prior technology and literature. If the invention contains the same claims as another invention that was patented or described in a printed publication more than one-year prior to the U.S. filing date of the patent, the examiner should deny the patent.[49] But, as there is no single, universally accepted definition of nanotechnology, encompassing either the field or its products, materials, and applications, examiners may be unable to perform a proper search.[50] The lack of a uniform nomenclature, as well as the patent applicant's prerogative to act as his or her own lexographer and define terms as he or she chooses makes searches to determine

[47]501(k) Summary for Westaim Technologies, Inc.'s Acticoat™ Silver Coated Dressing, K955453, May 31, 1996.

[48]35 U.S.C. § 102 (2000 and Supp. 2003); 35 U.S.C.A. § 103 (2001 and West Supp. 2006).

[49]35 U.S.C. § 102(b) (2000 and Supp. 2003) ("A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States . . . "). Note that the patent or publication can come from any country.

[50]Some states, for example, provide funding or other incentives for nanotechnology research and development which incorporate a requirement that the nanoscale research involve structures with novel properties; others do not. Compare the definition Arkansas employs ("the materials and systems whose structures and components exhibit novel and significantly improved physical, chemical, and biological properties, phenomena, and processes due to their nanoscale size," ARK. CODE ANN. § 15-4-2103(5) (West 2006), with Michigan, which defines nanotechnology as "materials, devices, or systems at the atomic, molecular, or macromolecular level, with a scale measured in nanometers," MICH. COMP. LAWS § 206.30 (West 2006).

whether the invention has already been invented, or whether it was obvious in light of prior inventions, more difficult and could create or exacerbate future patent disputes.[51]

Additionally, although nano is currently a popular marketing term,[52] its widespread use does not help to define a technology that already covers a wide array of scientific and engineering disciplines. However, it does provide an incentive for patent applicants to use the prefix "nano." More than 1200 American nanotechnology startups are basing their existence solely on the promise of nanotechnology.[53] Claiming they have nanopatent portfolios would make them seem more attractive to potential investors or licencees. However, some of the technologies described as nanotechnologies may, in fact, be similar to inventions that were previously patented in the field of molecular biology. A search of the prior nanotechnology patents would not reveal this prior art and could lead to patents being improperly granted.

The rush to patent nanotechnologies or even technologies that label themselves in some way as nano raise issues for the USPTO that have important implications for future research, development, and innovation. With nanotechnology's substantial funding and hypothesized potential, the USPTO has already seen an influx in nanotechnology patents.[15] However, as discussed, because of the lack of standardization in the use of terminology, the number of patents issued covering inventions in the field of nanotechnology is difficult to estimate. The USPTO's response to nanotechnology has only begun to be quantified.

The USPTO examines patent applications within technology centers, which are comprised of examiners responsible for related technologies and disclosures. It organizes patent applications by describing them with a class number that identifies similar prior art. This system is designed to facilitate searches for related technologies and disclosures.

In 2004, the USPTO created a class (Class 977) in which nanotechnology related prior art should be catalogued. After a subsequent amendment, the class, which is used to index the technology and not used to assign patents to examiners for review, now encompasses a collection of prior disclosures and technologies related to "nanostructures." The USPTO defines a nanostructure as "an atomic, molecular, or macromolecular structure that: (a) has at least one physical dimension of approximately 1–100 nm; and (b) possesses a special property, provides a special function, or produces a special effect that is uniquely attributable to the structure's

[51]For a survey of past studies that have attempted to quantify the number of nanopatents that have been issued, see Chapter 15.

[52]Products capitalizing on the "nano" craze include the Apple "iPod nano," the Whisper Light Nano-Ionic Conditioning Hair Dryer by BioIonic iDry, the Samsung Silver Nano Health System washing machine, and the GM Hummer H3, popularly referred to as the "Nano Hummer."

[53]R. Bailey, "The Smaller the Better: The Limitless Promise of Nanotechnology—and the Growing Peril of a Moratorium," Reasonline, (December 2003). Available at http://reason.com/0312/fe.rb.the.html. (Last visited October 8, 2006.) Currently, more than 200 consumer products in the United States utilize nanotechnology. Project on Emerging Nanotechnologies, "A Nanotechnology Consumer Products Inventory." Available at http://www.nanotechproject.org/index.php?id=44 (last visited October 8, 2006).

nanoscale physical size."[54] The USPTO has reviewed previously issued patents to determine retroactively which should be classified under 977. However, the 977 classification has many exceptions. For example, enzyme and protein complexes are generally excluded from 977. Similarly, viruses utilized for viral functions are categorized in separate classes, rather than 977. But, a virus utilized to form a nanostructure is included in 977 classifications.[54]

To determine how the USPTO is using this class, we analyzed all patents issued between January 1976 and July 1, 2006, that contain "quantum dot" or its synonym "nanocrystal" in their title.[55] "Quantum dot" refers to semiconducting crystals created on the nanoscale.[56] It might seem that disclosures and technologies related to quantum dots would be catalogued in Class 977. But of the 280 patents found by our search, the USPTO placed only 48 patents examined in the study (17.1%) into Class 977. This may indicate that not all patents claiming nanotechnology are being put into a class that will be useful for future searches, or it may indicate that the numerous exceptions may keep patents claiming nanotechnology out of Class 977. This makes it possible that patents that do not meet the statutory requirements, or that are overlapping with already issued patents, will be granted.

In addition to overlapping patents, there is evidence that overly broad nanotechnology patents have been issued.[57] This may be problematic later when the patent holders step in to assert broad rights. Patent holders sometimes allow researchers and institutions to use a patented technology in research without alleging infringement. This allows the patent holder to create a demand for its technology with the potential of benefiting later. Once a commercial application is derived, patent holders will typically assert patent rights to the subsequent researcher's invention based on their previous patent.[58]

Returning to carbon nanotube technology, Japan's NEC Corporation declares it holds patents on the basic building blocks of nanotube technology, and within the last several years began asserting that any company wishing to work with that material must obtain licenses from it.[58] One of the patents NEC holds is U.S. Pat. No. 5,457,343.[59] The first claim is:

> A carbon tubule of a nanometer size in diameter which comprises: a plurality of tubular monoatomic graphite sheets coaxially arranged; and a foreign material enclosed in a center hollow space which is defined by an internal surface of the most inner tubular monoatomic graphite sheet, said foreign material being a metal selected from the group consisting of lead, tin, copper, indium, mercury, and alkali metals.[59]

[54]Class 977 Definition. Available at http://www.uspto.gov/go/classification/uspc977/defs977.htm. The class functions as a cross-reference collection of art and is not a primary classification.

[55]The search was conducted on the USPTO's online issued patents database. Available at http://patft.uspto.gov/netahtml/PTO/search-adv.htm using the search terms: *ttl/(nanocrystal$ or nano-crystal$ or "nano crystal$") or ttl/(quantumdot$ or quantum-dot$ or "quantum dot$")*. The first patent to meet these criteria was issued in 1990.

[56]P. Weiss, "Quantum-Dot Leap: Tapping Tiny Crystals' Inexplicable Light-Harvesting Talent," 169 Science News 344 (June 3, 2006).

[57]A. Regalado, "Nanotechnology Patents Surge as Companies Vie to Stake Claim," Wall Street Journal, June 18, 2004, at A1; Susan J. Ainsworth, "Nanotech IP: As Nanometer-Scale Materials Start Making Money, Intellectual Property Issues are Heating Up," 82 Chemical and Engineering News 17–22 (April 12, 2004).

[58]S. J. Ainsworth, "Nanotech IP: As Nanometer-Scale Materials Start Making Money, Intellectual Property Issues are Heating Up," 82 Chemical and Engineering News 17–22 (April 12, 2004).

[59]Carbon Nanotubule Enclosing a Foreign Material, U.S. Patent No. 5,457,343 (filed December 21, 1993).

NEC, therefore, claims patent rights to concentric tubes of single layers of carbon atoms with a metal filling. This claim appears to be overbroad. It could be read to include any multiwalled carbon nanotube with any quantity of a listed material in it. A researcher filling a nanotube with certain metals to experiment with their conducting capabilities would infringe the patent. The patenting of so basic a building block for nanotechnology could run counter to the creation of incentives for innovation, the very foundation of patent law.

When NEC began enforcing its carbon nanotube patents,[60] several companies, such as Houston-based Carbon Nanotechnologies, Inc. (CNI), decided to pay NEC's royalty request rather than pursue costly litigation even though CNI believes that NEC's patents are most likely invalid.[61] In 2006, nanotube manufacturer SouthWest NanoTechnologies licensed NEC patents to facilitate production and distribution of the tubes.[62] As more nanotechnology-based products are brought to market, litigation of patents thought to be overbroad will be inevitable as companies like NEC enforce patents that many believe to be invalid.

Practical Review Issues Faced by the USPTO

In addition to the legal issues raised by nanotechnologies, there are practical review issues faced by the patent office. Some of the issues facing the USPTO are analogous to those it encounters when inventors seek patent protection for any dramatically new technology. The USPTO reports being underfunded and understaffed, and generally underequipped to deal with the number of patent applications filed annually.[63] Other issues the USPTO faces, however, are unique because of the extraordinary characteristics of nanotechnology.

Nanotechnology crosses several scientific fields and the potential benefits of nanoscale research "reach into electronics, biotechnology, medicine, transportation, agriculture, environment, national security, and other fields."[64] It is likely nanopatents will cross several areas, but the USPTO is not organized for analyzing

[60]S. J. Ainsworth, "Nanotech IP: As Nanometer-Scale Materials Start Making Money, Intellectual Property Issues are Heating Up," 82 Chemical and Engineering News, 17–22 (April 12, 2004).

[61]S. J. Ainsworth, "Nanotech IP: As Nanometer-Scale Materials Start Making Money, Intellectual Property Issues are Heating Up," 82 Chemical and Engineering News, 17–22 (April 12, 2004). (As quoted from Bob Gower, president and chief executive officer of CNI: "We have acted as if some claims are valid because we don't want to fight about it. One could argue that single-wall nanotubes were discovered much earlier than NEC claims, but that really isn't the issue we think is important at this stage.")

[62]S. Shankland, "Nanotube Manufacturer Licenses NEC Patents," CNET News.com (August 3, 2006). Available at http://news.com.com/2061-11204_3-6101848.html (last visited October 8, 2006).

[63]V. Koppikar et al., "Current Trends in Nanotech Patents: A View From Inside the Patent Office," 1 Nanotechnology Law & Business 24, 24 (2004).

[64]U.S. Department of Energy, "Nanoscale Science, Engineering, and Technology in the Department of Energy," at 4. Available at http://www.sc.doe.gov/bes/brochures/files/NSRC_brochure.pdf (last visited October 8, 2006).

multidisciplinary patents. Instead it is divided into eight specific technology centers: biotechnology and organic chemistry; chemical and materials engineering; computer architecture, software and information security; communications; semiconductors, electrical and optical systems and components; designs; transportation, construction, electronic commerce, agriculture, national security, and license and review; and mechanical engineering, manufacturing, and products. When an inventor submits a patent application, the USPTO routes it to the technology center with expertise in the particular discipline covered by the patent application for examination. Each technology center is responsible for reviewing patent applications that fall within its particular area of expertise. However, nanotechnology has the possibility of falling within several areas simultaneously, and the USPTO does not have a technology center devoted to nanotechnology.

Nanotechnology inventions create problems for the USPTO during the examination process because true nanotechnology inventions possess unique properties that require a different type of expertise (e.g., knowledge of quantum physics) than that typically found in many USPTO technology centers.[65] Examiners may not be gaining sufficient expertise in dealing with nanopatents.

To analyze the way in which nanopatents are assigned, we analyzed all the patents issued between January 1976 and July 1, 2006, that contain "quantum dot" or its synonym "nanocrystal" in their title.[66] Quantum dots have wide-ranging applications in highly diverse fields, such as healthcare and medical procedures, cosmetics, environmental remediation, and national security.[67] The survey revealed: 45.4% were assigned to the chemical and materials engineering technology center (center number 1700); 41.4% were assigned to the semiconductor, electrical and optical systems technology center (center number 2800); and the remainder were scattered among biotechnology and organic chemistry, transportation, and mechanical engineering.[68] The spread of patent reviews across centers may not facilitate the necessary build up of expertise.

In addition, examiners do not seem to be developing specialties in nanotechnology. These 280 patents we identified that dealt with "quantum dots" or "nanocrystals" were examined by 147 different USPTO examiners. Sixty-six percent of these examiners examined only one quantum dot patent. Almost 80% of the examiners examined only one or two quantum dot patents. Only 8.2% of these examiners looked at five or more quantum dot patents. This data is consistent with the

[65]See, e.g., T. K. Tullis, Comment, "Application of the Government License Defense to Federally Funded Nanotechnology Research: The Case for a Limited Patent Compulsory Licensing Regime," 53 UCLA Law Review 279, 291–293 (2005).

[66]The search was conducted on the USPTO's online issued patents database. Available at http://patft.uspto.gov/netahtml/PTO/search-adv.htm using the search terms: *ttl/(nanocrystal$ or nano-crystal$ or "nano crystal$") or ttl/(quantumdot$ or quantum-dot$ or "quantum dot$")*. The first patent to meet these criteria was issued in 1990.

[67]Lux Research Inc., "Statement of Findings: The Nanotech IP Landscape," (2005). Available at http://www.foley.com/files/tbl_s31Publications/FileUpload137/2655/SOF_NTS-R-05-002.pdf (last visited October 8, 2006).

[68]In a very small percentage of patents, it was not possible to discern to which technology center the nanopatent application had been assigned.

concern that nanotechnology patents are too broadly distributed across the patent office, possibly to examiners lacking expertise in the field.[69]

If examiners are inexperienced within a specific technology, or never see more than a few nanopatents, it might be expected that patents that are overbroad and overlapping will be granted. Our initial results returned overlapping patents. For example, patent numbers 6,444,143[70] and 7,060,252[71] both claim quantum dots 1.2–15 nm, that are water soluble (or do not require insolubility), that are coated by an organic outer layer, and that emit light or fluorescence. These two patents appear to claim the same or a very similar technology. They were examined by different examiners. Overlapping patents create conflicting intellectual property rights, inhibit research, and could result in costly litigation.

Patent Infringement and the Strict Liability Standard

As a new technology, nanotechnology raises issues similar to those of other new technologies with respect to the need for trained examiners and the proper application of legal standards. But the intellectual property issues go far beyond either. Some of the unique properties of nanoproducts that make them so exciting to use also create problems in enforcement.

On the one hand, the small size of nanotechnologies may make infringing uses difficult to discover and lead to less protection of patent holders than may be optimal. On the other hand, the potential for nanoproducts to spread in unintended ways could lead to an even more problematic scenario where people unwittingly infringe and are inappropriately found to owe royalties.

The patent holder can demand royalties from anyone who "uses" the invention. While usually it is fairly easy for an individual to avoid infringing on a patent, the unique characteristics of nanotechnology make it possible that an individual could "use" a nanotechnology without meaning to do so. Researchers are currently working on nanosized machines that will be inserted into the blood stream to clear cholesterol from clogged arteries.[72,73] Nanotechnology eventually may be used to help fight a person's cold or flu by the insertion of nanosized machines or particles into a person's blood stream or airway that could hunt and destroy viruses.[73] Depending on the nature of these devices, a person may only need to share fluids, mix blood, or sneeze to pass on his or her nanotechnology device to another.

[69]See also B. N. Sampat, "Examining Patent Examination: an Analysis of Examiner and Applicant Generated Prior Art," NBER Summer Institute, Working Paper, 1–62, 25 (2004). Available at http://faculty.haas.berkeley.edu/wakeman/ba297tspring05/Sampat.pdf (finding similar results with respect to patent examiners).

[70]Water-soluble Fluorescent Nanocrystals, U.S. Patent No. 6,444,143 (filed May 29, 2001).

[71]Functionalized Encapsulated Fluorescent Nanocrystals, U.S. Patent No. 7,060,252 (filed June 1, 2004).

[72]B. Behkam and M. Sitti, "Design Methodology for Biomimetic Propulsion of Miniature Swimming Robots," 128 Journal of Dynamic Systems, Measurement, and Control 36–43 (March 2006).

[73]L. Rubinstein, "A Practicle NanoRobot for Treatment of Various Medical Problems," The Foresight Nanotech Institute, Eighth Foresight Conference on Molecular Nanotechnology, Nov. 3–5, 2000. Available at http://www.foresight.org/conference/MNT8/Papers/Rubinstein/index.html (last visited October 8, 2006).

Imagine a person going to visit her brother who is a recent recipient of an injection of artery cleaning nanobots. While talking, the brother sneezes, exhaling some nanobots that are immediately and unwittingly inhaled by the sister. Now the nanobots begin coursing through the sister's arteries, clearing them of plaque. For purposes of the Patent Act, the sister is "using" the nanobots, even though she did not intend to use them and did not take any action to start using the technology, apart from breathing. Under the patent statute, the sister is liable for infringement of the patent.

This scenario is possible because patent infringement is judged by a strict liability standard.[74] Under strict liability, one will be held liable for infringement even if the infringing activity was unintentional, inadvertent, or unknowingly committed.[75] Intent is irrelevant to infringement,[76] and damages can be awarded regardless of the infringer's state of mind.[77]

The purpose behind the strict liability standard is to enhance social welfare by minimizing the social costs of wrongdoing through encouraging careful conduct and deterring wrongdoing.[78,79] It provides an incentive for companies and individuals to take preventative measures to avoid liability.[79] In patent law, this harsh standard strongly encourages potential infringers to take all safeguards possible against infringement. It is designed to prevent companies and inventors from avoiding liability by claiming they were unaware of another inventor's patent. Because their awareness is irrelevant, they will be held accountable for infringement whether or not they had knowledge of a patent. Therefore, prudent companies and inventors will take precautions to determine if they risk infringing another inventor's patent prior to creating an invention. The precautions should include making certain no one else has any rights in the invention. Companies and inventors that do not perform this search may face costly patent infringement litigation, damages for infringing on the patent, an order enjoining it from the

[74]35 U.S.C.A. § 271 (2001 and West Supp. 2006); R. D. Blair and T. F. Cotter, "Strict Liability and its Alternatives in Patent Law," 17 Berkeley Technology Law Journal 799, 821 (2002).

[75]R. D. Blair and T. F. Cotter, "Strict Liability and its Alternatives in Patent Law," 17 Berkeley Technology Law Journal 799, 821 (2002).

[76]35 U.S.C.A. § 271(a) (2001 and West Supp. 2006). In *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*, the Federal Circuit reiterated, "intent is not an element of direct infringement, whether literal or by equivalents. Neither Graver Tank nor any other authority supports the proposition that preventing 'fraud on a patent'... turns on the subjective awareness or intent of the accused infringer .... Infringement is, and should remain, a strict liability offense." 62 F.3d 1512, 1527 (Fed. Cir. 1995) (citing *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 609, 610 (1950)), *overruled on other grounds*. See also *Eye-Ticket Corp. v. Unisys Corp.*, 155 F. Supp. 2d 527, 544 (E.D. Va. 2001).

[77]35 U.S.C. § 284 (2000). *Jurgens v. CBK, Ltd., Inc.*, 80 F.3d 1566, 1570 n.2 (Fed. Cir. 1996) (stating that infringement is a strict liability offense and damages must be awarded regardless of "the intent, culpability or motivation of the infringer").

[78]A. Hamdani and A. Klement, "The Class Defense," 93 California Law Review 685, 708 (May 2005).

[79]J. Arlen and R. Kraakman, "Controlling Corporate Misconduct: An Analysis of Corporate Liability Regimes," 72 New York University Law Review 687, 692 (October 1997).

infringing activity, and, if found liable of willful infringement, risks treble damages and attorney's fees.[80]

Moreover, the harshness behind the strict liability standard also encourages individuals and companies to obtain patents. They are willing to fulfill their statutory obligation to disclose their inventions to the public because the intellectual property rights conferred upon them are strictly enforced.

To infringe a patent, a person or company has to make, use, sell, or import the invention. In most other areas that means individuals or companies would have to take some sort of action. Before taking the action, they could attempt to ascertain whether the action would cause them to infringe on a patent, rendering them liable. With nanotechnology, however, people engaging in no action or choice could be held liable for infringement. The sister who inhaled the nanobots did not take any action beyond breathing, which is required for her survival and that probably could not be reasonably anticipated to result in an infringing activity. The actions that would allow her to avoid infringement (namely, not breathing or not visiting her brother) are not reasonable precautions.

The result of applying the strict liability standard to nanotechnology is that rather than being able to avoid liability by taking reasonable precautions, the individual might have to take some sort of affirmative action to avoid liability for infringement. In a Canadian genetically modified (GM) crop patent case in which a farmer was found liable for infringement where he had saved seed from patented GM plants, which blew on to his land, the court suggested that a truly innocent bystander who did not intend to use patented GM seed might be able to avoid liability by acting to arrange for the seed's removal.[81] The court, therefore, left open the possibility that a farmer had at least a minimal affirmative duty to ensure that if the patent holder's property (its patented GM seed) enters his land and contaminates his crops, he must take some action to remove the patented material. This could also leave open the possibility that the farmer has some affirmative duty to determine whether his crops have been contaminated with GM pollen, and if so, act accordingly.

Applying this reasoning to the sister who inhaled the nanobots, to avoid infringement she might need to determine whether she had inhaled nanobots and then take affirmative steps to have them removed. Even if she could make the company pay for the removal of the nanobots, she would still have to undergo a medical procedure to have them removed. Now, her bodily integrity has been violated twice, first by the nanobots entering her body without her consent, and next, by being required to

[80]The American Intellectual Property Law Association reported in 1997 a median cost of $2,510,000 per party for a patent infringement suit totaling over $5 million for the entire lawsuit. M. A. Lemley, "Rational Ignorance at the Patent Office," 95 Northwestern University Law Review 1495, 1502 (Summer 2001) *citing* AIPLA Report of Economic Survey (of U.S. IP Practitioners) (1997). By 2005, the reported cost for litigation (depending on at what stage of the litigation the case was resolved) ranged from $650,000 and $4.5 million. American Intellectual Property Law Association, Report of the Economic Survey 102 (2005).

[81]*Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, ¶ 86 (Can.).

undergo a medical procedure to avoid liability for patent infringement. Clearly, this is not a viable alternative.

The integration of these nanobots into innocent bystanders could also have damaging effects far beyond infringement liability. The particles and machines could affect the bystanders' health. For example, the sister might not need any cholesterol removed, so this function could negatively affect her health. A person whose health is damaged might still be liable for infringement and damages. In addition, a patent holder could intentionally or negligently infect bystanders with his or her invention. Although the patent holder is the cause of the infringement and might be held liable for battery, the bystander is enmeshed in litigation, and still liable for infringement, rewarding the patent holder for his or her improper conduct.

The purpose of the strict liability standard is to promote diligence and encourage precautions, and more specifically, in patent law, to encourage research into the patent rights of others before action. But, as the previous scenario illustrates, these infringers engaged in no action. If the infringer did not choose to use or make anything, he or she cannot take the precautions the patent system is designed to promote. Nanotechnology patent holders can also abuse their patent rights by using the unique properties of nanotechnology to intentionally cause another to infringe. Therefore, regardless of research and even sometimes regardless of choice, the bystander will be an infringer. Nanotechnology extends patent rights and the strict liability standard beyond their intended scopes. These problems could be exacerbated if patents are granted on discoveries and inventions that do not meet the statutory requirements.

The strict liability standard creates even more mischief when viewed in the context of reproduction. Nanotechnology may be used someday to modify a person's DNA to cure a genetic or another type of disease. Children receive one-half of their DNA from each of their parents. Therefore, a mother who has purchased a nanotechnology that modifies her DNA to cure a disease could pass on her altered DNA to her child. But just because a patented technology can replicate itself, it does not necessarily mean the purchaser of a patent has the right to use replicated copies of the technology.[82] If companies allow people to pass on genetic cures through reproduction, they will not have a future market for their products. A company might attempt to hold a parent liable for inducement and/or contributory infringement for the child's inheritance of the modified genes because the parent would be inducing the child to infringe the patent.[83] Consequently, a child who inherits the replicated DNA might be subject to a claim for infringement, and liable for damages or an injunction.[82] A company might attempt to require

[82]*Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336 (Fed. Cir. 2006).

[83]"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C.A. § 271(b) (2001 and West Supp. 2006); "Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C.A. § 271(c) (2001 and West Supp. 2006).

parents to pay additional fees if they intended to have children, but this scheme would infringe on the parents' freedom to make reproductive decisions.

The application of intellectual property law and policies to nanotechnology can also inhibit people's right to travel. For example, if an overly broad patent has been granted on a building block of nanotechnology, it may increase research and development costs, and eventually will increase consumer costs. An end product, such as nanobots, may cost more in the United States than in countries that have not been granting overbroad patents. A person may thus seek to have a nanomedical device implanted in another country, where costs are lower. When that person returns to the United States, he or she could be sued by the patent holder for infringing on the patent by using and importing it. When a technology is inside a person, however, issues of bodily integrity conflict with corporate interests in the enforcement of nanotechnology patents.

CONCLUSIONS

Appropriate legal regulation will be critical to the development of nanotechnology. As indicated by M. C. Roco, "Nanotechnology success is determined by an architecture of factors such as creativity of individual researchers, training of students in nanoscale science and engineering, connections between organizations, patent regulations, physical infrastructure, legal aspects, state and federal policies, and the international context."[84]

An analysis of the current intellectual property landscape and comparisons with other technologies suggests that we can expect some contentious debates and court cases arising from the development, patenting, and commercialization of nanotechnologies, added to, in the near future, by the unfamiliarity of the USPTO and the courts with this new science. These debates and cases have the potential to impede research and stifle innovation. The patent system's role of encouraging innovation must apply to nanotechnology.

Patents that are overly broad and overlapping may inhibit research, prevent new inventions, and waste judicial resources through patent disputes. The USPTO should not be granting, and courts should not be upholding, patents on laws and products of nature. Eligible subject matter for patents must be more than a discovery of a basic scientific fact even if it has a useful or tangible result—there must be human invention that produces a result beyond what the law or product of nature produces itself. Patents should add to the public store of knowledge, not remove knowledge from public domain. Patents should also be invalidated if it is shown that they impede people's rights, including freedom of speech, of reproduction, to travel, and to research.

[84]M.C. Roco, "Broader Societal Issues of Nanotechnology," 5 Journal of Nanoparticle Research 181–189, 181 (2003).