APPLICATION OF THE GOVERNMENT LICENSE DEFENSE TO FEDERALLY FUNDED NANOTECHNOLOGY RESEARCH: THE CASE FOR A LIMITED PATENT COMPULSORY LICENSING REGIME

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Nanotechnology's potential impact on worldwide industries has nations around the world investing billions of dollars for research in order to capture a part of the projected trillion dollar market for nanotechnology products in 2010. The current rush to patent nanotechnologies may lead to an overcrowded nanotechnology patent thicket that could deter critical innovation and continued product development in the United States. At this early stage of nanotechnology's life cycle, increasing numbers of broad and potentially overlapping patents are being issued—while few nonexclusive licenses are being offered. Furthermore, the lack of significant case law provides little guidance on proper nanotechnology patent scope and validity, while the decline of legal defenses such as experimental use leaves innovators exposed to potential infringement liability for even the most fundamental of scientific research studies. In this Comment, the author proposes that the U.S. government exercises the full extent of its rights under the twenty-five year old Bayh-Dole Act and develop the government license defense to create a limited patent compulsory licensing regime for the fruits of federally funded research. The author argues that recipients of the billions of dollars in federal nanotechnology research funds should provide broad, nonexclusive licenses to the privatized patent rights they obtain as a result of public funding. Ultimately, a well-formulated government license defense, which assesses the extent to which an "infringing" act against a federally funded patent falls along a spectrum of fair use, would provide a means for overcoming the innovation-impeding effects of absolute exclusion rights.

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INTRODUCTION: THE EMERGING NANOTECHNOLOGY PATENT THICKET

Recognizing that nanotechnology is likely to be the next great technological frontier,[1] United States government officials have cited the potential of nanotechnology to transform society and the economy on a scale comparable to the effects of the Industrial Revolution.[2] In order to promote nanotechnology research and development, on December 3, 2003, President Bush signed the 21st Century Nanotechnology Research and Development Act (the Nanotechnology Act), which authorizes $3.7 billion in funding for federal nanotechnology research and development commencing in 2005 and continuing through 2008.[3] This newly enacted

1. *See* SUBCOMM. ON NANOSCALE SCI., ENG'G, & TECH., NAT'L SCI. & TECH. COUNCIL, *National Nanotechnology Initiative: The Initiative and Its Implementation Plan* 13 (July 2000), http://www.nano.gov/html/res/nni2.pdf (making the observation that "[t]he effect of nanotechnology on the health, wealth, and lives of people could be at least as significant as the combined influences of microelectronics, medical imaging, computer-aided engineering, and man-made polymers" developed in the last century).

2. Christine Hines, *Nanotech: Firms Hope for Small Miracle*, LEGAL TIMES, Nov. 11, 2003 (citing statement by Benjamin Wu, Deputy Undersecretary for Technology at the Commerce Department), *available at* http://www.law.com/jsp/newswire_article.jsp?id=1067351019290.

3. The Nanotechnology Act is codified at 15 U.S.C.S. §§ 7501–7509 (2005). The Nanotechnology Act passed the House (H.R. 766) with support from House Science Committee

legislation makes nanotechnology the highest priority technological effort in the United States since the 1960s space race.[4]

In 2003, drafters of the Nanotechnology Act expected the worldwide market for nanotechnology products and services to reach $1 trillion by 2015;[5] by late 2004, nanotechnology forecasts escalated to as much as $1 trillion by 2010 and over $2 trillion by 2015.[6] Nor is the U.S. government alone in recognizing the potential of nanotechnology: The governments of Europe, Japan, China, Canada, and Singapore already have invested billions of dollars in advancing their own nanotechnology programs.[7] Worldwide investments are paying off—nanotechnology products already are in development and estimates in 2004 of nanotechnology's overall financial impact ranged from about $20 billion to $50 billion in revenues.[8] The nanotechnology race is well underway.

The first step in securing the commercial potential of nanotechnology is establishing intellectual property rights to protect innovation. Patents, which essentially provide inventors with a limited monopoly to practice, license, and transfer exclusive rights in technology in exchange for disclosure

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Chairman Sherwood Boehlert (R-NY) and Representative Mike Honda (D-CA), who cosponsored the House legislation. Senators Ron Wyden (D-OR) and George Allen (R-VA) were cosponsors of the Senate bill (S. 189). Cate Alexander, President Bush Signs Bill Authorizing U.S. Nanotechnology Program, (Dec. 3, 2003), *at* http://www.nano.gov/html/news/PresSignsNanoBill.htm (last visited June 1, 2005).

4. Charles Choi, *Analysis: Nano bill promises real results*, UNITED PRESS INT'L, Dec. 3, 2003, ¶ 3, *at* http://www.upi.com/view.cfm?storyId=20031203-122327-6052 (last visited June 1, 2005) (citing statement by F. Mark Modzelewski, Executive Director of the NanoBusiness Alliance in New York: "It makes nanotechnology the highest priority funded science and technology effort since the space race").

5. R. Colin Johnson, *Nanotech R&D Act Becomes Law*, EE TIMES, Dec. 3, 2003, ¶ 3, *at* http://www.eetimes.com/story/OEG20031203S0025 (last visited June 1, 2005) (citing estimates from the National Science Foundation and quoting statements by California House Representative Mike Honda, who co-drafted the Nanotechnology Act).

6. Associated Press, *Nanotechnology-Based Products Such As Self-Cleaning Windows Starting to Have Big Consumer Impact* ¶ 9 (Nov. 8, 2004), *at* http://abcnews.go.com/Business/wireStory?id=235614&CMP=OTC-RSSFeeds0312 (last visited June 1, 2005). In this article, Lux Research, a New York consulting company focused on nanotechnology, forecasts that by 2014 products incorporating nanotechnology will account for $2.6 trillion of all products and 15 percent of global manufacturing output. *Id.* ¶ 10.

7. According to a study by Toronto's Joint Centre for Bioethics, combined spending on nanotechnology by Western Europe, Japan, and the United States increased from $678 million in 1997 to more than $2 billion in 2002, and increased spending projections indicate that this trend will continue. *See* Vicki Norton, *What Nanotechnology Means for IP*, MANAGING INTELL. PROP., June 1, 2003, at 38. In late 2002, the European Commission announced plans to invest another €1.3 billion ($1.5 billion) in nanotechnology in its next research program. *Id.* In 2003, Korea announced its plans to invest $2 billion in nanotechnology, while Japan's estimated investment in 2003 exceeded $1 billion. *Id.*

8. Associated Press, *supra* note 6, ¶ 9.

of novel, useful, and nonobvious innovations, may be the strongest form of available intellectual property protection.[9] In September 2005, the number of issued U.S. patents incorporating the term "nano"[10] in their titles reached 2042, while the term appeared in 96,312 patent descriptions.[11] Also as of September 2005, the term "nano" had been incorporated into an additional 1235 published patent application titles and 42,293 published patent application descriptions.[12] In 2002 alone, there were 526 nanotechnology patents issued by the United States Patent and Trademark Office (USPTO).[13] Given that the USPTO receives roughly 300,000 patent applications a year, nanotechnology could account for as much as 10 percent of all U.S. patent applications currently under consideration.[14]

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9. In order to secure a patent, the invention must be "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . ." 35 U.S.C. § 101 (2000).

10. One might take the position that the use of the term "nano" to identify nanotechnology-specific patents is not ideal because the term shows up in measurements in other fields, such as nanometers and nanomoles in materials science and chemistry. However, these patents are still indicative of the growing presence and importance of nanotechnology because they deal with methods or structures at the nanoscale. The use of this proxy, while unfortunate, is still necessary due to the lack of a publicly available nanotechnology classification system in the U.S. Patent and Trademark Office (USPTO). *See infra* Part III.A. Notably, use of the term "nano" has shown geometric growth in recent years, much like other terms used as proxies to track nanotechnology-related patents, such as "dendrimer," "AFM," "atomic force microscope," and "quantum dot." *See* Vivek Koppikar et al., *Current Trends in Nanotech Patents: A View From Inside the Patent Office*, 1 NANOTECHNOLOGY L. & BUS. J., Jan. 2004, at 2–3.

11. Between February 17, 2004 and September 2, 2005, the number of issued U.S. patents incorporating the term "nano" in patent titles grew 51 percent (from 1348 to 2042) while the term's usage in patent descriptions grew 16 percent (from 82,740 to 96,312). In the same time period, the growth of the use of the term "nano" in newly published patent application titles increased 36 percent (from 911 to 1235) while its use in published patent application descriptions increased 47 percent (from 28,779 to 42,293). *See* U.S. Patent & Trademark Office, Patent Databases, *at* http://www.uspto.gov/patft/index.html (last visited Sept. 2, 2005) (comparisons to listings from Feb. 17, 2004).

12. *Id.*

13. *See* R. Douglas Moffat & Ruben Serrato, *Emerging Nanotechnology Firms and Access to Capital Markets*, 1 NANOTECHNOLOGY L. & BUS. J., Sept. 2004, at 4 (citing JOHN C. MILLER ET AL., THE HANDBOOK OF NANOTECHNOLOGY: BUSINESS, POLICY, AND INTELLECTUAL PROPERTY LAW (2004)).

14. "In [fiscal year] 2003, the [USPTO] received 333,452 Utility, Plant, and Reissue patent applications. Additionally, preliminary data indicates that 243,007 pending applications were published within eighteen months after filing and [that] 173,072 patents were granted." U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2003, http://www.uspto.gov/web/offices/com/annual/2003/2003annualreport.pdf [hereinafter FISCAL YEAR 2003]. "[I]n fiscal year 2004, the Patent organization received 353,342 Utility, Plant, and Reissue (UPR) patent applications." *See* U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2004, http://www.uspto.gov/web/offices/com/annual/2004/040201_patentperform.html (last visited Sept. 2, 2005).

Unfortunately, the rush to secure worldwide intellectual property rights in nanotechnology could lead to the development of a "patent thicket." This term, coined by intellectual property scholars, refers to an overlapping set of patent rights that requires researchers, inventors, and entrepreneurs seeking to commercialize new technologies to obtain licenses from multiple patentees.[15] The development of such a patent thicket could deter further innovation,[16] and the active enforcement by nanotechnology patent holders of their exclusivity rights ultimately could result in the creation of a nanotechnology anticommons—a situation in which a scarce resource becomes prone to underuse because there are too many owners holding the right to exclude others from that resource, and no one has an effective privilege of use.[17] For the purposes of this Comment, the terms "patent thicket" and "anticommons" are used interchangeably to describe the troubling phenomenon that takes place when inventors are unable to compete and innovate effectively due to: the abundance of potentially overbroad and overlapping patents issued by the USPTO; the resistance to broad voluntary licensing of those patents by parties involved in research and development; and the failure of patent scope-limiting doctrines to provide sufficient freedom of operation for innovators.

If the aim of the Nanotechnology Act is to produce nanotechnology innovation that encourages rapid economic growth, a reassessment of the level of available patent protection for nanotechnology is appropriate, especially in the area of patent infringement defenses for researchers. Part I of this Comment thus provides an overview of the technical aspects behind nanotechnology. Part II examines the similarities between nanotechnology

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15. *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POL'Y & THE ECON. 119, 121 (Adam Jaffe et al. eds., 2001), *available at* http://faculty.haas.berkeley.edu/shapiro/thicket.pdf (stating that patent thickets impose "an unnecessary drag on innovation by enabling multiple-rights owners to 'tax' new products, processes, and business methods," and asserting that a "vast number of patents . . . being issued in a particular field creates a very real danger that a single product or service will infringe on many patents," resulting in a holdup of innovation through royalties and injunctions against new products).

16. *See* FED. TRADE COMM'N, COMPETITION POLICY IN THE NEW HIGH-TECH GLOBAL MARKETPLACE, STAFF REP. NO. 6 (1996), *cited in* Ted Sabety, *Nanotechnology Innovation and the Patent Thicket: Which IP Policies Promote Growth?*, 1 NANOTECHNOLOGY L. & BUS. J., Sept. 2004, at 2 (stating that "[i]f you get monopoly rights down at the bottom, you may stifle competition that uses those patents later on and so . . . the breadth and utilization of patent rights can be used not only to stifle competition, but also have adverse effects in the long run on innovation").

17. *See* Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition From Marx to Markets*, 111 HARV. L. REV. 622, 624 (1998) ("In an anticommons . . . multiple owners are each endowed with the right to exclude others from a scarce resource, and no one has an effective privilege of use. When there are too many owners holding rights of exclusion, the resource is prone to underuse—*a tragedy of the anticommons*.") (citations omitted).

and biotechnology in their respective intellectual property regimes. Part III reviews the problems with the current state of nanotechnology patents. Finally, Part IV describes a potential solution for promoting increased innovation in nanotechnology through the application of the government license defense in nanotechnology research.

I. OVERVIEW OF THE TECHNICAL ASPECTS OF NANOTECHNOLOGY

Nanotechnology is not confined to a single industry. Rather, it crosses several boundaries of technology including engineering, chemistry, physics, biological sciences, medicine, and optics. Nanotechnology involves the visualization, manipulation, design, and manufacturing of products at the nanometer level. A nanometer is one billionth of a meter, and the nanoscale generally refers to measurements between one and a hundred nanometers.[18] But nanotechnology is more than the study of small things; it is the research and the development of materials, devices, and systems that exhibit physical, chemical, and biological properties that are different from those found at larger scales and that "exhibit extraordinary properties with revolutionary applications."[19]

The basic science at the nanoscale is not new. Scientists have known that matter is made of atoms for over a century, and for decades they have known how to describe many of the properties of matter. However, only recently have developments in instrumentation and computing made atomic-level measurements possible. The ability to measure, manipulate, simulate, and visualize matter at the atomic scale has the potential of redefining our interaction with the world around us—prompting some to consider nanotechnology as revolutionary rather than just another step in technological progress.[20]

Nanotechnology is a young field that focuses on two categories: basic research and materials science products. In 2003, the United States had approximately 104 nanotechnology research institutions and 430 nanotechnology

18. To put this into perspective, a human hair is roughly 80,000 nanometers in diameter. *See, e.g.*, National Nanotechnology Initiative: Frequently Asked Questions, http://www.nano.gov/html/facts/faqs.html (last visited Sept. 2, 2005). The diameter of a human blood cell is on the order of 6000 to 8000 nanometers, a virus is on the order of 20 to 400 nanometers, and a single hydrogen atom is about 0.12 nanometers. *See* Wikipedia, The Free Encyclopedia, *at* http://en.wikipedia.org (last visited Sept. 2, 2005).

19. Q. Todd Dickinson, *Foreword*, 1 NANOTECHNOLOGY L. & BUS. J., Jan. 2004, at 1.

20. *See* John Marburger, Office of Sci. & Tech. Policy, Workshop on Societal Implications of Nanoscience and Nanotechnology of the National Science Foundation (Dec. 3, 2003) (transcript *available at* http://www.ostp.gov/html%5CjhmremarksSocImpworkshop.pdf).

startups producing commercial products.[21] Basic nanotechnology research undertaken in U.S. research institutions, including universities, public laboratories, and private laboratories, primarily focuses on areas such as chemistry, physics, computer science, and biology. The first successful wave of commercial nanotechnology products has been in materials science. Materials science companies are producing innovative products in areas such as coatings, powders and particulates, nanoengineered chemicals, carbon nanotubes, clays, and biomedical devices.[22] The commercial viability of more complex technologies like ultraefficient batteries or molecular computer chips historically has been limited by the materials used to make them. However, "with 'building block' materials being assembled at smaller and more stable levels, near-term developments in nanotechnology should enable remarkable advances in" many significant areas of manufacturing.[23]

Nanotechnology already is generating such varied technologies as stronger and lighter building materials, more durable coatings, efficient batteries and fuel cells, improved television display technology, and microscopic computer chips. Someday, nanotechnology is expected to enable environmental cleaning mechanisms for air and water, as well as injectable biosensors to detect the presence of infectious agents.[24] At present, medical researchers are actively exploring nanotechnology potential in drugs, drug delivery, diagnostics, devices, gene therapy, and tissue engineering.[25] To date, gene therapy and biotechnology already attempt to manipulate living mechanisms to reconfigure molecules at the nanoscale. However, these processes are limited by natural mechanisms; for example, although bacteria can be used to reconfigure molecules at the nanoscale to produce certain

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21. James Flanigan, *Nanotechnology—Small Things for Big Changes*, L.A. TIMES, Nov. 23, 2003, at C1 (citing statistics from Cientifica, a European consulting firm).

22. *See* John L. Petersen & Dennis M. Egan, *Small Security: Nanotechnology and Future Defense*, DEFENSE HORIZONS, Mar. 2002, ¶ 10, *available at* http://www.ndu.edu/inss/efHor/DH8/DH08.htm.

> Nanomaterials development focuses mostly on . . . the carbon nanotube, a superthin pipe made of a rolled sheet of carbon atoms. Nanotubes have the greatest tensile strength of any fiber—60 times greater than that of steel of the same weight—and they also have extraordinary electrical properties. In certain configurations, they are semiconductors or insulators, while in others they are electrical conductors, and they might even be configured as superconductors.

Id.

23. Lynn Easter, *Nanotechnology Yellow Pages: Industry Report and Yellow Pages* (2001), http://www.larta.org/ecommerce/shop/Reports/Nano2001.pdf.

24. *See* Norton, *supra* note 7, at 38 (noting that chemical and biological sensors also may be integrated into clothing to detect nerve gas, SARS, and anthrax).

25. *See* John Miller, Note, *Beyond Biotechnology: FDA Regulation of Nanomedicine*, 4 COLUM. SCI. & TECH. L. REV. 5 (2002/2003).

proteins, they cannot likewise be used to manipulate molecules in order to produce inorganic diamonds.[26] Nanotechnology, conversely, presents the opportunity to go beyond what natural mechanisms currently allow by creating assembly systems that can build virtually any molecule from elemental atoms.

Future applications of nanotechnology likely will focus on the complex task of automatically manipulating individual atoms and molecules to build gears, motors, and molecule-sized machinery.[27] Once this "molecular manufacturing" is ready for commercial application, it will reverse a fundamental basis of traditional manufacturing. Historically, manufacturing has been a top-down process, essentially taking larger materials and cutting and shaping them down into product parts. Molecular manufacturing, on the other hand, starts with the building blocks of atoms and molecules and combines them to form objects from the bottom up—an approach used by nature for billions of years.[28] Eventually this approach may replace many of today's production processes.

Although the potential for nanotechnology is promising, at present nanotechnology is still much more of a nanoscience than a producer of commercial nanoproducts. Going forward, in order to foster the continuing innovation that is vital to achieving its technical and economic potential, nanotechnology must develop within an intellectual property regime that fosters an appropriate balance between maintaining freedom of operation for a large number of innovators, while at the same time rewarding innovations with exclusive patent rights.

II. A COMPARISON WITH THE BIOTECHNOLOGY INTELLECTUAL PROPERTY REGIME

In several respects, nanotechnology appears to be following the model of biotechnology patent policy. The current "patent land rush" by nanotechnology patent prospectors in many ways mimics the biotechnology experience of the early 1980s.[29] As with nanotechnology today, biotechnology involved considerable scientific research funded by the government in several universities and labs. Many biotechnology startups developed out of "broad

26. Petersen & Egan, *supra* note 22, ¶ 11 ("With nanofabrication techniques that allow individual atom manipulation, carbon atoms (from crude oil, for example) could easily be arranged in the lattice structure of a diamond, allowing a great number of things to be constructed of that material.").

27. *Id.*

28. *See* Frederick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593, 596–97 (1994) ("Putting these natural molecular machines to work is nothing new, of course, as every living thing does so constantly.").

29. *See* Raj Bawa, *Nanotechnology Patenting in the US*, 1 NANOTECHNOLOGY L. & BUS. J., Jan. 2004, at 17 n.36.

university patents or groups of patents that were licensed to startups following an initial round of venture capital funding."[30] Like nanotechnology now, biotechnology held the promise for a new generation of revolutionary products and treatments in the 1980s. However, twenty years later, the promise of biotechnology potential remains only a promise; the general market perception is that biotechnology still offers more "potential" than product. Although several significant biotechnology innovations have proven themselves on the market,[31] the pace of the introduction of new biotechnology products and innovations remains far below initial expectations. Arguably, this shortfall in biotechnology innovation is the result of a biotechnology anticommons.[32]

Two events in 1980 provided the spark for the biotechnology anticommons: the enactment of the Bayh-Dole Act,[33] and the granting of the first U.S. patent on a genetically modified life form in *Diamond v. Chakrabarty*.[34] The Bayh-Dole Act, which is discussed in more detail in Part V of this Comment, for the first time allowed universities and small business entities to obtain exclusive intellectual property ownership rights in government-sponsored research. In response to the Bayh-Dole Act, universities and professors quickly patented many aspects of fundamental biotechnology. Lacking significant expertise and prior art in biotechnology, the understaffed USPTO soon began to approve and issue broad and overlapping biotechnology patents to the universities.[35] Professors and researchers subsequently began to leave the universities to found biotechnology startups, and they licensed the biotechnology patents from the universities that held them. Finding that Congress intended to "include anything under the sun that is made by man" as patentable subject matter,[36] the Court in *Chakrabarty* enabled these early startup firms to attract venture capital financing by providing some measure of certainty that biotechnological inventions could be patented.

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30. *Id.*

31. Examples of biotechnology successes include Amgen's Epogen and Neupogen, *see* Amgen Products, *at* http://www.amgen.com/patients/products.html (last visited June 1, 2005), and Genentech's recombinant DNA-based human insulin, *see* Genentech, Corporate Chronology, *at* http://www.gene.com/gene/about/corporate/history/timeline/ (last visited June 1, 2005).

32. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, *in* PERSPECTIVES ON PROPERTY LAW 159, 162–64 (Robert C. Ellickson et al. eds, 3d ed. 2002) (originally published in 280 SCIENCE 698 (1998)).

33. The Bayh-Dole Act, 35 U.S.C. §§ 200–12 (2000 & Supp. 2002).

34. Diamond v. Chakrabarty, 447 U.S. 303, 318 (1980) (upholding a patent by construing 35 U.S.C. § 101 (2000) to include genetically engineered bacteria within patentable subject matter).

35. *See* Heller & Eisenberg, *supra* note 32, at 161.

36. *Chakrabarty*, 447 U.S. at 309 (citing S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

Seeking to profit from their patents, universities also began using reach-through license agreements to capture returns from future technological developments based on their patented work.[37] A reach-through license agreement basically gives the owner of a patent, used in upstream stages of research, rights in subsequent downstream discoveries. Such rights may take the form of a royalty on sales that result from use of the upstream research tool, an exclusive or nonexclusive license on future discoveries, or an option to acquire such a license.[38] Because the granting of a singular license was rarely sufficient in conducting the further incremental research necessary to further develop biotechnology applications, other innovators and researchers were required to acquire numerous licenses held by the universities, many of which either were already licensed to certain biotechnology startup firms pursuant to exclusive licenses or were subject to onerous reach-through license agreements.

The complexity of the licensing arrangements with the universities, and the concomitant transaction costs, eventually escalated to the point that biotechnology innovation was hampered. Although it is difficult to quantify the effect of an anticommons—because delays and outright failures in licensing are not tracked publicly—there is evidence that a biotechnology anticommons exists. Notably, a study conducted by the National Institutes of Health (NIH) Working Group on Research Tools determined that "[m]any scientists and institutions involved in biomedical research are frustrated by growing difficulties and delays in negotiating the terms of access to research tools"; that "[c]ase by case negotiations for permission to use research tools and materials create significant administrative burdens that delay research"; that "[s]ome users of biomedical research tools have limited resources for paying up-front fees, although their use of the tools could potentially yield valuable future discoveries"; and that "[l]icense mechanisms by which tool providers seek to profit from the future discoveries of tool users often involve future royalty obligations or rights to future intellectual property that constrain future opportunities for research funding and technology transfer."[39] Indeed, the chief scientific officer at Bristol-Myers Squibb stated that "his company was not able to work on more than fifty proteins that could

37. *See* Heller & Eisenberg, *supra* note 32, at 163.

38. *Id.*

39. *See* NAT'L INST. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS (June 4, 1998), *at* http://www.nih.gov/news/researchtools/#exec (last visited Dec. 1, 2004).

potentially be involved in cancer 'because the patent holders either would not allow it or were demanding unreasonable royalties.'"[40] Another pharmaceutical executive complained that his company has

> frustration internally because we can't do what we consider basic research with a cloned gene . . . just using it to make another discovery. . . . [A]t the end of the day, you are cut off from tools, from making a breakthrough discovery. In a number of cases, we can't work with this protein or this gene and it slows things down.[41]

Outside the pharmaceutical industry, academic scientists report similar problems of access to important biotechnologies in their agricultural research; some owners refuse to grant licenses "because they mistrust licensees [or] wish to retain a field of research for themselves."[42]

Given the similarity between nanotechnology and biotechnology, it is likely that continued innovation in nanotechnology will face analogous impediments if numerous and potentially overlapping nanotechnology patent rights are granted and exclusively licensed. Realistically, the traditional concept of a single, strong nanotechnology patent capturing the final value of a product is fairly remote at this early stage of fundamental research. Rather, the early stages of successful nanotechnology innovation are more likely to depend on the cross-pollination of many patents tying together many

40. Michael A. Carrier, *Resolving the Patent-Antitrust Paradox Through Tripartite Innovation*, 56 VAND. L. REV. 1047, 1087 (2003) (citing Andrew Pollack, *Bristol-Myers and Athersys Make Deal on Gene Patents*, N.Y. TIMES, Jan. 8, 2001, at C2).

41. *Id.* (citing John P. Walsh et al., *Research Tool Patenting and Licensing and Biomedical Innovation*, *in* 9 SCI., TECH. & ECON. POL'Y BD. NAT'L ACAD. OF SCI. 285, *available at* http://tigger.cc.uic.edu/~jwalsh/BioIPNAS.pdf).

42. Michael R. Taylor & Jerry Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J.L. & TECH 321, 350 (2004). Taylor and Cayford noted:

> At Iowa State University, plant breeders were rebuffed when they approached a company about licensing a technology. "We were refused, even though the company is licensing to many other companies," said Patricia Swan, vice provost for research and advanced studies at Iowa State University. "The company indicated that [it] did not want to license to us because [it] did not believe that universities were capable of managing and looking after the intellectual property in the way that it should be looked after."

Id. at 350 n.99 (alteration in original) (citing NAT'L RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND PLANT BIOTECHNOLOGY 8 (1997), *available at* http://www.nap.edu/html/intellectual/); *see also* Taylor & Cayford, *supra*, at 350 n.100 (discussing how Agracetus "uses its patent on all transgenic cotton to prevent anyone else from researching a certain aspect of cotton production" and how Agracetus "has licensed to Monsanto and Calgene . . . use [of] the technology to improve the insect resistance of cotton. But all efforts to alter the genome of cotton to improve its fiber characteristics have not been authorized by the company") (citing Jeroen Van Wijk, *Broad Biotechnology Patents Hamper Innovation*, 25 BIOTECH. & DEV. MONITOR, Dec. 1995, at 16, *available at* http://www.biotech-monitor.nl/2506.htm).

inventions.[43] Thus, in order to foster a more innovative environment in nanotechnology, the U.S. patent and licensing system needs to be examined and changed to avoid the innovation-retarding effects of a nanotechnology patent thicket.

III. PROBLEMS WITH THE CURRENT STATE OF U.S. NANOTECHNOLOGY PATENTS

Various challenges face the nanotechnology field as it establishes its intellectual property regime. This Comment focuses on fundamental nanotechnology research conducted in universities and funded by the U.S. government.[44] From this perspective, there is a distinct set of issues relating to the prosecution and licensing of patents in an academic and a legal environment.

A. The USPTO Is Not Adequately Prepared to Handle Nanotechnology Patent Applications

As described in the introduction of this Comment, the rate of nanotechnology patent applications and patent issuances is increasing. The USPTO patent grant rate for the entire pool of applications is approximately 52 percent per year, and the likelihood of a single, diligently prosecuted patent being granted over the course of the years it is reviewed at the USPTO may be as high as 97 percent (taking into account continuing patent applications).[45] "Since the acceptance rates for the European, German and Japanese Patent

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43. *See* Sabety, *supra* note 16, at 17. Sabety devises a methodology to compare the history of intellectual property development in the radio and telecommunications industry with nanotechnology development, and he concludes that "[i]n order to imitate the [success of the] early information technology industry, the foundational [nanotechnology] I.P. should be widely licensed while the narrow refinements or follow-on innovations should receive exclusivity to attract private capital." *Id.*

44. Notwithstanding government funding, private funding has been escalating in recent years as the potential market for nanotechnology has gained wider recognition. Global companies including IBM, Hewlett-Packard (HP), 3M, General Electric, Lockheed Martin, ChevronTexaco, Samsung, Mitsubishi, and DaimlerChrysler are making significant investments in nanotechnology research efforts. Choi, *supra* note 4, ¶ 6 (citing NanoBusiness Alliance estimates). IBM, HP, and 3M are allocating approximately one-third of their respective research budgets to nanotechnology. Miller, *supra* note 25. Venture capital investment is growing rapidly, with a total of over $1 billion in funding over the last three years and as much as $700 million in investments for 2004. Choi, *supra* note 4, ¶ 6 (citing NanoBusiness Alliance estimates).

45. In 2003, the USPTO granted 173,072 of the 333,452 utility, plant, and reissue patent applications it received for an approval rate of approximately 52 percent. *See* U.S. PATENT & TRADEMARK OFFICE, FISCAL YEAR 2003, *supra* note 14. For discussion of the 97 percent grant rate, see Note, *Estopping the Madness at the PTO: Improving Patent Administration Through Prosecution History Estoppel*, 116 HARV. L. REV. 2164, 2165 (2003) (citing Cecil D. Quillen, Jr. & Ogden H. Webster, *Continuing Patent Applications and Performance of the U.S. Patent Trademark Office*, 11 FED. CIR. B.J. 1, 12-13 (2001-2002)).

Offices are substantially lower, some patent experts claim that [the high U.S. grant rate] indicates a less rigorous examination at the USPTO."[46] In the long term, the USPTO may shape its policies and performance more consistently with foreign patent practices in response to international intellectual property harmonization efforts, but in the near term, the differences between the USPTO and foreign patent offices[47] are particularly important in light of the considerable global market potential of nanotechnology and the worldwide efforts in nanotechnology research and invention. Today, the threat of poor U.S. nanotechnology patent quality can be attributed to a number of problems at the USPTO.

For example, given the multidisciplinary nature of nanotechnology, it is unclear whether the USPTO can handle the anticipated increases in nanotechnology patent applications, especially in regional patent offices where examiners are generally assigned to examine a single class or related classes of technology. At a fundamental level, the USPTO examiners should know what may be classified as nanotechnology. Although the U.S. Patent Classification System organizes issued patents, published applications, and prior art[48] references based on their common subject matter,[49] as of September 2005 the

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46. *See* Bawa, *supra* note 29, at 3 n.9. In 2003, the European Patent Office granted 59,992 patents of the approximately160,000 applications it received for an approval rate of approximately 38 percent, while the Japanese Patent Office registered 111,276 of the 413,092 patents it received for an approval rate of approximately 27 percent. *See* EUROPEAN PATENT OFFICE, FACTS AND FIGURES, http://annual-report.european-patent-office.org/facts_figures/_pdf/facts_figures_04.pdf; *see also* JAPAN PATENT OFFICE, ANNUAL REPORT 2004, PART 6: STATISTICAL DATA, http://www.jpo.go.jp/shiryou_e/toushin_e/kenkyukai_e/pdf/ar2004/ar2004_part06.pdf.

47. For example, unlike the USPTO, the European Patent Office (EPO) process provides a post-grant opposition period wherein parties opposed to a broad or overlapping patent may file a protest without having to resort to U.S.-style litigation. *See* EPO, Guidelines for Examination in the European Patent Office, *at* http://www.european-patent-office.org/online/index.htm (last visited Dec. 1, 2004).

48. Generally, "prior art" is any previously disclosed technology or patent tending to show that a new invention is obvious, which precludes the new invention from patentability under 35 U.S.C. §103(a) (2000). That statute states:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Id.

49. *See* Lance D. Reich, *Protecting Tiny Gizmos: The Patent and Trademark Office is preparing for nanotech applications*, NAT'L L.J., Jan. 29, 2004, *available at* http://www.law.com/jsp/newswire_article.jsp?id=1075219818243. Reich notes:

> The classification of an incoming patent application initially determines which technical group and art unit will examine the application, and also determines the technical area(s) of search to locate potential prior art to the patent application. Generally, the existence of prior art that either discloses or makes obvious the invention claimed in the new patent application will block issuance of a patent.

Id.

USPTO still had not publicly released a nanotechnology classification system.[50] Although the USPTO's effort is underway, the specific patents being classified into nanotechnology subgroups are not yet available to the public or to examiners.[51] As it stands, the USPTO designates ten classes as potentially containing prior art for nanoproducts.[52] A potential problem with the lack of a unique classification for nanotechnology-specific prior art to date is that examiners likely have encountered a difficult time locating the best available prior art for nanotechnology patent applications. Specialized examiners are unlikely to be familiar with advances in other areas necessary for a complete examination of nanotechnology. In addition, industry experts fear that the convergence of fields using different terminologies for the same classification "increases the chance that patents will be issued without proper narrowing of the scope of claims in view of prior work and publications, or in view of the practical difficulties in applying the technology."[53] Notably, one term in chemistry compared to another in physics or materials science for the same phenomenon can create potential hidden links in prior art that go unnoticed by examiners. Furthermore, nanotechnology patent prosecutors must exercise increased diligence in their role as lexicographers because there are no effective "dictionaries" to interpret nanotechnology claim construction. For example, in U.S. Patent 6,500,622, the patentees created and used the term "quantum dot" in describing their invention when the invention's generic name, "semiconductor nanocrystal," was already in existence.[54] Although it has undertaken affirmative efforts to educate its patent examiners in nanotechnology,[55] the

50. On October 18, 2004, the USPTO announced that it would create a Nanotechnology Digest for Class 977 (Nanotechnology) and eventually set up a nanotechnology cross-reference art collection to replace the digest. *See* Barnaby J. Feder, *Tiny Ideas Coming of Age*, N.Y. TIMES, Oct. 24, 2004, § 4, at 12; *see also* U.S. Patent & Trademark Office, New Cross-Reference Digest for Nanotechnology, *at* http://www.uspto.gov/web/patents/biochempharm/crossref.htm (last visited Sept. 2, 2005).

51. *See* sources cited *supra* note 50. Attempts to search the USPTO patent database using links for the Class 977 Nanotechnology Digest site by following the link to the Lists of Patents resulted in zero results under the preprogrammed USPTO search query CCL/977/DIG1. *See* http://www.uspto.gov/go/classification/uspc977/sched977.htm (last visited Sept. 2, 2005).

52. Reich, *supra* note 49. These ten USPTO nanotechnology-related classes "range from Class 57, Textiles: Spinning, Twisting, and Twining; to Class 435, Chemistry and Molecular Biology and Microbiology; to Class 438, Semiconductor Device Manufacturing Process." *Id.*

53. Norton, *supra* note 7.

54. John Josef Molenda, *The Importance of Defining Novel Terms in Patenting Nanotechnology Inventions*, 1 NANOTECHNOLOGY L. & BUS. J., May 2004, at 3; *see also* Edward Rashba et al., *Standards in Nanotechnology*, 1 NANOTECHNOLOGY L. & BUS. J., May 2004, at 7.

55. Through a partnership, the USPTO sought speakers who could give technical training to patent examiners in nanotechnology, and also requested suggestions for information sources for the searching of nanotechnology-specific prior art. *See* U.S. Patent & Trademark Office, Nanotechnology Customer Partnership Meeting (Sept. 11, 2003), *at* http://www.uspto.gov/

USPTO must put its nanotechnology digest into practice as soon as possible to put U.S. patent quality on par with foreign efforts.[56] The lack of cross-functional nanotechnology expertise at the USPTO,[57] and delays in establishing nanotechnology-specific guidelines, may lead to the issuance of overly broad patents by examiners despite the existence of relevant prior art.

Finally, from a substantive standpoint, unique forms of claim rejections on the basis of anticipation, obviousness, and enablement in a nanotechnology context are new to both patent prosecutors and examiners. It is not clear if the level of written disclosure in a nanotechnology patent may need to meet or exceed the relatively high bars set for biotechnology patent claims and specifications because, to date, there has been no nanotechnology patent infringement litigation that has come to judgment.[58] Patent examiners at the USPTO thus lack appropriate guidelines to help effectively process the multitude of nanotechnology applications being filed.

B. The Failure of Voluntary Licensing in a Patent Thicket

To the extent that the USPTO issues a proliferation of broad and potentially overlapping nanotechnology patents, the development of a nanotechnology patent thicket could impede the licensing process required for further innovation. Typically in universities, once fundamental nanotechnology research is ready for patent prosecution and licensing, a technology transfer or intellectual property administration office coordi-

web/patents/nanotech/meet091103.htm (last visited Sept. 15, 2005). Another meeting was held on May 4, 2005 to present high level nanotechnology art cross-reference efforts to date and to elicit additional feedback. *See* U.S. Patent & Trademark Office, Nanotechnology Customer Partnership Meeting (May 4, 2005), *at* http://www.uspto.gov/web/patents/biochempharm/ncpmmay04.htm (last visited Sept. 15, 2005).

56. *See* Reich, *supra* note 49. By contrast, certain foreign patent offices already have established working classifications for inventions in nanotechnology. For example, the World Intellectual Property Organization's International Patent Classification system includes a specific nanotechnology classification (IPC Class B82B), and the Japanese Patent Office likewise has created an internal patent classification ("Micro-Structural Technology; Nanotechnology"). *Id.*

57. *See* Hines, *supra* note 2.

58. "In the past, when confronted with a new area of technology and potential inventions, such as biotechnology, the first reaction" of the USPTO was to refuse issuance of a patent. *See* Reich, *supra* note 49. "In the 1980 case of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the U.S. Supreme Court [held] that biotechnology, and specifically that a genetically engineered life form, is patentable." *Id.* But subsequent cases continually raised the level of technical description required in order to have a valid biotechnology patent. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997) (holding biotechnology patent claims invalid for not providing an adequate written description of the subject matter of the asserted claims to the explicit molecular structure of the invention).

nates the exercise of university patent rights.[59] Income from patent licensing as a percentage of total university budgets tops out at 3–5 percent at some university labs, while most universities are in the range of 1–2 percent.[60] Important licensing terms include duration and manner of payment by cash, equity, or royalties, as well as consideration of who bears the responsibility for patent prosecution costs.

Patent licenses tend to be exclusive, nonexclusive, or field-of-use exclusive. Most nanotechnology startups seek exclusive licensing because it generally takes longer to develop costly research-intensive nanoproducts, and it is difficult to achieve significant sales until five to ten years after the license is granted. In 2003, twelve of fifteen publicly announced nanotechnology intellectual property license agreements were exclusive, with such universities as MIT and NYU selling exclusive commercialization rights to individual companies.[61] Among publicly announced nanotechnology deals between January and December 2004, seventeen disclosed that the terms were exclusive while only three were clearly nonexclusive licenses.[62] The

59. With the increasing importance of securing nanotechnology patent rights in early stages of research, universities and laboratories have refined mechanisms to ensure that researchers are aware of the diligence required to establish and transfer intellectual property rights. Universities have established intellectual property procedures governing invention disclosures, notebook keeping, publication approval, patent filing approval, and confidentiality agreements, as well as implemented reasonable precautions against the theft of trade secrets. For example, the California NanoSystems Institute (CNSI) at UCLA and UC Santa Barbara coordinates all its intellectual property administration with the already established campus Office of Intellectual Property Administration (OIPA). Telephone Interview with Derrick Boston, Senior Vice President of the California NanoSystems Institute (Feb. 20, 2004) [hereinafter Boston Interview]. The OIPA has attorneys specializing in assessing innovative research and securing intellectual property rights on behalf of the Office of Technology Transfer (OTT) for the University of California Regents. The OIPA works with researchers and performs all the necessary steps in filing provisional, utility, and international patents for all nanotechnology research for each campus. Telephone Interview with Rebecca Goodman Esq., Technology Transfer Officer for Outgoing Material Transfer Agreements with the Office of Intellectual Property Administration at UCLA (Feb. 20, 2004).

Once a patent has been issued, the UCLA OIPA coordinates licensing contracts with entities outside the university for technology transfer. In 2004, the OIPA offered fourteen UCLA nanotechnology license listings. *See* UCLA Technologies Available for Licensing, *at* http://www.research.ucla.edu/tech/nanotech.htm (last visited Sept. 2, 2005). The University of California Regents offered 103 nanotechnology related licenses. *See* University of California Technologies Available for Licensing, *at* http://patron.ucop.edu/ncd/ncd.html (last visited Sept. 2, 2005).

60. Behfar Bastani et al., *Technology Transfer in Nanotechnology: Licensing Intellectual Property From Universities to Industry*, 1 NANOTECHNOLOGY L. & BUS. J., May 2004, at 2.

61. *See Nanotechnology Updates*, 1 NANOTECHNOLOGY L. & BUS. J., Jan. 2004, at 2–3 [hereinafter *Jan. 2004 Updates*] (of the fifteen listed publicly announced nanotechnology licensing agreements, twelve were exclusive, two were nonexclusive, and one did not disclose exclusivity terms).

62. *See Nanotechnology Updates*, 1 NANOTECHNOLOGY L. & BUS. J., May 2004, at 1–2 [hereinafter *May 2004 Updates*]; *Nanotechnology Updates*, 1 NANOTECHNOLOGY L. & BUS. J., Sept. 2004, at 1 [hereinafter *Sept. 2004 Updates*]; *Nanotechnology Updates*, 1 NANOTECHNOLOGY L. &

exclusivity trend continued between December 2004 and May 2005 with eight exclusive nanotechnology licensing deals and three nonexclusive licensing deals.[63] Every publicly announced nanotechnology licensing deal involving a university between January 2003 and May 2005 was exclusive in nature.[64]

Traditionally, market incentives tend to lead patentees to exploit their innovations efficiently, often by licensing them to others in the field. Licensing facilitates patent policy goals by allowing the public to benefit from the commercialization of inventions and by encouraging incremental innovation by licensees and others who purchase licensed products. Occasionally, strategic bargaining can lead to an impasse where one side overestimates and the other underestimates the value of an invention. Sometimes there is difficulty in determining if the negotiator's assessment is being used as a bargaining tool or in good faith, and there are always uncertainties surrounding patent license development success and profitability. In spite of these impediments, however, traditional licensing tends to work effectively overall. Yet when a patent thicket develops, traditional assumptions may prove invalid.

First, if rights necessary to develop nanotechnology are held by numerous patentees pursuant to broad, overlapping patents, the transaction costs for a licensee to accumulate all the required licenses needed to enable production may become prohibitive. With the confounding number of patents that a researcher can attempt to license, and the corresponding monetary risk of choosing the "wrong" license, innovators waste time and money seeking the "right" license instead of innovating. Furthermore, the risk of liability for punitive damages to licensees of new technologies is increasing: Courts interpreting these early stage deals have imposed a fiduciary duty on

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BUS. J., Dec 2004, at 1 [hereinafter *Dec. 2004 Updates*] (noting that in 2004, an additional twelve publicly announced nanotechnology licensing deals did not disclose whether they were exclusive or nonexclusive).

63. *See Nanotechnology Updates*, 2 NANOTECHNOLOGY L. & BUS. J., Feb. 2005, at 1 [hereinafter *Feb. 2005 Updates*]; *Nanotechnology Updates*, 2 NANOTECHNOLOGY L. & BUS. J., May 2005, at 1 [hereinafter *May 2005 Updates*] (between December 2004 and May 2005, one additional publicly announced nanotechnology licensing deal did not disclose whether it was exclusive or nonexclusive).

64. *See Jan. 2004 Updates*, *supra* note 61, at 2–3 (Columbia University, Rockefeller University, MIT (two deals), NYU, Rensselaer Polytechnic Institute); *May 2004 Updates*, *supra* note 62, at 1 (University of Dayton, Caltech, MIT); *Sept. 2004 Updates*, *supra* note 62, at 1 (Stanford University, University of Massachusetts, University of Queensland (Australia)); *Dec. 2004 Updates*, *supra* note 62, at 1 (MIT, University of Illinois, Caltech); *Feb. 2005 Updates*, *supra* note 63, at 1 (University of Texas, UCLA); *May 2005 Updates*, *supra* note 63, at 1 (Caltech).

licensees, threatening punitive damages of hundreds of millions of dollars in the event of a breach.[65]

Importantly, unlike in other fields, nanotechnology patent holders are not likely to coalesce voluntarily in order to form patent pools and circumnavigate these patent thicket licensing problems.[66] First, with billions of dollars of funding from the Nanotechnology Act being funneled into many universities and labs, in conjunction with the privatization of patent rights from the Bayh-Dole Act, many upstream foundational nanotechnology research efforts are being funded—resulting in little perceived need to pool patents. Because exclusivity in patents and licensing potentially can result in such tremendous profits, moreover, parties are more likely to keep their patents than consider sharing them in a patent pool. Second, there has been little demonstrated need for pooling with the limited number of transactions and deals that have taken place. Although some universities may demonstrate acumen in making business deals, to date only a few dozen licensing deals exist despite thousands of nanotechnology patents,[67] perhaps because many publicly funded institutions have limited resources for absorbing licensing transaction costs and also because they maintain

65. Recently, a California appeals court upheld more than $300 million in compensatory damages and $200 million in punitive damages against Genentech for violating fiduciary duty by acting fraudulently in failing to pay royalties on a license with the City of Hope National Medical Center (City of Hope), a cancer research center. In 1976, Genentech, then a startup company, negotiated a patent agreement to develop and market human insulin and human growth hormone based on a genetic engineering breakthrough by City of Hope. Genentech paid City of Hope a 2 percent royalty on the sale of products developed from the technology but did not pay the medical center for licensing revenue, claiming that the contract required royalty payments only on patents using DNA synthesized by City of Hope. City of Hope eventually sued Genentech for breach of contract. At issue were twenty-seven licenses with twenty-two companies involving thirty-five products. The appeals court held that the relationship between the inventors at City of Hope and the developers at Genentech should be treated as fiduciary in nature because "a fiduciary relationship exists where an inventor entrusts an idea or device to a third party for development." City of Hope Nat'l Med. Ctr. v. Genentech, Inc., 20 Cal. Rptr. 3d 234 (Ct. App. 2004), *review granted*, City of Hope Med. Ctr. v. Genentech, Inc., 105 P.3d 543 (2005); Mike McKee, *California Court: Genentech Owes $500M in Royalties*, RECORDER, Oct. 22, 2004, *available at* http://www.law.com/jsp/article.jsp?id=1098217039594.

66. *See* Heller & Eisenberg, *supra* note 32, at 163. A patent pool consists of a packaged set of licenses for a similar group of patents. Some traditional communities of intellectual property owners who deal with each other on a repeated basis may create institutions to reduce transaction costs by bundling multiple licenses. For example, copyright collectives have developed in the music industry to facilitate broadcasting, and patent pools have emerged in the automobile, aircraft, and rubber industries when licenses under multiple patent rights have been required to develop new products. *Id.*

67. *See* U.S. Patent & Trademark Office, *supra* note 11; *Jan. 2004 Updates*, *supra* note 61, at 1–3; *May 2004 Updates*, *supra* note 62, at 1–2; *Sept. 2004 Updates*, *supra* note 62, at 1; *Dec. 2004 Updates*, *supra* note 62, at 1; *Feb. 2005 Updates*, *supra* note 63, at 1; *May 2005 Updates*, *supra* note 63, at 1.

limited competence in fast-paced, market-oriented bargaining. Third, nanotechnology research is multidisciplinary and requires the use of a diverse set of similar or even identical techniques that may be concurrently patented. Thus, researchers specializing in one area are likely to find it difficult to compare the values of patents from other branches of science. Finally, much of nanoscience is in its early stages, and the costs and uncertainty relating to licensing unproven technologies in a patent pool rise in conjunction with the uncertainty of the outcome of projects. As researchers and developers explore numerous potential nanotechnologies, hedging bets becomes expensive.

Productive nanotechnology licensing is further hampered by the heterogeneous interests of the negotiating parties. Cognitive biases among researchers tend to make patent holders overestimate the value of their patents and the likelihood of future success. Universities and commercial businesses can have potentially conflicting agendas. Meanwhile, politically accountable government agencies who fund much of the research may want to make technologies widely available at a low price, while private companies seek product monopolies to reward shareholders and to fund future products. Differences between public and private research additionally result in few standard licensing terms, thereby increasing the cost of case-by-case negotiations. These conflicts and complexities are amplified when both private and public funding is mixed to fund university research projects.[68]

Licensing in a patent thicket is difficult. Ultimately, the inefficiencies stifle the ability of innovators to use necessary scientific techniques and tools in order to continue researching and developing nanoproducts. As licensing difficulties come to a head, innovators and hopeful licensees must resort to the judicial system to seek a path through the thicket.

68. A vast amount of funding from corporate and private sources has made its way into sponsorships of university research. For example, companies have made alliances with CNSI at UCLA and UC Santa Barbara by investing millions of dollars in sponsorship of nanotechnology research. In exchange for funding, companies generally share intellectual property rights for specifically sponsored research projects. Contractual agreements between the CNSI and corporate alliance members provide that if a sponsor funds up to 50 percent of a nanotechnology project with CNSI, that sponsor gets up to 50 percent of the intellectual property rights on that project. Boston Interview, *supra* note 59.

C. The Failure of Judicial Doctrines in Facilitating Nanotechnology Patent Licensing

Unlike the European Patent Office, the USPTO does not provide a post-grant opposition period when parties opposed to a broad or overlapping patent may file protests. The only opportunity for innovators to attempt to challenge patents is through litigation. If researchers and product developers decide to use a patented technology or method without securing a license, they must attempt to seek a declaratory judgment that the patent is invalid or wait to be sued for patent infringement.

Innovators seeking potential limitations to the scope of a contested patent may rely on a number of statutory or common law doctrines during an infringement action. A federal district court may hold a patent invalid after a de novo reevaluation of the USPTO's decision to grant patent protection for the particular invention. Even if the court does not hold the patent invalid, it will construe the scope of a patent's claims through formal *Markman* hearings, which define and interpret the bounds of the patentee's exclusive rights.[69] If a defendant's acts are deemed to fall within these bounds, the defendant also may attempt to excuse the infringing activity under the reverse doctrine of equivalents and the experimental use defense. However, as the following sections illustrate, these doctrines have not proved useful to date for nanotechnology.

1. The Lack of Nanotechnology Infringement Litigation Results in Few Patent Validity Guidelines

Thousands of nanotechnology patents have been issued and thousands more have entered the application process. However, outside of suits relating to biotechnology at the nanoscale,[70] nanoscale measuring instruments,[71]

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69. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 388–89 (1996) (holding that the construction of a patent, including terms of art within its claim, is exclusively within the province of the district court). After *Markman*, the Federal Circuit generally held that it would review claim construction issues de novo, without any deference to other institutions that must interpret claims.

70. To date, litigation over nanotechnology-scale patent infringement has been focused primarily on biotechnology products such as nanogold particle labels used in diagnostics, microfluidic devices, and microarrays (also known as biochips, a lab-on-a-chip, and genome chips). For example, Affymetrix and Oxford Gene Technology each have brought a series of patent infringement lawsuits against competitors in the field of DNA microarrays. Norton, *supra* note 7.

71. In March 2005, Nova Measuring Instruments, Ltd. (Nova) sued Nanometrics, Inc. (Nano) for infringement of U.S. patent 6,752,689 (an apparatus for optical inspection of wafers during polishing). *See* Business Editors, *Nanometrics Believes Patent Infringement Claim Has No Merit*, BUSINESS WIRE, Mar. 14, 2005, http://home.businesswire.com.

and trade secret-based employments suits,[72] there has been no significant nanotechnology-specific infringement litigation reaching judgment in the United States to provide guidelines on the validity of nanotechnology patents.[73] Long lead times for the commercialization of some nanotechnologies will delay challenges to patents, creating business uncertainty and concerns that patents may be invalidated years in the future. Considering the expense of litigation, patent holders have little incentive, and may very well lack standing, to enter early litigation if they cannot identify activity to enjoin and cannot collect any damages. In other words, innovators lacking the resources to litigate patent validity may be forced to attempt to license "bad" patents rather than contest them.

Although the lack of litigation precludes the ability to measure exactly how well each judicial doctrine may be used in the nanotechnology context, each doctrine does have a history of application in other specialties and industries that sheds some light on how they may be applied to nanotechnology. For example, under the reverse doctrine of equivalents, courts may excuse an infringement when the "[infringing] device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim."[74] Although an infringer may try to use this doctrine as leverage during licensing negotiation, the reverse doctrine of equivalents rarely has been used successfully in court to limit the scope of a valid patent. In fact, the Federal Circuit has never affirmed a

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72. Litigation surrounding nanotechnology trade secrets involving employment suits tends to settle rather than reach judgment. For example, in July 2000, Caliper Technologies Corporation (Caliper) sued Aclara BioSciences (Aclara) for misappropriation and conversion of Caliper's proprietary technical, strategic, and intellectual property information relating to microfluidics. In response, Aclara sued Caliper for patent infringement. After Caliper obtained a jury verdict against Aclara in its trade secret suit, the parties settled. *See* Norton, *supra* note 7. Later in October 2002, Nanogen announced the settlement of a lawsuit with former employee Donald Montgomery for taking its trade secrets to Acacia Research Corporation's (Acacia) CombiMatrix unit and filing patent applications related to the disputed technology under his name. *See Business Briefing*, SAN DIEGO UNION-TRIB., Oct. 3, 2002, at C2. Under the terms of the settlement, Acacia agreed to pay Nanogen royalties on sales of products developed by either CombiMatrix or its affiliates using the disputed technology. *Nanogen Reports Favorable Ruling in Its Litigation Against CombiMatrix Corp. and Dr. Donald Montgomery*, PR NEWSWIRE ASS'N, INC., Aug. 7, 2003. Finally, Zyvex Corporation, a company developing NanoElectroMechanical Systems (NEMS) for prototype nanoscale assemblers, obtained a permanent injunction against a former employee for misappropriation of trade secrets. Norton, *supra* note 7.

73. Among the few nanotechnology patent infringement cases pending, parties to date have sought settlement prior to final judgment. *See, e.g.*, Nanotechwire.com, Caliper Technologies Settles Patent Infringement Suit Against Molecular Devices (Nov. 4, 2003), *at* http://nanotechwire.com/news.asp?nid=534&ntid=125&pg=1 (last visited Sept. 2, 2005).

74. Graver Tank & Mfg. Co., Inc. v. Linde Air Prods. Co., 339 U.S. 605, 608–09 (1950).

decision finding noninfringement under the reverse doctrine of equivalents; therefore, the doctrine is unlikely to be useful in nanotechnology litigation.[75] Unlike the reverse doctrine of equivalents, the experimental use defense does have a history of successful application.[76] However, as discussed in Part III.C.2 *infra*, recent case law indicates that the experimental use defense is becoming less likely to shield innovators from infringement liability.

2. The Demise of the Experimental Use Defense

Faced with difficulties in licensing nanotechnology patents, innovators using patented fundamental research techniques may hope to seek refuge in the experimental use defense, which permits experimentation with the patented invention of another.[77] This defense rarely has been necessary, as the cost of litigation makes it unlikely that a plaintiff will pursue an infringement claim against a defendant if there is no immediate commercial threat. Nevertheless, researchers seeking to verify or use patented nanotechnology methods or products for the sake of research alone may attempt to assert an experimental use defense in cases in which seeking licensing was either too confusing or too expensive, or where the request was rejected.

Recent Federal Circuit cases, however, suggest that patent grantees' "right to exclude is almost absolute and is tempered only by the narrowest of exceptions based on experimental use."[78] In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,[79] the Federal Circuit held that the experimental use defense only applied to infringing acts "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[80] In *Embrex, Inc. v. Service Engineering Corp.*,[81] the Federal Circuit adopted a rule in which the experimental use exception would be inapplicable to any infringing act comprising

75. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 993 (3d ed. 2002) (citing Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1368 (Fed. Cir. 2002)).

76. "The so-called experimental use defense to liability for infringement generally is recognized as originating in an opinion written by Supreme Court Justice Story while on circuit in Massachusetts." Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 862 (Fed. Cir. 1984) (citing Whittenmore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813)).

77. *See* Barry Newberger, *Intellectual Property and Nanotechnology*, 11 TEX. INTELL. PROP. L.J. 649, 656 n.6 (2003) ("The 'experimental use defense' to infringement should not be confused with the experimental use 'exception' to [patent novelty-related] anticipation under 35 U.S.C. § 102.").

78. Andrew J. Caruso, Comment, *The Experimental Use Exception: An Experimentalist's View*, 14 ALB. L.J. SCI. & TECH. 215, 218 (2003).

79. 733 F.2d 858 (Fed. Cir. 1984).

80. *Id.* at 861–63.

81. 216 F.3d 1343 (Fed. Cir. 2000).

"the slightest commercial implication."[82] Finally, in 2002, the Federal Circuit completely emasculated the defense in *Madey v. Duke University*,[83] holding that the experimental use defense cannot further the alleged infringer's legitimate business.[84] In this case, Duke University's infringing use of patented laboratory equipment was viewed as falling within the ambit of its "legitimate business objectives," and the court specifically held that the university's nonprofit status was not determinative.[85] Under this standard, all professional labs and virtually all university labs are excluded from the experimental use defense, effectively eliminating the defense in nanotechnology litigation as a practical matter in the United States. Furthermore, the Federal Circuit's narrow construction of the experimental use exception appears to be more restrictive than similar doctrines in Europe and Japan, a fact likely to create a disincentive to perform research in the United States.[86]

The lack of an experimental use defense is deeply troubling for nanotechnology innovation. Basic tenets of scientific research require the duplication of tests to validate past procedures. If an exclusive licensee of a nanotechnology patent decides to not allow competitors even to repeat a patented fundamental method or technology of nanoscience, then any attempt to validate or even improve upon that patent will result in liability for infringement. Without an experimental use defense, the widely established use of blocking patents,[87] which is encouraged by the patent system to further competition and improvements on existing technologies, would become impracticable. Rather than have initial patent holders rest on the laurels of broad patents, the requirements for patentability allow these improvement patents to exist in order to benefit the public with better products. Patents are published to provide information to the public, thereby allowing competitors to invent around existing patents or to create improvements to existing patents

82. *Id.* at 1353 (Rader, J., concurring) (holding that the experimental use exception does not allow for patent infringements in commercially based scientific experimentation).

83. 307 F.3d 1351 (Fed. Cir. 2002).

84. *Id.* at 1362–63.

85. *Id.*

86. *See* Caruso, *supra* note 78, at 219–20.

87. Blocking patents describe a situation in which patent rights overlap: "e.g., where one inventor patents a broad basic technology and another patents an improvement within that technology—both patent holders have the right to exclude within the areas of overlap." *See* MERGES & DUFFY, *supra* note 75, at 48. To illustrate using a scenario based on an example given by Merges and Duffy, if Sam has a patent on pencils and Ruby gets a patent on pencils with attached erasers, Ruby cannot practice her invention without a license from Sam for his broad patent right to pencils. On the other hand, Sam cannot infringe on Ruby's patent by selling pencils with erasers attached either. The parties must agree on a licensing deal; otherwise, both are subject to infringement when making or selling pencils with attached erasers. *See id.* at 33–35.

knowing that they will need to pay a license for the existing patent.[88] Without the experimental use defense, any attempt to create a noninfringing patent or to show why an improvement on a patent is "nonobvious" also is likely to require a willfully infringing act as a comparison point.[89] Under these circumstances, to the extent that there is an abundance of unchallenged, overly broad nanotechnology patents already issued, continued innovation is likely to become stifled by the fear of infringing a patent claim. Without an experimental use defense, innovators are stuck in limbo between unintentional infringement, willful infringement, and seeking fundamental patent licenses that already may have been granted exclusively to competitors. In the interest of preserving the incentives to innovate through research, the Supreme Court should review and overturn the restrictive limitations on experimental use exemptions adopted in the Federal Circuit cases. Until this review takes place, the absence of a doctrine permitting some privilege of unlicensed use, while simultaneously protecting patentees' incentives, will lead to a patent system that may function to thwart the very innovation that it is intended to promote.

Fortunately, however, the Federal Circuit in *Madey* left one door open that may be used to protect nanotechnology innovation: the possibility of a "government license defense."[90] This novel defense to general patent infringement is based on clauses from the Bayh-Dole Act,[91] and it may allow potential infringers to assert third-party beneficiary rights to practice the patents at issue on the government's behalf—based on government rights in the use of allegedly infringing processes and devices in the performance of government-sponsored research.

IV. APPLICATION OF THE GOVERNMENT LICENSE DEFENSE IN FEDERALLY FUNDED NANOTECHNOLOGY RESEARCH

Congress should alleviate the stifling effects of a patent thicket on U.S. funded nanotechnology innovation by codifying a government license

88. "Because the first patentee usually has an incentive to obtain access to the improvement, the blocking patent gives the infringer some bargaining power in negotiations." Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1194 (2000).

89. *See* Caruso, *supra* note 78, at 234.

90. In a section entitled "Duke's Assertion of a Government License Defense," the *Madey* Court asserted that "the government license issue needs further development before the district court if it is to ultimately provide Duke the defense it seeks." *Madey v. Duke Univ.*, 307 F.3d 1351, 1364 (Fed. Cir. 2002).

91. 35 U.S.C. §§ 200–212 (2000 & Supp. 2002).

defense based on the government license clause of the Bayh-Dole Act.[92] By integrating the essence of the now-defunct experimental use defense into the context of federally funded research, Congress can relieve restrictions on the advancement of nanotechnology instead of forcing researchers to waste time diverting resources to struggle with the metes and bounds of patent claims before carrying out even simple experiments. The Constitution directs Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[93] Excessively strong patent protection in the context of nanotechnology impedes the progress of science instead of promoting it.

This Comment's proposed expansion of the government license defense is based on the traditional recognition that a patent holder's right to exclude is not so absolute that courts will always treat noncommercial acts of infringement as wrongful acts.[94] Furthermore, it is consistent with public policy for the public to have a say in how public funds are used. Such an approach fosters innovation rather than stifles it, and it supports the patent system's constitutional mandate while comporting with the reality that the U.S. nanotechnology industry must innovate in order to compete within the global economy.

A. The Bayh-Dole Act and the Government License Defense

Before the Bayh-Dole Act took effect in 1981, the patenting of federally funded innovation generally was limited to various governmental agencies that could not exclusively license patents to nongovernmental entities.[95] Instead, publicly funded research was made available to the public either through the use of nonexclusive licensing or as free public domain information.[96] However, in the 1970s few commercial applications were developed from federally funded research, and useful research stagnated within the halls

92. Although this proposal is limited to federally funded nanotechnology research and does not affect privately funded efforts, this solution should provide significant relief to U.S. efforts in circumventing a nanotechnology patent thicket in light of the substantial government funding of nanotechnology research. In avoiding a complete patent compulsory licensing royalty scheme, the proposal avoids resistance to the creation of new (and likely unpopular) law by offering a broad interpretation of existing, well-accepted law. Furthermore, this focused approach should not retard the flow of commercial investments and private venture capital funding of nanotechnology research.

93. U.S. CONST. art. I, § 8, cl. 8.

94. *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).

95. *See* Sabety, *supra* note 16, at 4–5.

96. *Id.*

of academia.[97] In response, Congress set out to amend the Patent Act to promote technology transfer from universities and to foster private investment and the development of publicly financed research. The resulting amendments to the Patent Act, as codified in the Bayh-Dole Act, were signed into law in December 1980. The purpose of the Bayh-Dole Act was codified in 35 U.S.C. § 200:

> It is the policy and objective of the Congress to use the patent system to *promote the utilization of inventions arising from federally supported research or development*; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to *ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery*; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.[98]

The Bayh-Dole Act reversed prior policy by permitting universities and small business entities ("contractors") to retain private intellectual property ownership rights based on government sponsored research.[99] This legislation immediately invigorated the development of biotechnology on a fundamental level, producing patents, licensing revenues, and biotechnology licensees through the 1980s.[100] However, as discussed in Part III, a biotechnology patent anticommons also developed, ultimately slowing the overall pace of innovation in an otherwise promising field by creating a thicket of patent rights on fundamental research techniques and technologies. Yet while the Bayh-Dole Act has served to foster the development of a patent thicket, it also provides the framework for a solution to that very problem.

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97. *See* 126 CONG. REC. 23,30360 (1980) (statement of Sen. Dole). Senator Dole states that of the 28,000 inventions funded by the Government, only about 5 percent have been used commercially. *Id.*

98. 35 U.S.C. § 200 (2000) (emphasis added).

99. 35 U.S.C. § 202(a), (c) ("The term 'contractor' means any person, small business firm, or nonprofit organization that is a party to a funding agreement."). 35 U.S.C. § 201(c).

100. Mary Eberle, Comment, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155, 158–59 (1999) ("Prior to 1981, university researchers obtained less than 250 patents per year, whereas slightly a decade later, this number increased to almost 1600 per year.").

In exchange for the right of contractors to take private title to patents, funding federal agencies retain two significant rights under the Bayh-Dole Act. First, the federal agency retains march-in rights, which allow it to require the contractor, assignee, or exclusive licensee of a funded patent to grant a reasonable license to a responsible applicant.[101] If the contractor refuses the federal agency's request, the agency can grant a license to the applicant itself if "the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use" or if "action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees . . . ."[102] Theoretically, the march-in right demonstrates the power of the government to prevent the nonuse of patents in the context of patent hoarding or blocking patents used to stifle competition. However, the march-in right never has been exercised by the U.S. government in the twenty-four-year history of the Bayh-Dole Act.[103] The typical refusal by a federal agency to exercise its march-in rights is based on the government's view that exclusive licensees are taking effective steps to achieve practical application of the subject patent irrespective of the probability of success or delay in application of those steps.[104] From a practical standpoint, it is unlikely that innovators can influence federal agencies to march in on licensing disputes ex ante, and therefore nanotechnology advocates need to seek an alternate approach for promoting innovation above a patent thicket.

The second significant right the funding federal agency retains is the government license—a royalty-free license to practice any patented

101. 35 U.S.C. § 203(1)(a) states:

> [T]he Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license . . . .

Id.

102. 35 U.S.C. § 203(1)(a)–(c).

103. SUSAN KLADIVA, U.S. GEN. ACCT. OFF., GAO/RCED-98-126, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 4 (1998) ("According to Commerce officials, no agency has yet taken back the title to any inventions because they were not being commercialized."); *see also* Eberle, *supra* note 100, at 160.

104. *See* Eberle, *supra* note 100, at 166–68. For example, CellPro, a biotechnology company, asked the National Institutes of Health (NIH) in 1997 to exercise march-in rights and force Johns Hopkins University to grant CellPro a license to certain bone marrow transplant patents that had been licensed to Baxter International, Inc. *Id.* Although the FDA had approved CellPro's unlicensed product, Baxter's product had not been approved by the FDA. *Id.* The NIH refused to march in on the ground that Baxter was still making efforts to practice the licensed patent. *Id.*

technology funded by the government. The right to a government license for a federally funded invention is set out in § 202(c)(4) of the Bayh-Dole Act:

> Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:
>
>> (4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up *license to practice or have practiced for or on behalf of the United States* any subject invention throughout the world . . . .[105]

While it is clear from the above language that federal agencies have a government license to practice funded inventions, there is also room in this language to suggest that the congressional intent behind the Bayh-Dole Act supports a wider range of applicable licensed uses.[106] The phrase "license to practice or have practiced for or on behalf of the United States" traditionally has been interpreted—and exercised with little dispute—as it relates to military or space program contractors. However, this reading could be augmented to include contractors as defined by the Bayh-Dole Act: researchers who, through concurrent funding by the government, are conducting research "on behalf of the United States."[107] From this interpretation it follows that, under the right circumstances, contractors being funded by the government (through such laws as the Nanotechnology Act) should be able to practice governmentally funded, fundamental nanotechnology patents. Although the government license has been in operation as a part of the Patent Act since the Bayh-Dole Act's inception over two decades ago, it rarely has been mentioned in any litigation. The exception is *Madey v. Duke University*, which left the government license defense open for further interpretation.[108] Given the Federal Circuit's recent willingness to uphold the government's exercise of its rights to privatized patents held by

105. 35 U.S.C. § 202(c)(4) (emphasis added).

106. The legislative history of the Bayh-Dole Act reveals a congressional intent to read the government licenses broadly. The final language was amended to become more expansive than the final House draft of the bill, which merely secured minimum government rights to "a royalty-free worldwide license *to practice* the invention or *have it practiced for the Government*." (emphasis added). H.R. REP. NO. 96-1307, at 15 (1980), 1980 U.S.C.C.A.N. 6460, 6474. The Senate amendment to the Act expanded the scope of the government license from "to practice" and "have it practiced for the government" to a broader situation: "on behalf of" the government. H.R. 6933, 96th Cong., 94 Stat. 3015, 3024 (1980).

107. *See* 35 U.S.C. § 201(c).

108. *See supra* Part III.C.2.

contractors,[109] this more expansive interpretation of a government license defense to privatized patent infringement merits further examination.

By interpreting the government license as a broad defense against infringement for federally funded nanotechnology research, courts will further "promote the utilization of inventions arising from federally supported research or development" and "ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery."[110] Yet this interpretation of the government license need not be so radical as to presume that all recipients of government funding have an implicit license to infringe without compensating the patent holder. Infringers, even as fellow contractors of federally funded research, should not share the same rights as the federal agency's "nonexclusive, nontransferrable, irrevocable, paid-up license."[111] Instead, the government license should be made available to defendants in litigation involving federally funded patents in exchange for a compulsory licensing fee.

B. The Government License Defense as a Compulsory Licensing Regime

Compulsory licensing is generally defined as the granting of a license by a government to a third party to use intellectual property without the authorization of the intellectual property holder.[112] The intellectual property holder is unable to enjoin the infringer's use of the patent, but may receive royalty fees from the infringer. The U.S. Patent Act does not contain a general compulsory licensing section, as the United States generally promotes strong patent protection rights both domestically and abroad. However, although the concept of a general compulsory licensing regime in patent law is likely to meet strong resistance, compulsory licensing is not a completely alien aspect of U.S. law. Certain federal statutory provisions authorize compulsory licensing "for preventing air pollution, public health purposes, government use, atomic energy, aerospace,

109. *See* Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, 389 F.3d. 1243, 1249–50 (Fed. Cir. 2004). On Nov. 10, 2004, the Federal Circuit affirmed a decision seizing title to an invention because of the patent owner's failure to follow disclosure regulations requiring disclosing that the invention was government funded. *Id.* at 1244. This is the first time the government has used this power since the Bayh-Dole Act was passed in 1980. *Id.* at 1249–50.

110. 35 U.S.C. § 200 (policy and objective) (emphasis added).

111. 35 U.S.C. § 202(c)(4).

112. *See* BLACK'S LAW DICTIONARY 938 (8th ed. 2004) (defining compulsory license for patents as "[a] statutorily created license that allows certain people to pay a royalty and use an invention without the patentee's permission").

and national security."[113] In addition, compulsory licenses can be issued under antitrust laws to remedy anticompetitive practices,[114] and under copyright laws relating to the reproduction and distribution of musical compositions.[115]

A well-formulated government license defense would provide a means for overcoming the innovation-impeding effects of absolute exclusion rights by assessing infringement along a spectrum of use. If a court were to excuse an act of infringement under the government license defense, infringing contractors would have the chance to neutralize infringement liability by paying reasonable royalties.[116] The more commercial the infringement, the higher the royalty payment should be. The more experimental the infringement, such as use for scientific validation, the lower the royalty payment should be. Ultimately, the government license defense would satisfy the congressional intent of the Bayh-Dole Act in permitting the use of publicly funded research, free of injunctions, to other federally funded contractors to carry out research on behalf of the United States.[117]

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113. *See* Grace K. Avedissian, Comment, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of "Super-Terrorism,"* 18 AM. U. INT'L L. REV. 237, 253–54 (2002–2003). On air pollution, *see* The Clean Air Act, 42 U.S.C. § 7608 (2000). On public health, *see* David Reisner, *Bootstrap Approach to Nanotechnology Development & Value Creation: The View From Down Here*, 1 NANOTECHNOLOGY L. & BUS. J., May 2004, at 3 n.8. The case of the antibiotic Cipro also is illustrative:

> Consider the case of Bayer Healthcare, patent holder for the antibiotic Cipro for the treatment of inhaled anthrax. In 2001, the federal government needed large quantities of Cipro fast and did not care who made it—the government felt it had a right based on need in the public interest of health and safety to insist that Bayer make it available or it would go to generic drug manufacturers.

Id. On government use, *see* 28 U.S.C. § 1498(a) (2000) (giving patent holders the right to sue and claim compensation for the federal government's unauthorized use of a patent, or the government's licensing of a patent to third parties acting by or for the government). This code is not relevant in the context of this Comment, as the government has explicit authorization for the use of funded patents under the Bayh-Dole Act, 35 U.S.C. § 202(c)(4). On atomic energy, *see* The Atomic Energy Act, 42 U.S.C. § 2183(e). On aerospace, *see* 42 U.S.C. § 2457. On national security, *see* 35 U.S.C. § 181.

114. *See* James Love & Michael Palmedo, *Examples of Compulsory Licensing of Intellectual Property in the United States*, ch. 3 (Sept. 29, 2001) (listing antitrust cases arising from mergers and acquisitions involving companies such as Dow Chemical, Union Carbide, Halliburton, and Pharmacia/Upjohn, as well as antitrust activity relating to Microsoft Windows licensing), *at* http://www.cptech.org/ip/health/cl/us-at.html (last visited Aug. 14, 2005).

115. *See* The Copyright Act, 17 U.S.C. § 115 (2000).

116. Congressional intent to use royalties in the context of the Bayh-Dole Act is expressed in floor debates discussing provisions of the bill that provide royalties from contractors to compensate the government, in order to offset "windfall profits" at the expense of the taxpayers, while still encouraging commercialization of the inventions. *See* 126 CONG. REC. 29,899 (1980) (statement of Rep. Ertel).

117. The use of the government license in this manner is supported by the concerns voiced in the House Committee Report about the use of public tax funds to "create exclusive rights to one company." In promoting research free of injunctions, for the benefit of the public and for increased technological production, the government license defense

The spectrum of federally funded patent use by contractors can be assessed using a concept similar to the fair use doctrine of copyright. Although no fair use doctrine currently exists for patent infringement, Professor Maureen O'Rourke describes a system that could be used by a court to assess practically the amount of the royalty to pay under a proposed compulsory licensing regime.[118] "The copyright doctrine of fair use arose in part, and is justified, as a mechanism to overcome market failures that would otherwise prevent socially desirable uses of the protected work from occurring."[119] The fair use defense is "a long-standing equitable doctrine that fine-tunes the scope of a copyright over time."[120] In proposing an extension of fair use principles in patent law, O'Rourke describes five factors relevant to a fair use finding:

> (i) the nature of the advance represented by the infringement; (ii) the purpose of the infringing use; (iii) the nature and strength of the market failure that prevents a license from being concluded; (iv) the impact of the use on the patentee's incentives and overall social welfare; and (v) the nature of the patented work.[121]

In addition to these factors, an assessment of how well the infringing use aligns with the goals of the Bayh-Dole Act—as set out in the text and legislative history of the Act[122]—should be conducted before determining the reasonable level of a royalty to pay the patentee when a court finds that the government license defense applies.

The practical application of such a proposed government license defense, coupled with a compulsory licensing mechanism, is further suggested by the text of the Bayh-Dole Act. Under § 202(c)(5), federal agencies retain the right to periodic reporting on utilization and efforts at obtaining utilization by the researcher and his licensees.[123] This right gives the

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resolves a primary argument against the privatization of publicly funded patents. H.R. REP. No. 96-1307(I), at 29–32 (1980), 1980 U.S.C.C.A.N. 6460, 6487–91 (dissenting views of Hon. Jack Brooks).

118. *See* O'Rourke, *supra* note 88, at 1177.

119. *Id.* at 1180.

120. *Id.* at 1188.

121. *Id.* at 1205.

122. *See supra* Part IV.A for the specific goals of the Bayh-Dole Act as set out in 35 U.S.C. § 200 (2000). The legislative history behind these goals reveals that it was Congress's intent to promote a primary patent policy that encouraged innovation and commercialization. 126 CONG. REC. 22,29890–29899 (1980) (comments by Sen. Kastenmeier).

123. 35 U.S.C. § 202(c)(5) provides in pertinent part:

> That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.

Id.

government a means to monitor how effective funded patent holders are in making efforts to license nanotechnology to others. Section 202(c)(6) further provides clear notice to any potential patent licensee of the status of the government's license by requiring that a contractor's patent specification include an express statement indicating that the invention was made with government support, and that the government has certain rights in the invention.[124] In cases involving nonprofit organization contractors, § 202(c)(7) already provides detailed and specific instructions on royalty percentage distributions and uses of the royalties in supporting additional research.[125] This approach could be expanded to include instructions on calculating reasonable royalties among contractors.

Furthermore, the existing government license text of § 202(c)(4) of the Bayh-Dole Act states that "the funding agreement may provide for such additional rights . . . as necessary for meeting the obligations of the United States under any treaty, international agreement . . . or similar arrangement."[126] Given the significant level of international interest in nanotechnology, as evidenced by research and development funding as well as world market estimates, special attention to U.S. obligations to

124. 35 U.S.C. § 202(c)(6).

125. 35 U.S.C. § 202(c)(7) provides:

> In the case of a nonprofit organization . . . (B) a requirement that the contractor share royalties with the inventor; (C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year up to an amount equal to 5 percent of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility; provided that if said balance exceeds 5 percent of the annual budget of the facility, that 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent shall be used for the same purposes as described above in this clause (D); and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

Id.

126. 35 U.S.C. § 202(c)(4).

current and future international treaties relating to nanotechnology may have an impact on what the government is already authorized to "provide for . . . [as far as] additional rights."[127] In some countries, compulsory licensing of patents is allowed in such circumstances as when a patent is not being worked, when a dependent patent is being blocked, or when the patent relates to food or medicine.[128] In the area of patents, Article 31 of the TRIPS Agreement already permits World Trade Organization members to grant compulsory patent licenses under the limited circumstances of national emergency, antitrust violations, and public noncommercial use.[129] Future intellectual property harmonization or nanotechnology treaties could also expand existing government license rights. Other countries have little cause to object to this proposed augmentation of the government license defense because there is no impact on foreign intellectual property. The proposed changes only apply to domestic, federally funded research patents with title rights that, under the Bayh-Dole Act, the U.S. government has elected to give to contractors under certain conditions. This proposal merely adjusts those conditions.

C. Application of the Government License Defense to the Nanotechnology Act

The Nanotechnology Act effectively institutionalizes nanotechnology research at the federal level by requiring $3.7 billion in funding between 2005 and 2008 for research and development leading to potential breakthroughs in areas such as materials, manufacturing, electronics, medicine, biotechnology, environmental management, energy, chemicals, agriculture,

127. *Id.*

128. Joseph A. Yosick, Note, *Compulsory Patent Licensing for Efficient Use of Inventions*, 2001 U. ILL. L. REV. 1275, 1276 (citing examples of compulsory licensing in Japan, Germany, and the United Kingdom).

129. *See* Avedissian, *supra* note 113, at 251–52. The TRIPS Agreement, art. 31

> lists the following preconditions to granting a compulsory license: (a) each case must be considered on its merits; (b) the licensee must first attempt to seek authorization from the patent holder on reasonable commercial terms and within a reasonable time frame; (c) the scope and duration of the license must be limited to its authorized purpose; (d) the license cannot be exclusive; (e) the license cannot be assigned; (f) the licensee must predominately supply the domestic market of the country granting the license; (g) the license must terminate once an authoritative body determines that the circumstances giving rise to the compulsory licensing have ceased to exist and will not reoccur; (h) the patent holder must be adequately compensated; (i) decisions regarding the issuance of a license and royalty fees must be subject to judicial review; (j) provisions (b) and (f) shall not apply in cases arising from anti-competitive practices.

Id. at 251 n.75.

and information technology.[130] In particular, the Nanotechnology Act calls for the funding of federal agencies including the National Science Foundation (NSF), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), the National Institute of Standards and Technology (NIST), and the Environmental Protection Agency (EPA).[131] The legislation also requires the creation of research centers, education and training efforts, studies into the societal and ethical consequences of nanotechnology, and activities directed toward transferring technology into the marketplace. With nearly 47 percent of the funding, the NSF receives the most money from the Nanotechnology Act,[132] totaling over $1.7 billion over the next four years.[133] NSF funding is already earmarked for university research centers,[134] and several universities have leveraged groundbreaking discoveries and obtained government funding and private contributions to set up centers to promote multidisciplinary research in nanotechnology. These university-based nanotechnology research centers are in a prime position to secure bids for significant shares of the new funding from the Nanotechnology Act; ultimately, they should have an augmented government license defense in order to carry out incremental and innovative research effectively without becoming unduly encumbered by a nanotechnology patent thicket.

The government license defense could be implemented by amending the Nanotechnology Act to state clearly that, under § 202(c)(4) of the Bayh-Dole Act, all contractors are deemed to be conducting research "on behalf of the United States" and are therefore authorized to use a government

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130. *See* Johnson, *supra* note 5.

131. Alexander, *supra* note 3.

132. National Science Office, Office of Legislative and Public Affairs, National Science Board Approves Award for a National Nanotechnology Infrastructure Network (Dec. 22, 2003), *at* http://www.nsf.gov/od/lpa/news/03/pr03150.htm (last visited Sept. 15, 2005). The National Science Board stated:

> The NSF is an independent federal agency that supports fundamental research and education across all fields of science and engineering, with an annual budget of nearly $5.3 billion. NSF funds reach all fifty states through grants to nearly 2000 universities and institutions. Each year, the NSF receives about 30,000 competitive requests for funding, and makes about 10,000 new funding awards. The NSF also awards over $200 million in professional and service contracts yearly.

Id.

133. *See* 15 U.S.C.S. § 7505 (2005).

134. *See* National Science Office, *supra* note 132. For example, the National Science Board, the twenty-four-member policy advisory body of the NSF, has authorized an investment of at least $70 million to fund a National Nanotechnology Infrastructure Network (NNIN), consisting of thirteen university sites "that will form an integrated, nationwide system of user facilities to support research and education in nanoscale science, engineering, and technology." *Id.*

license defense in litigation arising out of infringement of other contractors' patents under the Nanotechnology Act. Although existing patent holders may complain that the expansion of the government license defense unduly impacts their rights, the defense is double edged: Any intellectual property rights secured under government sponsorship would be subject to the same defense to infringement by others.[135] Further, since the Nanotechnology Act goes into effect for funding in 2005, it is unlikely that any funded inventors have already filed or established patents from Nanotechnology Act-funded research. All researchers can begin on equal terms.

CONCLUSION

The application of nanotechnology has exciting prospects for people throughout the world, both in the near term and for many years to come. In light of the influx of funding from the Nanotechnology Act, contractors should be able to make many useful inventions. The importance of securing, maintaining, and leveraging nanotechnology patents has been recognized by nanotechnology innovators, but this protection also can impede innovation by creating a patent thicket. Too many overlapping, broad, and ill-conceived patents in the hands of a multitude of exclusive rights holders will deter future inventions. With the demise of the experimental use defense and the escalation in infringement damages, researchers using Nanotechnology Act funding need an augmented government license defense to help bring nanoproducts to market within reasonable time frames. For situations in which innovators are able to identify the particular patents they may be infringing, voluntary licensing of funded patents should, and still will, take place. In fact, the threat of a compulsory license or fair use royalty may inspire parties to come to a direct agreement from the outset. But when licensing attempts fail and the government continues to refuse to exercise its march-in rights, or when researchers unknowingly have infringed a claim from some obscure or overlapping patent, the government license defense will provide a fair and reasonable alternative to research and development stagnation.

135. *See* Newberger, *supra* note 77.

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