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Nanotechnology and the Experimental Use Defense to Patent Infringement

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I. INTRODUCTION

According to the American Cancer Society, "[c]ancer is the second leading cause of death in the United States."[1] Over 500,000 people died from cancer in

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The author would like to note that he drafted this comment primarily during the 2003-04 academic year. Subsequently, the Supreme Court decided a case involving the experimental use defense to patent infringement. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005). However, *Merck* concerns an interpretation of the statutory experimental use exemption under 35 U.S.C. § 271(e)(1). *See id.* at 2383-84 (holding that uses of patented inventions in preclinical research, the results of which are not ultimately submitted to the Food and Drug Administration, are exempted from infringement under section 271(e)(1)). *Merck* did not address the common law experimental use defense. Accordingly, the principal case discussed herein, *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), remains good law and is the most important decision to date involving the common law experimental use defense. In addition, in the interim between drafting this comment and publishing it, several articles have been published which discuss nanotechnology and patent law. *See, e.g.*, Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601 (2005).

1. American Cancer Society, *What is Cancer?*, http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_What_Is_Cancer.asp?sitearea= (last visited Mar. 19, 2006) (on file with the *McGeorge Law Review*).

2001.[2] Half of all men and one-third of all women will develop this disease during their lifetime.[3] However, early detection and treatment can lengthen patients' lives.[4] In fact, if cancer is found early enough, it can often be cured entirely.[5] As a result, medical professionals today face the complex problem of determining how to detect cancer early enough to prevent the death, or at least prolong the life, of a cancer victim.[6] So, how can cancer be detected early enough to prevent death or prolong life? One possible answer: nanotechnology.[7]

Scientists have recently developed a new technique involving the use of nanoparticles to detect certain diseased molecules in the human body.[8] By exposing human blood to nanoparticles that are covered with DNA and certain antibodies, molecules that indicate specific human diseases can be revealed.[9] Accordingly, this application of nanotechnology can be used to detect certain cancers, such as prostate cancer and breast cancer.[10] While nanoparticle disease detectors are not commercially marketable at this time,[11] this application of nanotechnology is merely an illustration of the many potential applications that nanotechnology promises to provide.[12]

Nanotechnology is predicted to trigger the next technological revolution.[13] As a result, the federal government and private industry provide billions of dollars per year in nanotechnology research and development funds.[14] As with any innovative commercial technology, nanotechnology inventors seek patent protection in increasing numbers.[15]

The grant of a patent by the United States Patent and Trademark Office gives its owner the exclusive right to make, use, and sell the patented invention.[16] If

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2. Infoplease, *Fifteen Leading Causes of Death in the U.S., 2001*, *available at* http://www.infoplease.com/ipa/A0005110.html (last visited Mar. 25, 2004) (on file with the *McGeorge Law Review*).

3. American Cancer Society, *supra* note 1.

4. *Id.*

5. American Cancer Society, *Can Cancer Be Prevented?*, http://www.cancer.org (last visited Mar. 25, 2004) (on file with the *McGeorge Law Review*).

6. *See id.* (describing ways to avoid getting cancer).

7. *See* John D. Schrock, *Nanosphere's Newest Detector Zeroes in on Specific Diseases*, SMALL TIMES (Jan. 7, 2004), *available at* http://www.smalltimes.com/document_display.cfm?document_id=7177 (copy on file with the *McGeorge Law Review*) (discussing nanotechnology-based molecular detection tools).

8. *Id.*

9. *Id.*

10. *Id.*

11. *See id.*

12. *See infra* Part II.C (discussing the wide range of applications of nanotechnology).

13. *See* Michael P. Williams, *Questions Abound About Patents and Nanotechnology*, N.Y.L.J., Sept. 15, 2003, at T7 (raising the possibility that nanotechnology could develop the next business revolution just as "railroads, radio, television, computers, biotechnology, and the Internet" did over the last two hundred years).

14. Barnaby J. Feder, *Technology Briefing Nanotechnology: House Authorizes $2.36 Billion for Research*, N.Y. TIMES, May 8, 2003, at C4; Williams, *supra* note 13.

15. *See* Williams, *supra* note 13 (noting that as of September 2003, more than three thousand patents have been issued to nanotechnology related inventions since 1996).

16. 35 U.S.C.A. § 154(a)(1) (West 2001).

someone other than the patent owner uses the patented invention, he will often be liable for patent infringement.[17] However, prior to 2002, a common law defense to patent infringement, known as the experimental use defense, allowed an alleged infringer to escape infringement liability if his use was for non-commercial experimental or research purposes.[18]

Then, in *Madey v. Duke University*, the Court of Appeals for the Federal Circuit virtually eliminated the experimental use defense by holding Duke University liable for patent infringement based on the use of patented inventions solely for experimental and research purposes.[19] Since nanotechnology is relatively new, and since there are billions of dollars in federal funding for nanotechnology, much of the development of nanotechnology will be by way of university-based research.[20] Therefore, *Madey* has the potential to stifle the development of nanotechnology by holding universities liable for patent infringement or, more practically, by requiring universities to obtain licenses from nanotechnology patent holders in order to avoid patent infringement.[21]

This Comment argues that the Federal Circuit's decision in *Madey*, by virtually eliminating the experimental use defense to patent infringement, will stifle the development of nanotechnology to the detriment of society.[22] Part II begins with a basic definition of nanotechnology and then details the development of nanotechnology as a legitimate science in the late-twentieth century.[23] Part II goes on to discuss the practical applications of nanotechnology and the patent rights available to nanotechnology inventions.[24] Part III provides a history of the judicially created experimental use defense to patent infringement prior to *Madey* and then discusses the Federal Circuit's decision in *Madey*.[25] Part IV explains how an exceedingly narrow experimental use defense will stifle the development of nanotechnology.[26] Specifically, Part IV elucidates similarities between arguments that have been made over the past two decades to protect biotechnology innovation and arguments that can be made today to prevent the stifling of nanotechnology.[27]

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17. 35 U.S.C.A. § 271(a) (West 2001).
18. *See infra* Part III.B.
19. Madey v. Duke Univ., 307 F.3d 1351, 1362-63 (Fed. Cir. 2002).
20. *See infra* Part IV.
21. *See infra* Part IV.
22. *See infra* Part IV.
23. *See infra* Part II.A-B.
24. *See infra* Part II.C-D.
25. *See infra* Part III.
26. *See infra* Part IV.
27. *See infra* Part IV.

II. NANOTECHNOLOGY

A. Definition(s)

The term "nanotechnology" is difficult to define precisely. Most commentators define nanotechnology in either a general sense or a specific sense.[28] In a general sense, nanotechnology refers to the branch of science that deals with objects on the nanometer scale.[29] A nanometer is one-billionth of a meter.[30] The nanometer scale thus involves very small objects that cannot be seen by the naked eye.[31] In a specific sense, nanotechnology refers to the process of creating materials by specifically rearranging atoms or molecules at the nanometer scale.[32] In any event, under both the general definition and the specific definition, nanotechnology essentially describes what nature has been doing since the beginning of time: "making things atom by atom with just the right properties to perform a specific function."[33]

B. Background

The concept of nanotechnology was first introduced in 1959.[34] Richard Feynman, a scientist and Nobel laureate, described his "ultimate vision" of nanotechnology in a speech at the California Institute of Technology.[35] As

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28. *See, e.g.*, Fredrick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593, 595 (1994) (defining nanotechnology specifically as "manipulating matter on an atom-by-atom or molecule-by-molecule basis to attain desired configurations"); Kelly Kordzik, *Small New World*, NAT'L L.J., Dec. 16, 2002, at C1 (defining nanotechnology generally as "technology at the nanoscale"); Barry Newberger, *Intellectual Property and Nanotechnology*, 11 TEX. INTELL. PROP. L.J. 649, 650 (2003) (defining nanotechnology generally as "the application of science at the nanoscale"); Joel Rothstein Wolfson, *Social and Ethical Issues in Nanotechnology: Lessons From Biotechnology and Other High Technologies*, 22 BIOTECHNOLOGY L. REP. 376, 376 (2003) (defining nanotechnology both generally and specifically as "the creation of molecule-size machines and other devices and the manipulation of substances molecule by molecule"); Wei Zhou, *Ethics of Nanobiotechnology at the Frontline*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 481, 482 (2003) (defining nanotechnology generally as "the science and technology pertaining to visualization, manipulation, and control of materials at the nanometer scale"); Williams, *supra* note 13 (defining nanotechnology specifically as involving "the methods and processes that create materials by specifically rearranging atoms or molecules at the nanometer scale").

29. Zhou, *supra* note 28, at 482.

30. Kordzik, *supra* note 28; *see also* R. Colin Johnson, *Descending From the Micro- to Nano-scale Electronics Promises to Extend Moore's Law Indefinitely—Nanotechnology Is Rebuilding Electronics One Atom at a Time*, ELECTRONIC ENGINEERING TIMES, Sept. 16, 2002, at A55 (noting that "nano" derives from the Greek word for "dwarf").

31. Kordzik, *supra* note 28. To put in perspective just how small the nanometer scale is, consider the following examples. The diameter of a human hair is 80,000 nanometers, which is enormous on the nanometer scale. On the other hand, an atom is slightly smaller than a nanometer. A nanometer is roughly the width of four atoms. *Id.*

32. Fiedler & Reynolds, *supra* note 28, at 595.

33. Kordzik, *supra* note 28.

34. Johnson, *supra* note 30.

35. *Id.*

Feynman prophetically suggested, "[t]he principles of physics, as far as I can see, do not speak against the possibility of maneuvering things atom by atom."[36]

Feynman's concept of molecular manipulation was innovative indeed. In fact, Feynman's idea did not gain acceptance in the scientific community for quite some time; instead, it provoked an abundance of science fiction literature regarding nanotechnology.[37] Science fiction authors surmised that nearly all devices could be created by microscopic robots working one atom at a time.[38] Some even hypothesized about an ultimate human catastrophe, called the Gray Goo catastrophe, in which self-replicating robots would multiply out of control and destroy humanity.[39] While some still believe nanotechnology has this inherent devastating potential,[40] the scientific community eventually embraced nanotechnology as a legitimate science.

In the early 1980s, scientific breakthroughs in nanotechnology at last emerged.[41] Researchers developed a technique called scanning probe microscopy, which allows for the arrangement of single atoms into particular molecular configurations.[42] This breakthrough, which permits scientists to manipulate single atoms, spurred scientific literature that explored the possibilities of nanotechnology.[43]

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36. Fiedler & Reynolds, *supra* note 28, at 597 (quoting Richard Feynman).

37. *See* Johnson, *supra* note 30 (discussing science fiction authors' speculations).

38. *Id.*

39. Barnaby J. Feder, *Nanotechnology Has Arrived: A Serious Opposition is Forming*, N.Y. TIMES, Aug. 19, 2002, at C3.

40. *See* Ralph C. Merkle, *Nanotechnology: What Will It Mean?*, IEEE SPECTRUM, Jan. 2001, at 19 (pointing out that two notable commentators, Eric Drexler and Bill Joy, have discussed the potential problems of nanotechnology). In 2000, Bill Joy, the cofounder and chief scientist of Sun Microsystems, wrote a controversial article that spurred much discussion throughout the scientific community. Bill Joy, *Why the Future Doesn't Need Us*, WIRED MAG., Apr. 2000, *available at* http://www.wired.com/wired/archive/8.04/joy_pr.html (on file with the *McGeorge Law Review*). Joy argued that the combination of twenty-first century technologies, consisting of robotics, genetic engineering, and nanotechnology, "are threatening to make humans an endangered species." *Id.* Joy's forecast for the future of technology was influenced by his career as a computer scientist, his general interest in technology, and his substantial review of technology literature (which, interestingly enough, included a discussion of Theodore Kacynski's Unabomber Manifesto). *Id.* Regarding nanotechnology, Joy proclaimed:

> Unfortunately, as with nuclear technology, it is far easier to create destructive uses for nanotechnology than constructive ones. Nanotechnology has clear military and terrorist uses, and you need not be suicidal to release a massively destructive nanotechnological device—such devices can be built to be selectively destructive, affecting, for example, only a certain geographical area or a group of people who are genetically distinct.

Id. Joy goes on to describe that the ultimate problem with nanotechnology, as well as with genetics and robotics, is that it has the power of destructive self-replication. *Id.* This self-replication argument has been rebutted by other commentators. *See* Merkle, *supra*, at 20 (pointing out that while nanotechnology will indeed use self-replication, it will not replicate living systems and therefore will not be able to self-replicate beyond human control in the way that a biological self-replicating system can). Ultimately, Joy proposes that the only realistic alternative to the possible destruction of humanity is to limit the pursuit of certain types of knowledge. Joy, *supra*.

41. Johnson, *supra* note 30.

42. *See id.* Scanning probe microscopy is comprised of two distinct tools: the scanning tunneling microscope and the atomic force microscope. *Id.*

43. For example, Eric Drexler popularized the term "nanotechnology" in his seminal 1986 book, *Engines of Creation*. *Id.*

This literature included nanotechnology pioneer Eric Drexler's proposal for an innovative manufacturing technology called bottom-up manufacturing.[44]

Traditional manufacturing processes employ top-down manufacturing.[45] Top-down manufacturing essentially means that one takes larger objects and makes smaller objects out of them.[46] For example, creating a sculpture from a large block of stone is a primitive type of top-down manufacturing. The sculptor must chisel, grind, shape, and sand the block of stone until he obtains the desired configuration. This process results in significant wasted stone and potentially damaging environmental effects from chiseling, grinding, shaping, and sanding the block.

Bottom-up manufacturing, conversely, takes smaller objects and creates larger objects.[47] The smaller objects can be individual atoms and molecules. By multiplying and manipulating these atoms and molecules in a particular way, one can create a desired object.[48] Living organisms, such as plants or human beings, are essentially created in this manner.[49] In the sculpture example, the same sculpture could be created using bottom-up manufacturing. If created in this manner, the sculpture would have all of its unique characteristics without any wasted stone or environmentally harmful manufacturing techniques.[50]

The next major development in nanotechnology came in 1991 with the discovery of carbon nanotubes.[51] A carbon nanotube is a "strawlike structure with a one-atom-thick wall of carbon atoms."[52] When multiplied, carbon nanotubes create a strong material that some expect to replace steel and aluminum as the fundamental material out of which many everyday objects and structures are composed.[53] One problem with carbon nanotubes is their high cost.[54] Presently, it

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44. Fiedler & Reynolds, *supra* note 28, at 596-97.

45. *Id.*

46. *Id.*; *see also* Johnson, *supra* note 30 (defining top-down as "the building of materials and devices by carving, molding, or machining bulk materials with tools and lasers").

47. Fiedler & Reynolds, *supra* note 28, at 596; *see also* Johnson, *supra* note 30 (defining bottom-up as "the construction of devices starting with individual atoms").

48. Fiedler & Reynolds, *supra* note 28, at 596.

49. *See id.* (describing how a human body begins as a single cell, an ovum, and grows into approximately 75 trillion cells, a mature human being).

50. *See generally* Rocky Angelucci, *A Beginner's Guide to Nanotechnology*, DALLAS BUS. J., Sept. 10, 2001, *available at* http://dallas.bizjournals.com/dallas/stories/2001/09/10/focus2.html (describing the transformation from today's manufacturing techniques to nanotechnology manufacturing techniques as "crude, inefficient, polluting factories into factories able to build many different things with little or no modification economically and cleanly").

51. Behfar Bastani & Dennis Fernandez, *Intellectual Property Rights In Nanotechnology*, INTELL. PROP. TODAY, Aug. 2002, at 36.

52. Angelucci, *supra* note 50; *see also* Johnson, *supra* note 30 (defining carbon nanotubes as "cylinders as small as 1 [nanometer] in diameter grown from fullerenes to resemble a rolled-up sheet of graphite").

53. Angelucci, *supra* note 50. In fact, as pointed out by one commentator, a carbon nanotube "is structurally 100 times stronger than steel of the same weight." Johnson, *supra* note 30.

54. Angelucci, *supra* note 50.

is significantly more expensive to produce carbon nanotubes than to produce steel or aluminum.[55]

Since 1997, federal funding for research and development in nanotechnology in the United States has increased significantly.[56] Some notable politicians began to promote nanotechnology and its potential to become the next major technological breakthrough.[57] President Bill Clinton began federal funding of nanotechnology research and development by creating the National Nanotechnology Initiative.[58] In May 2003, the House of Representatives approved a bill that would provide $2.36 billion for nanotechnology research and development over the next three years.[59] With federal funding for nanotechnology in the billions,[60] the science will undoubtedly continue to grow and develop in the coming years. Nanotechnology is currently on the forefront of technology and could provide the next technological revolution.[61]

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55. *See id.* (noting that "nanotubes are still too expensive to use in everyday construction materials"). Angelucci also notes that the cost of producing carbon nanotubes has decreased significantly in recent years and predicts that manufacturers will develop broad uses for carbon nanotubes in the near future. *Id.*

56. *See* National Nanotechnology Initiative, *Frequently Asked Questions*, http://www.nano.gov/html/facts/faqs.html (last visited Mar. 25, 2004) (on file with the *McGeorge Law Review*) (stating that in fiscal year 1997 federal funding of nanotechnology research and development was $116 million).

57. For example, former speaker of the U.S. House of Representatives Newt Gingrich is a strong advocate of nanotechnology. Steve Crosby, *Newt Goes Nano: Ex-House Speaker Named to Science/Business Alliance*, SMALL TIMES, (Dec. 13, 2001), *available at* http://www.smalltimes.com/document_display.cfm?document _id=2728. Gingrich believes that nanotechnology can lead to major breakthroughs in medicine, computers, manufacturing, and the environment. In addition, he believes that tremendous wealth will be generated by nanotechnology in the near future. As a result, Gingrich has argued heavily for increased governmental funding for nanotechnology. *Id.* In fact, Gingrich has even proposed government-funded monetary rewards for privately invented nanotechnology inventions. *See* Newt Gingrich, *National Woes? Dangle Prizes, Solutions Will Follow*, USA TODAY, Jan. 21, 2002, at 11A (arguing that by the government offering prizes, inventors would make scientific breakthroughs sooner).

58. Feder, *supra* note 14. The National Nanotechnology Initiative (NNI) is a federal research and development program that was created to centralize federal agency efforts in nanoscale science, engineering, and technology. National Nanotechnology Initiative, *About the NNI*, http://www.nano.gov/html/about/home_about.html (last visited Mar. 25, 2004) (on file with the *McGeorge Law Review*). The NNI consists of sixteen federal agencies of which ten have research and development budgets for nanotechnology. *Id.* The NNI's goals are the following: "(1) conduct R&D to realize the full potential of this revolutionary technology; (2) develop the skilled workforce and supporting infrastructure needed to advance R&D; (3) better understand the social, ethical, health, and environmental implications of the technology; and, (4) facilitate transfer of the new technologies into commercial products." *Id.* Thus far, the federally funded programs that are a part of the NNI have seen much advancement in nanotechnology, including developments involving semiconductor nanocrystals, nano-electro-mechanical sensors, and nanotube-based fibers. *Id.*

59. Feder, *supra* note 14.

60. Some commentators have argued, however, that the federal government should spend much more on nanotechnology research than is currently being spent. *See, e.g.*, Kevin Maney, *Tiny Technology That Could: Nanotech Could Solve Oil Issues*, USA TODAY, Oct. 1, 2003, at 3B (arguing that Congress should spend $20 billion a year on energy-related nanotechnology research in order to lessen the United States' dependence on Middle Eastern oil).

61. *See* Williams, *supra* note 13.

C. Applications

Nanotechnology has broad applications. Since nanotechnology is essentially the concept of making things smaller, it has the potential to affect nearly all aspects of our lives.[62] Some specific areas where nanotechnology is expected to be beneficial include the following: consumer products, [63] manufacturing and the environment,[64] energy,[65] the military,[66] medicine,[67] computer hardware,[68] and space travel.[69]

The most noticeable application of nanotechnology to the ordinary person will be in the area of consumer products. Several products currently available on the market utilize nanotechnology. Clothing retailer Eddie Bauer uses nanofibers in its innovative stain- and wrinkle-resistant pants.[70] In addition, sunscreen manufacturers have employed nanotechnology to create sunscreens that block harmful ultra-violet light.[71] Products that are soon expected to employ

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62. *See generally* Merkle, *supra* note 40, at 19 (discussing the impact nanotechnology will have on society).

63. *See* discussion *infra* notes 70-74 and accompanying text (discussing consumer products).

64. *See* discussion *infra* notes 75-84 and accompanying text (discussing manufacturing and the environment).

65. *See* discussion *infra* notes 85-89 and accompanying text (discussing energy).

66. *See* discussion *infra* notes 90-97 and accompanying text (discussing the military).

67. Nanotechnology is predicted to assist in many facets of medicine. For example, nano-sized biochips could be inserted into the human body in order to detect diseased cells. Fiedler & Reynolds, *supra* note 28, at 601 (discussing devices that "would have dramatic implications for the practice of medicine"). Nanoparticles could be ingested in order to deliver drugs to predetermined areas of the human body with exact precision. Michael Becker, *At Nanoscale, the Laws of Humans May Not Apply*, (July 30, 2001) *available at* http://www.smalltimes.com/document_display.cfm?document_id=1798 (noting that certain medical applications will require regulators to carefully consider how to monitor these devices); Zhou, *supra* note 28, at 484 (discussing the application of biochips in the area of medical diagnostics). In addition, nanodevices could actually repair cells damaged by aging, or even destroy diseased cells, such as cancer cells. Fiedler & Reynolds, *supra* note 28, at 601.

68. In recent years, computer chips have become significantly smaller while at the same time have been able to process an increasing amount of information. It is estimated that today's computer chips contain 40 million transistors. It is predicted that nanotechnology will enable scientists to create even smaller chips that are capable of holding trillions of transistors. The end result would be faster and much more powerful computing systems than are currently available. *See* Merkle, *supra* note 40, at 19 (discussing computer hardware innovations); Julia A. Moore, *The Future Dances on a Pin's Head; Nanotechnology: Will It Be a Boon – Or Kill Us All?*, L.A. TIMES, Nov. 26, 2002, at B13 (discussing developments in computer chips).

69. NASA currently employs a 60-scientist nanotechnology team at its Ames Research Center located in Silicon Valley. A primary focus of the nanotech team is to create a spacecraft that has enough computing power on board so that it would not be entirely controlled from Earth. Nanotechnology has the potential of creating smaller and lighter computing that could make NASA's goal a reality. This accomplishment could conceivably allow NASA to send the first manned mission to Mars. *See* Ariana Eunjung Cha, *Big Potential From Small Things*, WASH. POST, Mar. 21, 2002, at E1 (discussing NASA's interest in nanotechnology).

70. Bernadette Tansey, *Molecular Might: Nanotech "Battle Suits" Could Amplify Soldiers' Powers*, S.F. CHRONICLE, Apr. 7, 2003, at E1.

71. Edward Epstein, *Silicon Valley Pins Hopes on Nanotechnology Boom: U.S. Ready to Spend Billions on Revolutionary Science*, S.F. CHRONICLE, May 8, 2003, at A1.

nanotechnology include cosmetics,[72] scratch-resistant eyeglass lenses,[73] and big-screen televisions.[74]

Perhaps the most revolutionary application of nanotechnology will be in the areas of manufacturing and the environment. Manufacturing will no doubt be transformed by what is sometimes called parallel assembly.[75] Parallel assembly is a process in which individual atoms, controlled by computers, self-replicate to create larger structures.[76] The process begins with a single nanosized robotic arm being instructed to make identical copies of itself so that within a short period of time millions of robotic arms are created.[77] Each robotic arm has a "sticky" arm capable of manipulating individual atoms.[78] The composition of robotic arms could then be told to build a particular product by using its "sticky" arms to maneuver and rearrange millions of atoms at a time.[79] Parallel assembly is the method by which bottom-up manufacturing would be possible.[80]

Bottom-up manufacturing would eliminate many of the environmentally damaging effects inherent in traditional manufacturing methods.[81] Nanotechnology promises additional benefits to the environment, however. For example, water filtration systems could be designed at the molecular level, which would result in cleaner drinking water.[82] Natural gas pipelines could also be designed at the molecular level, which would result in cleaner burning.[83] Nanoparticles could also be used as sensors to monitor air and water for particular toxic substances.[84] In sum, the combination of nanotechnology's beneficial environmental effects and enhanced manufacturing capabilities will likely be some of its most promising applications.

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72. *See* National Nanotechnology Initiative, *Applications/Products*, http://www.nano.gov/html/facts/appsprod.html (last visited Mar. 25, 2004) (on file with the *McGeorge Law Review*) (stating that cosmetics involving nanotechnology are available today).

73. *Id.*

74. *See* Kevin Maney, *Finally a Purpose for Nanotech to Turn on Average Joe: Big-screen TVs*, USA TODAY, July 9, 2003, at 3B (describing Nano Emissive Display, which Motorola is expected to use within three years to create 50-inch-wide flat-screen televisions that will cost consumers less than $1000).

75. Commentators have used different terms to describe essentially the same manufacturing process. *See, e.g.*, Merkle, *supra* note 40, at 21 (using the term "exponential assembly"); Angelucci, *supra* note 50 (using the term "parallel assembly"); Maney, *supra* note 74 (using the term "self-assembly").

76. Angelucci, *supra* note 50.

77. *Id.*

78. *Id.*

79. *Id.* Some critics of nanotechnology and self-replication have argued that the robotic arms could become out of control and replicate themselves at will. However, this theory has been struck down by many scientists. *See, e.g.*, Merkle, *supra* note 40, at 19-21 (pointing out that computer controlled self-replication is distinct from biological self-replication in that computer controlled self-replication can be stopped at any time by humans simply by disconnecting the robotic arms' power supply).

80. *See supra* text accompanying notes 47-50 (discussing bottom-up manufacturing).

81. *See supra* text accompanying notes 47-50 (discussing bottom-up manufacturing and its lack of environmentally harmful manufacturing techniques).

82. Jim Krane, *Nanoparticles: The Best Thing Since Plastic?*, SEATTLE TIMES, Sept. 9, 2002, at C3.

83. *Id.*

84. *Id.*

Nanotechnology may also have important implications in the energy industry. One commentator notes that nanotechnology "has the potential to make solar energy viable on a massive scale, allow hydrogen and methane to replace gasoline in cars, and make vehicles and planes far lighter so they use less fuel."[85] Currently, solar energy is an expensive form of energy; however, it is expected that nanotechnology could reduce the cost of making solar panels and thus allow solar energy to enter the mainstream market.[86] Replacing gasoline with alternative fuel sources would decrease oil consumption and in turn decrease foreign oil dependency, which would not only have economic benefits for the United States but would offer political benefits as well.[87] As discussed previously,[88] nanotechnology will likely create stronger and lighter materials, thus allowing less fuel consumption in common modes of transportation, such as automobiles and airplanes.[89]

Nanotechnology also has important applications to the military. Already, the Massachusetts Institute of Technology (MIT) has created the Institute of Soldier Nanotechnologies (the Institute), which is funded by a five-year Army grant of $50 million.[90] MIT professors working in the Institute anticipate significantly improving a soldier's gear through the use of nanotechnology.[91] Some ideas that are currently being researched and designed include the following: waterproof Kevlar vests with a layer of one-molecule thick flouropolymer, self-protecting clothing that can harden on command, and simulated muscles made of polymer fibers that will assist soldiers in carrying heavy loads.[92] In addition to university-based research, private companies are also exploring applications that nanotechnology might have in the context of the military.[93] For example, Nanosys Inc. is developing thermoelectric devices that could be used to enable a soldier to send signals to other soldiers and devices that provide self-cooling systems for soldiers.[94] Each of these applications has the vital utility of increasing a soldier's capabilities while at the same time decreasing, or at least not significantly increasing, the weight of a soldier's gear.[95] Admittedly, many of these nanotechnology devices are in their early stages of development and may not be available for many years.[96] However, if made available, the scope of these

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85. Maney, *supra* note 60.

86. *Id.*

87. *Id.*

88. *See supra* notes 51-55 and accompanying text (explaining how carbon nanotubes will lead to stronger and lighter materials).

89. Maney, *supra* note 60.

90. Tansey, *supra* note 70.

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

devices is expected to extend beyond the military and include applications for police officers, firefighters, and emergency personnel.[97]

D. Patent Law and Nanotechnology

In the United States, patent rights were first recognized in the Constitution.[98] The framers granted Congress the explicit power "[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."[99] Congress exercised this power by enacting the Patent Act of 1790.[100] A subsequent version of this legislation, the Patent Act of 1952, is the modern statutory authority for patent rights in the United States.[101] The United States Patent and Trademark Office (USPTO), a federal agency within the Department of Commerce, is responsible for granting and issuing patents to inventors.[102]

A patent[103] gives its owner the legal right to exclude others from making, using, or selling his patented invention.[104] While a patent owner enjoys exclusive rights to his patented invention, an inventor must first meet stringent statutory requirements in order to obtain patent protection from the USPTO.[105] First, the inventor must demonstrate that the type of invention sought to be patented falls within the statutory definition of patentable subject matter.[106] Patentable subject matter is a low threshold requirement and is broadly defined to include any "process, machine, manufacture, or composition of matter."[107]

Once the patentable subject matter hurdle is overcome, the inventor must then satisfy several fundamental statutory elements required to obtain a patent.[108]

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97. *Id.*

98. U.S. CONST. art. I, § 8, cl. 8.

99. *Id.*

100. Graham v. John Deere Co., 383 U.S. 1, 6 (1966). The Patent Act was amended by Congress nearly fifty times between 1790 and 1950. *Id.* at 10.

101. *See* 35 U.S.C.A. §§ 1-376 (West 2001) (addressing patents); *Graham*, 383 U.S. at 12-17 (discussing the 1952 Patent Act with a particular focus on the nonobviousness requirement).

102. *See* 35 U.S.C.A. § 1 (West 2001) (establishing the USPTO); 35 U.S.C.A. § 2 (West 2001) (listing the general powers and duties of the USPTO).

103. Throughout this comment I will use the term "patent" to refer to a utility patent, which is the most common type of patent the USPTO grants. Two other types of patents, a design patent and a plant patent, are also granted by the USPTO.

104. 35 U.S.C.A. § 271(a) (West 2001); *see infra* text accompanying notes 121-22 (discussing patent infringement).

105. 35 U.S.C.A. §§ 101-03.

106. *See* 35 U.S.C.A. § 101 (West 2001) (describing patentable inventions).

107. *Id.* The design of a manufactured item also falls within the definition of patentable subject matter. *See id.* § 171 (defining a design patent as an "ornamental design for an article of manufacture"). In addition, a plant falls within patentable subject matter. *See id.* § 161 (defining a plant patent as a "distinct and new variety of plant").

108. *See id.* §§ 101-03 (describing patentable inventions and the conditions of patentability).

The invention must be shown to be useful, novel, and nonobvious.[109] First, the utility requirement of section 101 mandates that an invention be put toward some useful purpose.[110] Second, and more difficult to comply with in many cases, is the novelty requirement of section 102, which requires that an invention be new.[111] The novelty requirement mandates that the invention be different from any previously developed and recognized technology.[112] Third, the nonobviousness requirement of section 103 requires that the invention not be "obvious at the time the invention was made to a person having ordinary skill in the art."[113] In addition to these three statutory elements, the inventor must also disclose how to make the invention, how to use the invention, and the best mode of carrying out the invention.[114]

If an inventor satisfies the statutory requirements, the USPTO will issue a patent for a term of twenty years from the date the patent application was filed.[115] Once a patent is awarded to an inventor, a contract essentially has been created between the patent owner and society.[116] The patent owner enjoys the right to exclude others from making, using, and selling the invention.[117] Society, on the other hand, now has access to the full disclosure of how to use and make the patented invention.[118] Ideally, this *quid pro quo* arrangement is beneficial both to the patent owner and to society. The inventor has a significant monetary incentive to obtain patent protection of a new technology and society has a need to promote and encourage rapid technological development,[119] just as the framers envisioned.[120]

One who impedes a patent owner's exclusive right to make, use, or sell the patented invention is generally liable to the owner for patent infringement.[121] It is important to note that since a patent merely grants the right to exclude others from infringing on a patent owner's invention, a patent owner must affirmatively

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109. *Id.*

110. *Id.* § 101.

111. *Id.* § 102.

112. *Id.*

113. *Id.* § 103(a).

114. *Id.* § 112.

115. 35 U.S.C.A. § 154(a)(2) (West 2001).

116. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024-36 (1989) (discussing the exclusive rights an inventor gets in exchange for an invention and its corresponding disclosure).

117. 35 U.S.C.A. § 271(a) (West 2001).

118. *See* Eisenberg, *supra* note 116, at 1028-30 (discussing an inventor's incentive to disclose the contents of his invention).

119. *See id.* at 1024-30 (discussing the exclusive rights an inventor gets in exchange for an invention and its corresponding disclosure).

120. *See* U.S. CONST. art. I, § 8, cl. 8 (granting Congress the power "[t]o promote the Progress of Science and Useful Arts").

121. 35 U.S.C.A. § 271.

pursue any claims of patent infringement in order to protect his exclusive right to the patented invention.[122]

For the most part, nanotechnology falls within patentable subject matter and thus a nanotechnology invention can be patented so long as the other statutory requirements are met.[123] Some commentators have raised the idea that nanotechnology inventions should not be patentable.[124] Nanotechnology, so the argument goes, is essentially the process of making existing technology smaller.[125] Making something smaller is not in itself patentable since the nonobviousness requirement of section 103 will not be met.[126] While this argument has intuitive appeal, it is flawed in the context of nanotechnology since creating existing technology on the nanoscale will often change the properties and characteristics of a particular invention.[127] For example, quantum dots are semiconductor nanostructures that have different properties than typical semiconductors.[128] Quantum dots have exceptional optical properties, based on their size, that are not found in typical semiconductors. Therefore, quantum dots are highly desired in certain industries.[129] At this point, despite a lack of case law regarding nanotechnology patents, it seems nanotechnology will be the newest major technology deemed patentable, following the lead of biotechnology,[130] computer software,[131] and business methods.[132]

Recently, the USPTO has experienced a surge in patent applications for nanotechnology inventions or for inventions containing some nanosized component.[133] In fact, some commentators have argued that the surge in nanotechnology patent applications has resulted in the USPTO being inadequately trained to handle the relatively new scientific area of nano-technology.[134]

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122. *See id.* § 271(e)(4) (prescribing the remedies available to a patent owner); *see generally* 3 JOHN GLADSTONE MILLS III ET AL., PATENT LAW FUNDAMENTALS § 18:3 (2003) (discussing the general nature of patent infringement actions).

123. *See* 35 U.S.C.A. § 101 (defining patentable subject matter to include any "composition of matter").

124. *See* Williams, *supra* note 13 (discussing whether nanotechnology should be patentable subject matter).

125. *Id.*

126. *See id.* (discussing the obviousness requirement).

127. *Id.*

128. *Id.*

129. *Id.*

130. *See* Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (holding that an artificially created oil-eating bacterium is patentable subject matter).

131. *See* Diamond v. Diehr, 450 U.S. 175, 191-93 (1981) (holding that a molding process which utilized a mathematical formula and a programmed digital computer is patentable subject matter).

132. *See* State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998) (holding that a data processing system used in multi-tiered partnership fund services is patentable subject matter).

133. *See* Williams, *supra* note 13 (stating that more than three thousand patents had been issued to nanotechnology-related applications between 1996 and 2003).

134. Doug Brown, *U.S. Patent Examiners May Not Know Enough About Nanotech*, SMALL TIMES, (Feb. 4, 2002) *available at* http://www.smalltimes.com/document_display.cfm?document_id=3035 (noting that some

However, private institutions are actively offering assistance to the USPTO as to how it can improve the nanotechnology patent process, and the USPTO seems to be taking active steps to properly train examiners in nanotechnology.[135] As a result, a significant number of nanotechnology-related patents have already been granted.[136] One commentator notes that as of September 2003, "more than 3000 patents [have been] issued to nanotechnology-related applications since 1996."[137] This recent trend demonstrates that nanotechnology-related patents will continue to increase in the coming years.

As the USPTO increasingly grants nanotechnology patents, infringement of nanotechnology patents will no doubt increase as well. Therefore, it can be anticipated that owners of nanotechnology patents will enforce their right to exclude others from making, using, or selling their nanotechnology inventions by bringing claims for patent infringement. As a result, alleged infringers will likely look to defenses to patent infringement in order to escape liability. A specific exception to patent infringement, known as the experimental use defense, is discussed in the following section.

III. THE EXPERIMENTAL USE DEFENSE TO PATENT INFRINGEMENT

A. *Background*

Statutory law clearly defines what activity constitutes patent infringement.[138] Patents in general are addressed in Title 35 of the United States Code.[139] The rights granted to a patent owner are spelled out in section 154, which states that "[e]very patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, . . . or selling the invention."[140] Infringement is addressed in section 271, which states that "whoever without authority makes, uses, . . . or sells any patented invention . . . infringes the patent."[141] Therefore,

experts believe the "U.S. patent examiners must become better educated about nanotechnology if the burgeoning industry is going to fully thrive").

135. On November 8, 2001, the Foresight Institute, a nonprofit organization with the goal of guiding emerging technologies to the benefit of society with a particular focus on nanotechnology, hosted a nanotechnology patent roundtable. Foresight Institute, *Nanotechnology Patent Roundtable*, http://www.foresight.org/Conferences/MNT9/Patents.html (last visited Mar. 25, 2004) (on file with the *McGeorge Law Review*). The meeting was expected to draw a wide range of people, including senior USPTO officials, patent attorneys, nanotechnology industry leaders, and law school faculty members. *Id.* The planners expected the discussion to include "the possibility of creating a special classification for nanotechnology patent applications, a creation of a database of nanotechnology related prior art and a creation of a nanotechnology industry/USPTO partnership to provide training for patent examiners in the current topics of nanotechnology." *Id.*

136. Williams, *supra* note 13.

137. *Id.*

138. *See* 35 U.S.C.A. § 271 (West 2001) (addressing infringement of patent).

139. *See id.* §§ 1-376 (addressing patents).

140. *Id.* § 154(a)(1).

141. *Id.* § 271(a).

according to the language of the statute, *any* making, using, or selling of a patented invention constitutes infringement.[142]

The only statutory exception to patent infringement is a narrow one that can only be used in the context of pharmaceuticals.[143] In 1984, Congress created an exception for generic drug manufacturers enabling them to conduct tests on near-expired patented drugs in order to obtain Food & Drug Administration approval.[144] Outside of this narrow exception, though, an alleged infringer has no statutory argument that his making, using, or selling of another's patented invention is justifiable.[145] Therefore, an alleged infringer must turn to the common law in search of defenses to patent infringement.

The experimental use defense to patent infringement has been recognized in the common law for nearly 200 years.[146] However, after all this time, there is a remarkably small amount of case law discussing the experimental use defense.[147] The scarcity of existing judicial opinions most likely has to do with the nature of experimental use. Using an invention for experimental purposes, such as an independent inventor testing the disclosure of a patent or a public university testing a patented invention for academic purposes, often does not involve commercialization.[148] The primary reason that a patent owner brings an infringement action, on the other hand, is to redress some sort of violation of the patent owner's commercial interests.[149] Since a patent owner does not necessarily have monetary incentives to litigate noncommercial, experimental infringement of his patent, few experimental use cases are in fact litigated.[150] In these relatively few cases that do involve the experimental use defense, the defense has rarely enabled the alleged infringer to escape liability for patent infringement.[151]

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142. *See generally* MILLS, *supra* note 122, § 18:3 (discussing patent infringement in general and stating that one of the elements of a prima facie case of patent infringement is that the plaintiff introduce "evidence that the defendant has engaged in any of the activities proscribed by 35 U.S.C.A. § 271").

143. *See* 35 U.S.C.A. § 271(e)(1). "It shall not be an act of infringement to make, use, . . . or sell . . . solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use, or sale of drugs." *Id.*

144. *See* Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369, 375-76 (1992) (discussing this exception, which was part of the Drug Price Competition and Patent Term Restoration Act of 1984).

145. *See id.* at 369 (stating, "[w]ith one minor exception the patent statutes do not suggest any instance in which use of a patented invention is not infringement").

146. *See infra* text accompanying note 154 (stating that courts first recognized the experimental use defense in 1813).

147. *See* Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617, 624 (1985) (stating that there have been only about twenty-nine cases involving the experimental use defense since it was first recognized in 1813).

148. *See* Lauren C. Bruzzone, *The Research Exemption: A Proposal*, 21 AM. INTELL. PROP. L. ASS'N Q.J. 52, 57 (1993) (explaining why few defendants prevail in asserting the experimental use defense).

149. *Id.*

150. *Id.*

151. *See infra* note 166 (stating that only seven cases have allowed the experimental use defense); *see also* 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03[1][b] (2002) (discussing lower court decisions prior to 1983).

B. The Common Law: Developing a Narrow Experimental Use Defense

The experimental use defense to patent infringement[152] was first enunciated in the early nineteenth century by Justice Joseph Story, a member of the United States Supreme Court and an influential jurist in the area of patent law.[153] Justice Story, while a member of the Massachusetts Circuit Court, first mentioned the concept of experimental use in the 1813 case of *Whittemore v. Cutter*.[154] In approving a jury instruction that went against the defendant in an infringement action, Justice Story explained that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[155] That same year, in *Sawin v. Guild*, Justice Story clarified the holding of *Whittemore*.[156] He stated that "the making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."[157] Synthesizing *Whittemore* and *Sawin*, Justice Story developed an experimental use defense to patent infringement that would turn on whether the alleged infringer had a commercial intent when infringing on another's patent.[158] If the alleged infringer had a commercial intent, then patent infringement liability would be proper. If, however, the alleged infringer did not have a commercial intent, then liability for patent infringement could be avoided.

Some courts applied Justice Story's defense in the nineteenth century.[159] In 1861, the court in *Poppenhusen v. Falke* declared that it is "now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee."[160] The next noteworthy articulation of the

152. The "experimental use defense to patent infringement" is not the same as the "experimental use exception" to the on sale bar of 35 U.S.C.A. § 102(b). Tom Saunders, *Renting Space on the Shoulders of Giants:* Madey *and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261, 261 n.1 (2003). Since each legal doctrine uses the term "experimental use," the doctrines are sometimes confused. The experimental use exception to the on sale bar of 35 U.S.C.A. § 102(b) has nothing to do with patent infringement. *See* 1 MILLS, *supra* note 122, § 8:10 (discussing experimental use in the context of 35 U.S.C § 102(b)). Rather, the experimental use exception operates to not prevent an inventor from obtaining a patent on an invention that was sold for certain experimental uses that would otherwise violate the requirement that an invention cannot be "on sale" for "more than one year prior to the date of the application for patent." *Id.* §§ 8:8, 8:10.

153. *See* 5 CHISUM, *supra* note 151, § 16.03[1][a] (discussing the historical development of the "experimental purpose" limitation on infringement).

154. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

155. *Id.* at 1121.

156. 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

157. *Id.* at 555.

158. Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 20 (2001).

159. Bruzzone, *supra* note 148, at 56.

160. 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

experimental use defense was by William C. Robinson in his influential 1890 treatise.[161] Summarizing the existing law at the time, Robinson stated:

> An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind. But if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent.[162]

Although some commentators have criticized Robinson's statements regarding the experimental use defense,[163] courts have consistently approved of his formulation.[164]

The common law experimental use defense described above was applied by some courts in the twentieth century.[165] *Ruth v. Stearns-Roger Mfg. Co.* was one of the few cases in which the alleged infringer successfully asserted the defense.[166] In *Ruth*, the defendant manufactured mining machinery and was sued for contributory infringement for selling several patented machines.[167] Defendant's sales included sales of machines and replacement parts to the Colorado School of Mines.[168] The School of Mines used its machines for experimental purposes in the school's laboratory.[169] The court held that most of the defendant's sales constituted infringement, but that the sale of parts to the School of Mines did not constitute infringement.[170] The court reasoned that the

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161. 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTION § 898 (1890).

162. *Id.*

163. *See* Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 819, 827 (1989) (discussing criticism by two commentators, Richard E. Bee and Ronald D. Hantman).

164. *See* Bruzzone, *supra* note 148, at 56 n.27 (noting that recent cases have cited Robinson's explanations with approval).

165. For an excellent discussion of all the cases from 1813 to 1984 that are said to involve the experimental use defense to patent infringement see Hantman, *supra* note 147, at 624-38.

166. 13 F. Supp. 697 (D. Colo. 1935). Analyzing the existing case law, Hantman found that only seven cases (three involving private parties and four involving the United States Government) allowed the experimental use defense. Hantman, *supra* note 147, at 624-38.

167. 13 F. Supp. at 699.

168. *Id.* at 699-700.

169. *Id.* at 703.

170. *Id.* at 713.

"making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement."[171] Therefore, in *Ruth*, the District Court of Colorado seemed to endorse the proposition that university research on patented technology in furtherance of educational purposes does indeed fall within the purview of the experimental use defense.

A more recent case out of the Court of Claims rejected the experimental use defense and held the defendant liable for patent infringement damages.[172] In *Pitcairn v. United States*, the defendant manufactured several models of helicopters that infringed eleven patents held by the plaintiff.[173] The defendant argued that the use of helicopters for testing and experimental purposes should not contribute to the plaintiff's infringement damages.[174] The appellate court adopted the trial judge's opinion, which held that the experimental use defense does not relieve the defendant of any liability.[175] The trial judge reasoned that "[o]bviously every new helicopter must be tested for lifting ability, for the effect of vibration on installed equipment . . . and numerous other factors."[176] The trial judge further concluded that "[t]ests, demonstrations, and experiments of such nature are intended uses of the infringing aircraft . . . and are in keeping with the legitimate business of the using agency."[177]

In 1984, the Federal Circuit heard one of the most important cases involving the experimental use defense.[178] In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, the defendant sought to market a generic version of the plaintiff's drug, a sleeping pill, immediately upon the expiration of the plaintiff's patent term.[179] It obtained the drug from a foreign source and began testing the drug during the final months of the plaintiff's patent term, in order to acquire FDA drug approval.[180] The Federal Circuit relied on *Pitcairn* in rejecting the defendant's experimental use argument and holding that the defendant infringed the plaintiff's patent.[181] The court reasoned that the defendant's use of the patented drug in hopes of marketing the drug was "solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[182] After *Roche*, it was evident that the experimental use defense was a narrow defense and

171. *Id.*

172. Pitcairn v. United States, 547 F.2d 1106, 1126 (Ct. Cl. 1977).

173. *Id.* at 1110.

174. *Id.* at 1124-25.

175. *Id.* at 1126.

176. *Id.* at 1125.

177. *Id.* at 1125-26.

178. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984). *See* Feit, *supra* note 163, at 830 (describing *Roche* as "[t]he most authoritative decision regarding the experimental use exception").

179. *Roche*, 733 F.2d at 860.

180. *Id.*

181. *Id.* at 863, 867.

182. *Id.* at 863.

could only be asserted by defendants to avoid liability for patent infringement in limited instances.[183]

That same year, Congress essentially overruled *Roche* by enacting 35 U.S.C.A. § 271(e), a narrow exception to patent infringement which allows generic drug manufacturers to take steps to obtain FDA approval during the patent term of the drug's patent owner.[184] This statutory exception is available only in factual situations similar to *Roche*, however, and does not broaden the common law experimental use defense to patent infringement.[185]

After *Roche*, the Federal Circuit left the experimental use defense untouched until 2000.[186] In *Embrex, Inc. v. Service Engineering Corp.*, the defendant hired scientific consultants to run tests in an effort to design around the plaintiff's patent, which was for a method of inoculating chicks against disease before hatching.[187] The court rejected the defendant's arguments that the tests were merely experimental.[188] The court, citing *Roche*, emphasized that the experimental use defense is to be construed "very narrowly."[189] The court further reasoned that the defense is limited to uses "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[190] In a concurring opinion, Circuit Judge Randall R. Rader argued that in light of a recent Supreme Court decision involving an unrelated patent doctrine known as the doctrine of equivalents,[191] the experimental use defense should no longer exist at all.[192] Based on the idea that infringement does not depend on the intent of alleged infringer, Circuit Judge Rader would refuse to recognize the defense "even in the extraordinarily narrow form recognized in *Roche*."[193]

Emerging from the case law, therefore, is an experimental use defense with quite a narrow scope. Courts have agreed that uses for direct commercial purposes or some foreseeable commercial benefit do not fall within the defense.[194] The test that materialized was whether the use was for "amusement, to

183. *See* Hantman, *supra* note 147, at 620 (noting that most commentators agree that *Roche* has "narrowed the experimental use exception, or at the very least, confirmed the narrowness of the exception").

184. *See supra* notes 143-45 and accompanying text (discussing the narrow statutory exception).

185. *See supra* notes 143-45 and accompanying text; *but see* Mueller, *supra* note 158, at 25-27 (describing the Hatch-Waxman Act, which is the legislation that added section 271(e), and arguing that "the Hatch-Waxman Act supports . . . a broadened interpretation of the common law experimental use exemption that does not turn solely on the commerciality of the accused infringer's use").

186. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343 (Fed. Cir. 2000).

187. *Id.* at 1346-47.

188. *Id.* at 1349.

189. *Id.*

190. *Id.*

191. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 35 (1997) (holding that the doctrine of equivalents does not require proof of the intent of the alleged infringer).

192. *Embrex*, 216 F.3d at 1353.

193. *Id.*

194. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984).

satisfy idle curiosity, or for strictly philosophical inquiry.'"[195] Notably, courts had never found a defendant liable for patent infringement where the defendant's use was entirely non-commercial and no commercial purpose was foreseeable.

C. Madey v. Duke University*: Virtually Eliminating the Experimental Use Defense*

In 2002, the United States Court of Appeals for the Federal Circuit eliminated the experimental use defense to patent infringement for virtually all practical purposes.[196] The Federal Circuit held that an alleged infringer cannot assert the defense even if he is not "engaged in an endeavor for commercial gain."[197] The experimental use defense is now strictly limited to instances in which the alleged infringer infringed "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[198] In order to describe the reasoning behind the Federal Circuit's decision, a discussion of the facts of *Madey v. Duke University* is necessary.[199]

Dr. John Madey, a physics professor, developed an innovative free electron laser research lab while he was at Stanford University.[200] Madey obtained two patents based on equipment used in the lab.[201] Subsequently, Madey accepted a position at Duke University and brought his free electron laser research lab with him.[202] After Madey resigned from Duke, Duke continued to use the patented lab equipment for research purposes.[203] Madey subsequently sued Duke for patent infringement of his two patents.[204]

The district court ruled in favor of Duke on its motion for summary judgment based on the experimental use defense.[205] The district court recognized the defense as precluding liability for patent infringement "for uses that . . . are, 'solely for research, academic or experimental purposes.'"[206] The district court reasoned that Duke, as a university dedicated to teaching and research, is not engaged in commercial applications of patents and, therefore, could properly assert the experimental use defense.[207]

195. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000).
196. Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).
197. *Id.* at 1362.
198. *Id.*
199. *Id.* at 1351-52.
200. *Id.* at 1352.
201. *Id.*
202. Madey v. Duke Univ., 307 F.3d 1351, 1352 (Fed. Cir. 2002).
203. *Id.* at 1352-53.
204. *Id.* at 1353.
205. *Id.* at 1355-56.
206. *Id.* at 1355 (quoting the district court's summary judgment opinion).
207. *Id.* at 1356-57.

Madey appealed the district court's decision to the Court of Appeals for the Federal Circuit.[208] He asserted several arguments in support of his claim that the district court ruled incorrectly.[209] As a threshold argument, Madey claimed that the experimental use defense no longer exists at all in light of a recent Supreme Court decision.[210] Madey, making the same argument that Circuit Judge Rader made in his *Embrex* concurrence,[211] argued the experimental use defense requires that the intent of the alleged infringer be determined, contrary to *Warner-Jenkinson*.[212] The court rejected this argument based on the majority in *Embrex* and concluded that a narrow experimental use defense does still exist.[213]

Next, Madey argued that the district court erroneously shifted to him the burden of proving that Duke's infringing use was not experimental.[214] The court agreed with Madey on this point and reaffirmed the principle that the alleged infringer has the burden of establishing that its use was experimental and should thus preclude liability for infringement.[215]

Finally, and most importantly, Madey argued that the district court applied an overly broad experimental use defense that was inconsistent with existing Federal Circuit precedent.[216] The court accepted Madey's claim and reemphasized that the defense is a narrow defense, as enunciated in the *Pitcairn*, *Roche*, and *Embrex* line of cases.[217] The Federal Circuit rejected the district court's reliance on *Ruth* since it is a Colorado District Court case and is therefore not binding on the Federal Circuit.[218] Further, the court in *Ruth* allowed the experimental use defense based merely on the defendant's lack of commerciality and non-profit status as an educational institution.[219] The *Ruth* court did not thoroughly analyze the character, nature, and effect of the alleged experimental use as is now required by the Federal Circuit.[220]

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208. Madey v. Duke Univ., 307 F.3d 1351, 1352 (Fed. Cir. 2002).

209. *Id.* at 1360.

210. *Id.* The decision upon which Madey relied was *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997), which addressed the doctrine of equivalents. Madey, 307 F.3d at 1360. The doctrine of equivalents is a doctrine unrelated to the experimental use defense.

211. *See supra* notes 191-93 and accompanying text (discussing Rader's argument that the experimental use defense should no longer exist at all).

212. *Madey*, 307 F.3d at 1360-61.

213. *Id.* at 1361.

214. *Id.*

215. *Id.*

216. *Id.* at 1361-62. The court relied on three Federal Circuit cases: Pitcairn v. United States, 547 F.2d 1106 (Ct. Cl. 1977), Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984), and Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343 (Fed. Cir. 2000). *See supra* text accompanying notes 172-77 (discussing *Pitcairn*); *supra* text accompanying notes 178-83 (discussing *Roche*); *supra* text accompanying notes 186-93 (discussing *Embrex*).

217. Madey v. Duke Univ., 307 F.3d 1351, 1361-62 (Fed. Cir. 2002).

218. *Id.* at 1362; *see supra* text accompanying notes 165-71 (discussing *Ruth*).

219. Madey, 307 F.3d at 1362.

220. *Id.*

The court proceeded to define the scope of the experimental use defense and, in particular, its application to major research universities.[221] While pointing out that the defense is never available if the use is in any way commercial, the court analyzed the commerciality of Duke University.[222] The court noted that research projects "unmistakably further the institution's legitimate business objectives, including educating and enlightening [participating] students and faculty" as well as "increase the status of the institution and lure lucrative research grants, students and faculty."[223] In a footnote, the court suggested that Duke has an aggressive patent licensing program that generates a significant amount of income for the university.[224] The court went on to define the scope of the experimental use defense as follows:

> [R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.[225]

Ultimately, the court concluded that the district court gave too much consideration to Duke's educational status and failed to consider its legitimate business objective.[226] The court remanded the case and ordered the district court to apply the experimental use defense test described above.[227]

In sum, the *Madey* court reaffirmed the very narrow experimental use defense.[228] The court held that the defense is strictly limited to instances where the alleged infringer's use was "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[229] However, the court went beyond this traditional narrow formulation of the defense.[230] It virtually eliminated the experimental use defense for all practical purposes by holding that an alleged infringer cannot assert the defense even if he is not "engaged in an endeavor for commercial gain."[231] As one commentator pointed out, "the Court shifted the focus of the experimental use defense from the commercial versus non-

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221. *Id.*
222. *Id.*
223. *Id.*
224. *Id.* at 1362 n.7.
225. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002).
226. *Id.*
227. *Id.* at 1362-63
228. *Id.* at 1362.
229. *Id.*
230. *Id.*
231. *Id.*

commercial nature of the experimentation and the profit versus non-profit status of the alleged infringer to merely a question of whether the use was in furtherance of the alleged infringer's legitimate business."[232] Therefore, under the court's holding, universities can no longer assert the experimental use defense to avoid patent infringement liability for research projects conducted exclusively for educational purposes with arguably no commercial application whatsoever.[233]

Many universities and non-profit organizations hoped that the United States Supreme Court would choose to hear the case and ultimately overturn the Federal Circuit's decision in *Madey*.[234] In addition, some commentators opposed to the *Madey* decision hoped for the same.[235] However, these hopes were crushed when the Supreme Court denied Duke's petition for writ of certiorari.[236]

Commentary on *Madey*, for the most part, has been critical of the Federal Circuit's decision to severely restrict the experimental use defense.[237] It has been argued that universities should be allowed to conduct experiments on patented inventions and teach how patented inventions work.[238] The benefits that derive from allowing a university to experiment on and teach certain patented inventions include at least the following benefits: it is an efficient method of distributing information to others; the process may reveal additional information; the process may inspire further innovation; and, universities typically have ample resources and support to conduct experiments.[239] So, if the experimental use defense is too narrow after *Madey*, how broad should the defense be? The proper scope of the experimental use defense has been discussed in the literature.[240] Two schools of thought have emerged.[241] First, some commentators assert that the experimental use defense should only apply when the use is noncommercial.[242] Second, some commentators assert that whether the defense can be raised should depend on the nature of the experimentation at issue.[243] If the alleged infringer is

232. Jennifer Miller, *Sealing the Coffin on the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 12, 17 (2003).

233. Madey, 307 F.3d at 1361-63.

234. *See* Miller, *supra* note 232, at 20, 22 (stating that institutions which sought Supreme Court review included the Association of American Medical Colleges, the Association of American Universities, Consumer Project on Technology, and Public Knowledge).

235. *See, e.g.*, *id.* at 22-23 (arguing that the Supreme Court should decide *Madey* since the Federal Circuit ignored the history of the experimental use defense as applied to non-profit researchers).

236. Duke Univ. v. Madey, 123 S. Ct. 2639 (2003).

237. *See, e.g.*, Saunders, *supra* note 152, at 262 (arguing that the court in *Madey* erred and "should have instead crafted a more nuanced experimental use exception that protects educational experimentation on patented inventions").

238. *Id.* at 265-66.

239. *Id.*

240. *See id.* at 266 (noting that scholars disagree on the proper scope of the experimental use defense).

241. *Id.* at 266-68.

242. *Id.* at 266-67.

243. *Id.* at 266-68.

experimenting *on* an invention, then the experimental use defense should apply.[244] If the alleged infringer is experimenting *with* an invention, however, then the experimental use defense should not apply.[245] Regardless of the precise scope of the defense, commentators almost unanimously agree that it should be broader than the *Madey* court's extremely narrow formulation.

In conclusion, it seems clear that *Madey* has severely restricted the ability of non-profit research institutions such as universities to conduct research and experiments. These institutions will likely be overly cautious, or even hesitant, when conducting research involving cutting-edge technology that has been patented. In order to use patented technology, research institutions will be forced to enter licensing agreements with patent holders and may be prevented from experimentation completely if a patent holder refuses to license a particular invention.[246] With the recent emergence of nanotechnology, considerable funding has been dedicated to nanotechnology research and development.[247] *Madey* could significantly slow down the development of nanotechnology to the detriment of society.[248]

IV. STIFLING INNOVATION

A. *Biotechnology Arguments*

Biotechnology refers to the commercial development of scientific processes that are primarily related to living organisms.[249] In 1973, biotechnology became generally accepted when professors Stanley N. Cohen and Herbert W. Boyer found that a gene from one organism could confer its unique characteristics to a host organism through in vitro recombinant DNA techniques.[250] Initially, biotechnology inventions were not patentable subject matter. However, by the late-1970s, it became accepted that biotechnological innovations could indeed be patented.[251]

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244. *Id.*

245. *Id.*

246. *See* Miller, *supra* note 232, at 19 (discussing licensing agreements).

247. *See supra* text accompanying note 59 (stating that Congress recently has approved $2.36 billion for nanotechnology research and development).

248. *See* Miller, *supra* note 232, at 20 (stating that "[*Madey*] threatens to stifle [scientific] research and thereby endanger this nation's continued leadership in science and technology") (quoting Brief of Amici Curiae, Association of American Medical Colleges at 3, Duke Univ. v. Madey, 123 S. Ct. 2639 (2003)).

249. *See* Feit, *supra* note 163, at 819 (defining biotechnology).

250. Lorance L. Greenlee, *Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years*, 68 DENV. U. L. REV. 127, 127 (1991).

251. *See* Feit, *supra* note 163, at 819 (discussing the patentability of biological inventions); Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding that an artificially created oil-eating bacterium is patentable subject matter). The USPTO has granted patents for a variety of biotechnological inventions, including "cloned DNA sequences, stem cell lines, purified recombinant proteins, and transgenic animals." David C. Hoffman, Note, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1018-19 (2004).

Chemistry is the branch of science that is most similar to biotechnology.[252] Patents in the chemical arts, on the one hand, typically involve intermediate and final products, processes of making those products, and methods of using final chemical products.[253] Biotechnology patents, on the other hand, often cover basic laboratory methods and materials (i.e., research tools) used to create biotechnological products and processes.[254] Biotechnological research tools have been defined as "those patented tools used in development of new biotechnological or pharmaceutical products that do not themselves physically incorporate the tool."[255] Since biotechnology patents often involve research tools, and not final products and processes like in the chemical arts, the experimental use defense to patent infringement is particularly important in the context of biotechnology.[256]

Beginning in the late-1980s, several commentators have argued for a broader experimental use defense in order to prevent, or at least mitigate, the stifling of biotechnology innovation. Professor Rebecca S. Eisenberg initiated these arguments in her seminal article *Proprietary Rights and the Norms of Science in Biotechnology Research.*[257] Eisenberg examined the interaction between intellectual property law in the context of biotechnology inventions and traditional norms governing scientific research.[258] She concluded that the existing patent system, with its broad right to exclude others, impairs free use of technology and the extension of new discoveries.[259]

Eisenberg discussed the experimental use defense and suggested that its narrow scope might impede the progress of science.[260] She explained the situation in which an infringer should be permitted to invoke the defense:

> The case for allowing the defense appears strongest where the subsequent user is attempting to devise alternatives to the patented invention. In such a case, the interests of the research user are congruent with the interests of the public and the scientific community in advancing the state of human knowledge. The patent holder, by contrast, has an interest in prolonging the period in which the public is dependent on the patented technology. If the patentee sees the research user as a competitor rather than a customer, she may refuse to license the

252. Feit, *supra* note 163, at 819.

253. *Id.*

254. *Id.*

255. Mueller, *supra* note 158, at 14.

256. *See* Feit, *supra* note 163, at 819 (stating that "basic laboratory methods and materials often constitute the subject matter of [biotechnology] patent claims").

257. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987).

258. *Id.* at 177.

259. *Id.* at 177, 180.

260. *See id.* at 224-26 (discussing the experimental use defense).

invention. Without an experimental use defense, it is possible that no one would be able to build on the inventor's discovery until the patent expired.[261]

Eisenberg, however, acknowledged that too broad a defense could be undesirable as well.[262] Unduly restricting the patentee's rights would likely result in a decreased incentive to innovate and less financial investment in research and development. Ultimately, Eisenberg concluded that given the abundant commercialization of biotechnology research discoveries,[263] "the experimental use doctrine offers a potential mechanism for reconciling the patent monopoly with the interest of the research community in building upon prior discoveries through subsequent research."[264]

Subsequently, Irving N. Feit argued for a broader experimental use defense by way of legislative amendment in his article *Biotechnology Research and the Experimental Use Exception to Patent Infringement.*[265] Feit pointed out that many pioneering developments in the biotechnology field have been patented and threaten to disrupt further development.[266] He cautioned that threatening universities, non-profit organizations, and commercial biotechnology companies with patent infringement is undesirable and would lead to fewer resources available for innovation.[267] In light of case law suggesting that patentees have exclusive rights to certain recombinant DNA techniques, Feit explained that biotechnology firms are faced with a difficult decision.[268] "They can proceed with the research despite a one-time, unrepeated, yet possibly willful infringement at the very beginning of the project, or abandon the technology because a license from a competitor is unavailable."[269] As a result, Feit proposed that an experimental use defense should be created which permits the "making and using of patented technology for the purpose of significantly improving it."[270]

More recently, Professor Janice M. Mueller argued for a broadened rule allowing "development use" of certain patented biomedical research tools in her article *No "Dillettante Affair": Rethinking the Experimental Use Exception to*

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261. *Id.* at 224-25. *But see* Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2170 (1991) (arguing that the experimental use defense should be applied "in a very restrictive manner, consistent with the purpose and function of the patent system").

262. Eisenberg, *supra* note 257, at 224.

263. *Id.* at 229.

264. *Id.* at 230. *See also* Ned A. Israelsen, 16 AIPLA Q.J. 457, 478 (1989) (stating that "infringement should not be found unless the patented invention was practiced primarily to secure the benefits of that invention [and] patent law should not confer on a patentee the right to keep others from improving on his work").

265. Feit, *supra* note 163.

266. *Id.* at 820-21.

267. *Id.* at 822.

268. *Id.* at 838-39.

269. *Id.* at 839.

270. *Id.* at 840.

Patent Infringement for Biomedical Research Tools.[271] Mueller's analysis focused exclusively on patented research tools used in the biotechnological and biomedical industries.[272] She noted that when one seeks to acquire patented research tools by way of a license, a significant possibility exists that negotiations will fail and research will be delayed or forgone.[273] Since research tools are necessary to create further biotechnological innovation, Mueller proposed that the experimental use defense be expanded to include a specific "development use exception" for research tools.[274] Under this proposal, patented research tools that are not available for licensing or purchase could be used in creating biotechnology and biomedical inventions.[275] However, in exchange for reducing the patentee's exclusive rights, the user of the patented research tools would be required to give the patentee a royalty payment based on the commercial value of the subsequently created invention.[276]

Finally, one commentator has argued that the experimental use defense should apply to public sector researchers in the context of biotechnology research tools.[277] "[This] exception would cover noncommercial use of any biological material, reagent, or research tool for which an equivalent substitute is not readily available."[278] Absent this exception, a patentee would unjustifiably be able to prevent not only patent-protected competition, but also competition resulting from improving on the invention.[279] As a result, a broadened experimental use defense for public sector researchers is necessary to promote technological progress while maintaining the patentee's incentive to innovate.[280]

B. Nanotechnology Arguments

The arguments made to broaden the experimental defense in the context of biotechnology apply equally in the context of nanotechnology. Today, nanotechnology is at a similar point in its development as biotechnology was in the 1970s. Just as biotechnology innovation developed dramatically throughout the 1980s and 1990s, nanotechnology will likely see a similar expansion in the next decade or two. In order to balance patentees' exclusive rights in nanotechnology inventions with the overall promotion of nanotechnology

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271. Mueller, *supra* note 158.

272. *Id.* at 9.

273. *Id.* at 15.

274. *See id.* at 54-66 (discussing a proposed "development use" model).

275. *Id.* at 54-55.

276. *Id.*

277. *See* Hoffman, *supra* note 251, at 1036-39 (discussing broadening the experimental use defense to include public sector researchers as part of a three-pronged approach to alleviate problems associated with patent stacking).

278. *Id.* at 1037.

279. *Id.*

280. *Id.* at 1038.

innovation, a broader experimental use defense to patent infringement is essential. *Madey's* proclamation that non-commercial experimental activity can constitute patent infringement will unduly restrict nanotechnology innovation in the years to come.

Biotechnology, it could be argued, is a unique scientific discipline in that biotechnological innovation is highly dependent on access to fundamental research tools. In fact, most of the arguments for a broader experimental use defense in the biotechnology industry were made with respect to biotechnology research tools. These research tools are essential to the furtherance of biotechnological innovation since experimentation would not be possible without access to these tools.

Nanotechnology, however, seems to parallel biotechnology in this respect. Nanotechnology does indeed have certain pioneering technologies that are essential to the creation of further developments and inventions. For example, techniques such as scanning probe microscopy are essential for manipulating atoms and arranging them in particular molecular configurations. In addition, carbon nanotubes provide the building blocks for creating materials with superior characteristics. If scanning probe microscopy, carbon nanotubes, or similar fundamental tools are unavailable to research and development entities through purchase or license from patent owners, the scientific progress of nanotechnology will be stifled.

As with any emerging technology, a significant portion of nanotechnology research and development is based in universities and non-profit organizations. These research institutions and organizations may be hesitant to develop nanotechnology for fear of patent infringement liability. In order to maintain the United States' position as the global leader in nanotechnology, either the courts or Congress must address the realistic potential that a nearly non-existent common law experimental use defense will stifle nanotechnology innovation. A reasonable solution, which would preserve patent owners' exclusive rights and incentives to innovate, would be to permit non-commercial experimental use of patented nanotechnology inventions.

V. CONCLUSION

Nanotechnology is at the forefront of the next technological revolution. With federal funding for nanotechnology research and development in the billions of dollars, nanotechnology will likely expand significantly in the next ten to twenty years. In light of the Federal Circuit's decision in *Madey v. Duke University*, the current narrow scope of the experimental use defense to patent infringement will likely stifle nanotechnology innovation. The courts or Congress should listen to the arguments that were made in the biotechnology arena and broaden the scope of the experimental use defense to permit non-commercial experimental use.