NANOTECHNOLOGY PATENT PROLIFERATION AND THE CRISIS AT THE U.S. PATENT OFFICE

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Way, Ashburn, Virginia 20147, USA (Telephone Numbers: 703-582-1745; 703-723-0034; Fax: 571-223-1844; e-mail: bawabio@aol.com). This paper reflects the current views of the author, which are likely to evolve. Furthermore, they should not be attributed, in whole or in part, to the organizations listed above, nor should they be considered as expressing an opinion with regard to the merits of any particular company or product discussed herein. Nothing contained herein is to be considered as the rendering of legal advice.

I. ABSTRACT

There is enormous excitement and expectation regarding nanotechnology's potential impact. However, securing valid and defensible patent protection will be critical here. Although early forecasts for nanotechnology commercialization are encouraging, there are bottlenecks as well. One of the major hurdles is an emerging thicket of patent claims, resulting primarily from patent proliferation, but also because of issuance of surprisingly broad patents by the U.S. Patent and Trademark Office (PTO). Adding to this confusion is the fact that the U.S. National Nanotechnology Initiative's widely-cited definition of nanotechnology is inaccurate and irrelevant. This has also resulted in the PTO's flawed nanotechnology patent classification system. All of this is creating a chaotic, tangled patent landscape in various sectors of nanotechnology (*e.g.*, nanoelectronics and nanomedicine) in which the competing players are unsure as to the validity and enforceability of numerous issued patents. If this trend continues, it could stifle competition, limit access to some inventions, and simply grind commercialization efforts to a halt. Therefore, reforms are urgently needed at the PTO to address problems ranging from poor patent quality and questionable examination practices to inadequate search capabilities, rising attrition, poor employee morale, and a skyrocketing patent application backlog. Only a robust patent system will stimulate the development of commercially viable nanotechnology products.

II. INTRODUCTION

Governments around the world are impressed by nanotechnology's potential and are staking their claims by doling out billions of dollars, euros, and yen for research.[1] International

[1] The passage of the 21st Century Nanotechnology Research and Development Act (Pub. L. No. 108-153) in 2003 authorized $3.7 billion in federal funding dispersed from 2005 through 2008 for the support of nanotechnology R&D, which is fueling the fervor over nanotechnology in the U.S. *See* 21st Century Nanotechnology Research and Development Act, P.L. No. 108-153, § 6, 117 Stat. 1923, 1929 (2003) (to be codified as 15 U.S.C. § 7505). This legislation emphasizes the creation of R&D Centers in academia and government. 21st Century Nanotechnology Research and Development Act, P.L. No. 108-153, § 2, 117 Stat. 1923, 1923 (2003) (to be codified as 15 U.S.C. §

rivalries are growing, political alliances are forming,[2] and battle lines are being drawn. Globally, governments, corporations, and venture capitalists in 2006 spent 12.4 billion U.S. dollars on nanotechnology research and development (R&D), up 13% from 2005.[3] One market report noted that in 2005, nanotechnology was incorporated into more than 30 billion U.S. dollars worth of manufactured goods.[4] This report predicts that by 2014, 2.6 trillion U.S. dollars in globally manufactured goods may incorporate nanotechnology (about 15% of total output).[5]

Early forecasts for nanotechnology commercialization are encouraging; however, there are formidable challenges that include legal, environmental, safety, ethical, and regulatory questions, as well as emerging thickets of overlapping patent claims.[6] Patent systems in general are under greater scrutiny

7501). Presently, there are over fifty institutes and centers dedicated to nanotechnology R&D; for example, the National Science Foundation has established the National Nanotechnology Infrastructure Network—composed of university sites that form an integrated, nationwide system of user facilities to support research and education in nanoscale science, engineering and technology. National Nanotechnology Infrastructure Network (NINN) – Program Solicitation, http://www.nsf.gov/pubs/2003/nsf03519/nsf03519.html (last visited April 17, 2007). Similarly, there are currently numerous government agencies with R&D budgets dedicated to nanotechnology. *See* 21st Century Nanotechnology Research and Development Act, P.L. No. 108-153, § 2, 117 Stat. 1923, 1923-24 (2003) (to be codified as 15 .U.S.C. § 7501).

[2] *See* STEVEN A. EDWARDS, THE NANOTECH PIONEERS - WHERE ARE THEY TAKING US?, 172–73 (Wiley-VCH Verlag GmbH & Co. KgaA 2006); *see also* Michael A. Van Lente, *Building the New World of Nanotechnology*, 38 CASE W. RES. J. INT'L L. 173, 179 (2006).

[3] Marc S. Reisch, *Nano Goes Big Time: New York and Other States Dole Out Big Bucks to Boost Nanotechnology*, 85 CHEM. & ENG'G NEWS 22, 22–25 (2007), *available at* http://pubs.acs.org/cen/business/85/8504bus2.html (last visited March 24, 2007).

[4] LUX RESEARCH INC., THE NANOTECH REPORT: INVESTMENT OVERVIEW AND MARKET RESEARCH FOR NANOTECHNOLOGY iii (4th ed. 2006), *available at* http://www.luxresearchinc.com/TNR4_TOC.pdf (limited to key findings and table of contents).

[5] *Id*.

[6] At this stage, however, several obstacles beset nanoscience: R&D and nanotechnology commercialization, including (i) high production costs; (ii) the public's general reluctance to embrace innovative technologies without real safety guidelines; (iii) relative scarcity of venture funds; (iv) few near-term commercially viable products; (v) lack of knowledge regarding the interaction between nanomaterials and living cells (the issue of biocompatibility and toxicity of nanomaterials); (vi) reluctance of multi-nationals (e.g., "big pharma") to seriously invest in nanotechnology; (vii) production issues such as lack of quality control, reproducibility and scalability of most nanostructures of commercial interest; (vii) absence of clear guidance from the federal

and strain, with patent offices around the world continuing to struggle with evaluating the swarm of nanotechnology-related patent applications.[7] Given this backdrop, it is hard to predict whether nanotechnology will make small but valuable contributions or whether it will act as a catalyst for a vast technological revolution. One thing is certain, however, nanotechnology is here to stay and will generate both evolutionary as well as revolutionary products in the future, thereby improving all sectors of our life.[8] I am optimistic that current fears about self-replicating nanobots, the potential toxic effects of nanoscale materials, and focus on strict regulations or a moratorium will eventually give way to intelligent public dialogue on the realistic impact of nanotechnology.

III. DEFINING NANOTECHNOLOGY – PROBLEMS AND CONFUSION

One of the problems facing nanotechnology[9] is the confusion, hype, and disagreement among experts about its definition.[10] "Nanotechnology is an umbrella term used to define the [properties,] products and processes at the nano/micro scale that

government, including confusion and delay at the PTO (with respect to the burgeoning number of nanotech-related patent applications) and FDA (with respect to a lack of clear regulatory/safety guidelines); and (viii) the media's continuing focus on the negative aspects of nanomaterials and nanoparticles, often without proper scientific evidence (environmental, health and safety concerns are at the forefront). *See*, *e.g.*, EVA GUTIERREZ, ELECTRONIC PRIVACY INFORMATION CENTER, PRIVACY IMPLICATIONS OF NANOTECHNOLOGY, http://www.epic.org/privacy/nano/ (last visited April 17, 2007).

[7] *See* Raj Bawa, *Nanotechnology Patenting in the US*, 1 NANOTECHNOLOGY LAW & BUSINESS 1, 3, n. 8–n. 9 (2004) (stating that "patent applications [in the US] have been increasing, on average, by over 10% per year since 1996").

[8] A recent study claims that presently there are over 300 nanotech-based consumer products in the marketplace. PROJECT ON EMERGING NANOTECHNOLOGIES, A NANOTECHNOLOGY CONSUMER PRODUCTS INVENTORY, http://www.nanotechproject.org/44 (follow "browse products" link) (last visited Apr. 18, 2007). It should be emphasized that all such market reports rely on the flawed definition of nanotechnology to draw their conclusions. *See infra* Part II.

[9] A nanometer is "one-billionth of a meter…, or 1/75,000th the size of a human hair." Raj Bawa et al., *Bionanotechnology Patenting: Challenges and Opportunities*, *in* THE BIOMEDICAL ENGINEERING HANDBOOK 29-1, 29-1 n. 1 (3rd ed. 2006), *available at* http://www.nvcc.edu/home/rbawa/Bionanotechnology%20patenting%20(Bawa%20CRC%20Handbook%202006).pdf

[10] *See* Thomas Theis et al., *Nan'o • tech • nol' o • gy n*: *Governments invest billions in it and tens of thousands of papers are published on the subject every year, but what exactly is nanotechnology?*, 1 NATURE NANOTECHNOLOGY 8, 8–10 (2006) (providing different experts' views on defining nanotechnology).

have resulted from the convergence of the physical, chemical and life sciences."[11]

One of the most quoted definitions is the one used by the U.S. National Nanotechnology Initiative (NNI): *"[n]anotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications."*[12] This definition "excludes numerous devices and materials of micrometer dimensions, a scale that is [often] included within the definition of nanotechnology by many nanoscientists."[13] Therefore, some experts have cautioned against an overly rigid definition based on a sub-100 nm size, "emphasizing instead the continuum of scale from the nanoscale to the microscale."[14]

Various federal agencies are struggling with the definition of nanotechnology. For example,

> [federal] agencies, such as the [FDA] and the PTO, use [the NNI] definition based on a scale of less than 100 nm[.] . . . [T]his NNI definition . . . [continues to present] difficulties not only for understanding nanopatent statistics, but also for the proper assessment of [nanotechnology's] scientific, legal, environmental, regulatory, and ethical implications. This problem [persists] because nanotechnology represents a cluster of technologies, each

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[11] Raj Bawa et al., *Protecting new ideas and inventions in nanomedicine with patents*, 1 NANOMEDICINE: NANOTECHNOLOGY, BIOLOGY & MED. 150, 151 (2005).

[12] The National Nanotechnology Initiative, What is Nanotechnology?, http://www.nano.gov/html/facts/whatIsNano.html (last visited Jan. 20, 2008).

[13] K. John Morrow, Jr. et al., *Recent Advances in Basic and Clinical Nanomedicine*, THE MEDICAL CLINICS OF NORTH AMERICA 805-843 (2007), *available at* http://www.nvcc.edu/home/rbawa [hereinafter *Morrow*]; *see also* Raj Bawa, *Patents and Nanomedicine*, NANOMEDICINE 351-374 (2007), *available at* http://www.nvcc.edu/home/rbawa; *see also* Raj Bawa, *Nanotechnology Patenting in the US*, 1 NANOTECHNOLOGY L. & BUS., 31, 36 n. 20 (2004) (explaining the confusion and disagreement on the definition of nanotechnology); Raj Bawa et al., *Bionanotechnology Patenting: Challenges and Opportunities*, *in* THE BIOMEDICAL ENGINEERING HANDBOOK 29-1, 29-1-29-2 (3rd ed. 2006), *available at* http://www.nvcc.edu/home/rbawa/Bionanotechnology %20patenting%20(Bawa%20CRC%20Handbook%202006).pdf; s*ee also* Warren H. Hunt, Jr., *Nanomaterials: Nanonomenclature, Novelty, and Necessity*. J. OF MINERALS, METALS & MATERIALS SOC'Y., Oct. 2004, at 13, 13 (commenting on the varying definitions and applications of nanotechnology); *see also* FORESIGHT, INNOVATION, AND STRATEGY: TOWARDS A WISER FUTURE 31–33 (Cynthia G. Wagner ed., World Future Society Press 2005) (explaining the significance and definition of nanotechnology on nanomedicine).

[14] Morrow, *supra* note 13, at 7.

of which [has] different characteristics and applications.[15]

Although the sub-100 nm size range may be critical for a nanophotonic company where size-dependant quantum effects are particularly important (e.g., a quantum dot's size dictates the color of light emitted therefrom),[16] "this size limitation . . . is not critical to a drug company from a formulation [delivery] or efficacy perspective, because the desired or ideal property (e.g., improved bioavailability, reduced toxicity, lower dose, enhanced solubility) may be achieved in a size range greater than 100 nm."[17] Clearly, a definition based on physical limits tends to be an unorthodox way of defining a technology field. Other technologies tend to be defined by a key technology or breakthrough: genetic engineering technology is based upon recombinant DNA while the Internet is a collection of "bulletin boards" networked in a World Wide Web.[18] Furthermore, in my view, nanotechnology is nothing brand new; for example, "nanoscale carbon particles ('high-tech soot nanoparticles') have been used as a reinforcing additive in tires for more than a century."[19]

Another example is that of protein vaccines that squarely fall within the definition of nanotechnology. In fact, the scale of many biologic structures is similar to components involved with nanotechnology. For example, "peptides are similar in size to quantum dots (<10 nm), whereas some viruses are the same size

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[15] Raj Bawa, Commentary, *Will the nanomedicine "[p]atent [l]and [g]rab" thwart commercialization*?, 1 NANOMEDICINE: NANOTECHNOLOGY, BIOLOGY, & MED. 346, 346 (2005), *available at* http://www.rpitechnology.com/files/article_nano_patentlab.pdf [hereinafter *Patent Land Grab*]. *See also* Antonio Regalado, *Nanotechnology Patents Surge As Companies Vie to Stake Claim*, WALL ST. J., June 18, 2004, at A1.

[16] *See* Morrow, *supra* note 13, at 6.

[17] *Patent Land Grab*, *supra* note 15, at 346.

[18] CHINESE MEDICAL & BIOLOGICAL INFORMATION, WHAT IS GENETIC ENGINEERING?, http://cmbi.bjmu.edu.cn/cmbidata/biotech/conceptfiles/What%20is%20genetic%20engineering.html (last visited April 18, 2007). *See* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 654 (11th ed. 2003) (defining the Internet as "an electronic communications network that connects computer networks and organizational computer facilities around the world").

[19] Raj Bawa et al., *Protecting New Ideas And Inventions In Nanomedicine With Patents*, 1 NANOMEDICINE: NANOTECHNOLOGY, BIOLOGY, AND MEDICINE 150, 151 (2005), *available at* http://www.rpitechnology.com/files/article_protecting_nano.pdf [hereinafter *Bawa I*].

as drug delivery nanoparticles (<100 nm). Hence, most of molecular medicine and biotechnology may be [classified as] nanotechnology."[20] (sic.)

Given this confusion, I recently proposed a more practical definition of nanotechnology that is unconstrained by any arbitrary size limitation:

> The design, characterization, production, and application of structures, devices, and systems by controlled manipulation of size and shape at the nanometer scale (atomic, molecular, and macromolecular scale) that produces structures, devices, and systems with at least one novel/superior characteristic or property.[21]

IV. SEARCHING NANOTECHNOLOGY PATENTS – ISSUES AND CHALLENGES

Due to the burgeoning number of new nanotech-related patent applications filed at the PTO and continued pressure from industry, the PTO in August 2004 finally created a preliminary cross-reference classification for nanotechnology (designated as Class 977/Digest 1).[22] The purpose of this class was described by the PTO on its website:

> [e]stablishing this nanotechnology cross-reference digest is the first step in a multi-phase nanotechnology classification project and will serve the following purposes: [f]acilitate the searching of prior art related to Nanotechnology, [f]unction as a collection of issued U.S. patents and published pre-grant patent applications relating to [n]anotechnology across the technology centers, and [a]ssist in the development of an expanded, more comprehensive, nanotechnology cross-reference art collection classification schedule.23

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[20] *Id*. at 151.

[21] *Id*.

[22] Vance McCarthy, Nano Science and Technology Institute, *USPTO Poised to Ring in a New Era of Simplified Search and Better Visibility for Nano Patents*, Dec. 20, 2005, http://www.nsti.org/news/item.html?id=35; United States Patent and Trademark Office, New Cross-Reference Digest for Nanotechnology, http://www.uspto.gov/web/patents/biochempharm/crossref.htm (last visited April 18, 2007).

[23] United States Patent and Trademark Office, New Cross-Reference Digest for Nanotechnology, http://www.uspto.gov/web/patents/biochempharm/crossref.htm (last visited April 18, 2007). *See also* United States Patent and Trademark Office, USPTO Patent Full-Text and Image Database, http://patft.uspto.gov/netahtml/PTO/search-adv.htm (last visited April 18, 2007) (providing the search mechanism for the PTO database). The phrase "prior art" refers to various sources of information that the PTO uses to reject a patent

The PTO emphasized that its digest is a work in progress, stating, "Until the comprehensive nanotechnology cross-reference art collection classification schedule is published, this digest should not be construed as an exhaustive collection of all patent documents that pertain to nanotechnology." [24]

At best, this classification should be considered a rough estimate of the total number of nanotech-related patents. This is because the PTO has copied the NNI's narrow definition of nanotechnology for classification purposes, which has resulted in a skewed patent classification system, especially with respect to nanomedicine- and bionanotechnology-related inventions.[25] Furthermore, this classification scheme is neither sufficiently descriptive to accommodate many of the unique properties that nanotechnology inventions exhibit nor does it address the interdisciplinary nature and range of technologies encompassed by nanotechnology.[26]

In conclusion, the PTO's efforts to provide a home for a few thousand U.S. patents via a skewed classification system defeat

application. In other words, it is the "knowledge" that exists at the time of the claimed invention and is used by the PTO to establish whether an invention is novel. It can include documentary material like publications, patents, websites or other disclosures that suggest that the invention is not new. It can also include evidence of actual uses or sales of the technology within the United States. *See* Raj Bawa et al., *Bionanotechnology Patenting: Challenges and Opportunities*, *in* THE BIOMEDICAL ENGINEERING HANDBOOK 29-1, 29-9, 29-9 n. 18 (3d ed. 2006), *available at* http://www.nvcc.edu/home/rbawa/Bionanotechnology%20patenting%20(Bawa%20CRC%20Handbook%202006).pdf.

[24] United States Patent and Trademark Office, New Cross-Reference Digest for Nanotechnology, http://www.uspto.gov/web/patents/biochempharm/crossref.htm (last visited April 18, 2007).

[25] Raj Bawa et al., *Bionanotechnology Patenting: Challenges and Opportunities*, *in* THE BIOMEDICAL ENGINEERING HANDBOOK 29-1, 29-12 (3rd ed. 2006), *available at* http://www.nvcc.edu/home/rbawa/Bionanotechnology%20patenting%20(Bawa%20CRC%20Handbook%202006).pdf.

[26] *See id*. A recent search of Class 977 for issued nanotechnology patents yielded just over 3000 patents. This implies that out of more than seven million US patents issued to date, the PTO has listed only a few thousand patents pertaining to nanotechnology. This is a glaring error on the part of the PTO; it is a reflection of the flawed definition of nanotechnology that the PTO continues to rely upon. On the other hand, an extensive patent search by our group in 2003 (employing the Derwent World Patent Index followed by a manual reading of all the claims of the patents) uncovered close to 8,000 US patents pertaining to nanobiotechnology alone. United States Patent and Trademark Office, *available at* http://www.uspto.gov/patft/index.html (last visited Apr. 9, 2007) (search results on file with author).

the very purpose for the creation of Class 977, namely: (a) to gauge the number of nanotechnology patent applications filed and patents issued, and (b) to assist patent practitioners as well as patent examiners in searching nanotechnology patent documents.

Other issues pertaining to nanotech-related patent searching are of concern as well. "[T]he PTO lacks effective automation tools for . . . [nanotechnology] 'prior art' searching."[27] Additionally, the PTO databases are not exhaustive. This problem is particularly acute regarding non-patent prior art. For example, "[a]lthough there has been a dramatic rise in bionanotechnology patent activity, most of the prior art [still] exists in the form of journal publications and book articles. Web sites and pre-grant patent publications provide an additional resource."[28] I believe that a large amount of this wealth of non-patent scientific literature directed to nanomedicine predates many of the nanopatents that have been issued and are currently being issued. I am certain that the PTO examiners[29] lack access to most of this critical non-patent information, and therefore, often miss discovering it during their patent searches. The problem of access to non-patent information is not unique to nanotechnology patent examination; it is seen in most technology areas.[30] Furthermore, the Internet usage policies of the PTO prevent patent examiners from accessing relevant databases to access information.[31] The issue here is one of security since prior art searching on the Internet might run the risk of being tracked externally. Given these inferior search capabilities, I agree with

[27] Bawa, *Challenges and Opportunities*, *supra* note 25, at 29-2.

[28] *Id*.

[29] Patent examiners are government agents employed at the PTO who review patent applications and grant patents. United States Patent and Trademark Office, Careers FAQ, http://usptocareers.gov/faq.asp (last visited April 18, 2007).

[30] The difficulty and need for finding non-patent information is demonstrated by the host of public and private databases that have popped up in recent years to provide that service. *See*, *e.g.*, IP Partner, Services, http://.ip-partner.com/services.htm (last visited April 18, 2007); Scirus, *About Scirus…*, www.scirus.com (last visited Apr. 18, 2007); Annabel Griffiths, Thomson Scientific, *IP Matters, Patents, Literature and Citations: Information Partnerships for Competitive Advantage*, July 2003, *available at* http://scientific.thomas.com/free/ipmatters/infosearch/8179937/info-partnerships.pdf.

[31] *See* Internet Usage Policy, 64 Fed. Reg. 33,056, 33,061 (Dep't of Commerce June 21, 1999) (notice).

the conclusion that *"the informational burdens on the examiner are clearly heavy — even before the examiner engages in the heavy lifting of interpreting the prior art."* [32]

It seems that patent examiners are basing decisions about the grant of a nanotechnology patent on limited information. It is scary to envision that their faulty decision-making will shape a nascent industry for years to come. In sum, this information deficit has rendered examination unfocused and inefficient, resulting in the issuance of numerous "unduly broad" nanomedicine patents.[33] I think that the patent examination process will be further undermined by the PTO's recent proposal to separate out the patent search from patent examination.

Add to this confused state of affairs the general difficulty in searching nanotechnology prior art. Because of its broad definition, searching and retrieving nanotech-related patents and publications is complicated relative to other technology areas.[34] Because of this particular point, accurately mapping the patent landscape is also a real challenge. Patents or publications that are truly nanotech-based may not use any specific nano-related terminology.

In fact, patents or publications are "[o]ften . . . written 'not to be found' in order to keep potential competitors at a 'knowledge' disadvantage." [35] On the other hand, "there are business savvy inventors and assignees [who] might use key [words] incorporating a nano prefix [into their patents or publications to better] market[ ] their invention or concept."[36] Therefore, "part of the challenge in finding tru[e] nanotechnology . . . [prior art] is the judicious use of key terms[,] patent class[ification] codes," and alternative phraseology while searching patent and commercial databases.[37] Coupling this strategy with additional filtering (via an expert) is probably the most reliable way to find

[32] Lee Petherbridge, *Positive Examination*, 46 IDEA 173, 183 (2006).

[33] Raj Bawa, et al., *Protecting New Ideas and Inventions in Nanomedicine with Patents*, 1 NANOMEDICINE: NANOTECHNOLOGY, BIOLOGY AND MED. 150, 155, 156-57 (2005), *available at* http://www.rpitechnology.com/files/article_protecting_nano.pdf.

[34] Raj Bawa, *Nanotechnology Patents and Challenges*, IPFRONTLINE, May 18, 2004, http://www.ipfrontline.com/depts/article.asp?id=710&deptid=5.

[35] *Id*.

[36] *Id*.

[37] *Id*.

nanotechnology patents.[38]

V. WHAT ARE PATENTS? A PRIMER FOR LAWYERS

"Globally, industries that produce and manage 'knowledge' and 'creativity' have replaced capital, colonies, and raw materials as the new wealth of nations. Property, which has always been the essence of capitalism, is [increasingly] changing from tangible to intangible."[39] Intellectual property (IP) rights are a class of assets that accountants call intangible assets.[40] These assets play an ever-increasing role in the development of emerging technologies like biotechnology, drug development, and nanotechnology.[41] Modern IP consists of patents, trademarks, copyrights, and trade secrets.[42] Patents are the most complex, tightly regulated, and expensive form of IP.[43] They have the attributes of personal property – they may be assigned, bought, sold, or licensed.[44] Patent law is a subtle and esoteric area of law that has evolved in response to technological change and legal developments. It has been modified numerous times since 1790, the year the first U.S. Patent Act was enacted.[45] This is due to the PTO and by the courts' changing interpretations of existing laws or by Congress amending patent laws in response to new technology.[46]

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[38] *Id*.

[39] Raj Bawa, *Nanotechnology Patenting in the US*, 1 NANOTECHNOLOGY L. & BUS. 1, 2 (2004). *available at* http://www.rpitechnology.com/files/article_nano_patenting.pdf. "Intangible assets as a portion of corporate market capital are steadily rising." *Id*.

[40] J. Timothy Cromley, *Intellectual Property Valuation Standards*, INTELLECTUAL PROPERTY TODAY, Jan. 2007, *available at* http://www.iptoday.com/pdf/2007/1/Cromley-Jan2007.pdf.

[41] *See* Albert P. Halluin & Lorelei P. Westin, *Nanotechnology: The Importance of Intellectual Property Rights in an Emerging Technology*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 220, 225 (2004).

[42] Kevin M. Lemley, Note, *I'll Make Him an Offer He Can't Refuse: A Proposed Model for Alternative Dispute Resolution in Intellectual Property Disputes***,** 37 AKRON L. REV. 287**,** 289 (2004).

[43] David Sanker**,** Note, *Phillips v. AWH Corp.: No Miracles in Claim Construction* **,** 21 BERKELEY TECH. L.J. 101, 120 (2006).

[44] Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM & MARY L. REV. 469, 546 (2003).

[45] Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future After Festo*, 19 BERKELEY TECH. L.J. 1157, 1196 (2004).

[46] Stuart M. Reynolds, Jr., The Relationship of Antitrust Laws to Regulated Industries and Intellectual Property in the New Marketplace, 4 TUL. J. TECH. & INTELL. PROP.1, 2 (2002).

Patentable inventions need not be pioneering breakthroughs; improvements of existing inventions or unique combinations/arrangements of old formulations may also be patented.[47] In fact, the majority of inventions are improvements on existing technologies.[48] However, not every innovation is patentable. For example, abstract ideas, laws of nature, works of art, mathematical algorithms, and unique symbols and writings cannot be patented.[49] Works of art and writings, however, may be copyrighted[50] and symbols may be trademarked.[51]

A U.S. patent[52] provides protection only in the United States,

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[47] World Intellectual Property Org., *Inventions and Innovations: Key Elements in Strive for Competitive Advantages Conditions Necessary for Creating an Innovation Friendly Environment*, FORUM ON CREATIVITY AND INVENTIONS-A BETTER FUTURE FOR HUMANITY IN THE 21ST CENTURY, ¶ 8 (Oct. 2000). For a U.S. patent to be granted, an invention must meet all of the following criteria set forth in the U.S. Code, namely, it must: (a) be novel (i.e., sufficiently new and unlike anything that has been previously patented, marketed, practiced, publicized or published); (b) be non-obvious to a person with knowledge in the field related to the invention, meaning that the person would not automatically arrive at the present invention from a review of existing ones (*i.e.*, trivial variations that are readily apparent to a person with knowledge in the field related to the invention cannot be patented); (c) have utility (*i.e.*, the invention has some use and actually works or accomplishes a useful task); (d) be adequately described to the public in order to demonstrate "possession" of the invention at the time of filing; (e) enable a person with knowledge in the field related to the invention to make or carry out the invention without "undue experimentation" (*i.e.*, to make the claimed product or carry out the claimed process without undue trial and error); (f) enable a person with knowledge in the field related to the invention to use the invention; (g) be described in clear, unambiguous and definite terms; (h) set forth the best mode of making and using the invention contemplated by the inventor at the time of filing the patent application. *See* 35 U.S.C. §§ 101-103 (2000).

[48] World Intellectual Property Org., *Inventions and Innovations: Key Elements in Strive for Competitive Advantages Conditions Necessary for Creating an Innovation Friendly Environment*, FORUM ON CREATIVITY AND INVENTIONS-A BETTER FUTURE FOR HUMANITY IN THE 21ST CENTURY, ¶ 8 (Oct. 2000).

[49] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1979).

[50] 17 U.S.C. § 102 (2000).

[51] United States Patent and Trademark Office, Trademark, copyright or patent?, http://www.uspto.gov/web/offices/tac/doc/basic/trade_defin.htm (last visited May. 19, 2007).

[52] A patent is not a "hunting license"; it is merely a "no trespassing fence" that clearly marks the boundaries of an invention. In other words, a patent grant is a negative grant; it prevents other parties from using the invention without prior permission of the patent holder (which can be in the form of a license). This does not imply that the patent holder can automatically publicly practice (*i.e.*, commercialize) the invention. Often, appropriate government regulatory approval is required.

its territories, and its possessions for the term of the patent. It is estimated that 90% of the world's patents are issued through the three main patent offices – the United States, Europe, and Japan.[53] Legally speaking, a U.S. patent is a document granted by the federal government (at the PTO[54]) whereby the recipient (or "patentee") is conferred the temporary right to exclude others from making, using, selling, offering for sale, or importing the patented invention into the United States for up to 20 years from the filing date.[55] Similarly, if the invention is a process, then the products made by that process cannot be imported into the United States.[56] All patented inventions eventually move "off" patent at the end of their patent term ("patent expiration"), at which time they are dedicated to the public domain.[57] This is the basis for low-cost generic drugs that appear in the marketplace following expiration of the costlier versions of the patented branded drug.[58]

The basic rationale underlying patent systems, both in the U.S. and abroad, is simple enough: an inventor is encouraged to apply for a patent by a grant from the government of legal monopoly of limited duration for the invention.[59] This limited monopoly or proprietary right justifies R&D costs by assuring inventors the ability to derive economic benefit from their work. In exchange for this grant, the inventor publicly discloses the new technology

[53] Press Release, United States Patent and Trademark Office, World's Major Patent Offices Publish Results of Comparable Study on Patentability Issues of 3D Protein Structures (Nov. 29, 2002), *available at* http://www.uspto.gov/web/offices/com/speeches/02-70.htm.

[54] The PTO issues three types of patents as defined by the U.S. Constitution: (a) utility patents for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof[;]" (b) plant patents for "any distinct and new variety of plant" (i.e., asexually reproduced non-tuber plant varieties); and (c) design patents for "any new, original and ornamental design for an article of manufacture." (i.e., ornamental designs of an article of manufacture). 35 U.S.C. §§ 101, 161, 171 (2000).

[55] 35 U.S.C. § 154 (a)(1)–(2) (2000).

[56] 35 U.S.C. § 154 (a)(1) (2000).

[57] Brulotte v. Thys Co., 379 U.S. 29, 31 (1964) (stating that "[t]he right to make, the right to sell, and the right to use 'may be granted or conferred separately by the patentee'. . .But these rights become public property once the [20]-year period expires.") (*quoting* Adams v. Burke, 84 U.S. 453, 456 (1874)).

[58] Generic Drugs: Questions and Answers, U.S. Food and Drug Administration, Center for Drug Evaluation and Research, http://www.fda.gov/cder/consumerinfo/generics_q&a.htm (last visited May 19, 2007).

[59] *See* 35 U.S.C. § 261 (2000).

that might have otherwise remained secret (an "immediate benefit" to the public) and allows the public to freely use, make, sell, or import the invention once the patent expires (a "delayed benefit" to the public). Hence, the new technology that is brought to light in the form of valuable technical information provides a continuous incentive for future innovation. In this way, society obtains a *quid pro quo* from inventors in exchange for the temporary grant of exclusive rights. Such an advantageous exchange stimulates commerce (a "long-term benefit" to the public). Patent protection is the engine that drives industry and the incentive for it to invest in R&D to innovate. Clearly, without such protection, most big companies would avoid costly R&D and society would be deprived of the many benefits thereof. However, it is critical that the scope or breadth of the patent be just right; it should neither be unduly broad nor should it be too limiting. In other words, the invention should just fit within the boundaries of the patent.

Obtaining a patent for an invention is often a long, expensive, and tedious process that generally involves the inventor, patent counsel or practitioner (*i.e.*, patent agent or patent attorney), and PTO staff (especially a "patent examiner"). Patent examiners are PTO personnel who review the filed patent application to ensure that it fulfils all pertinent requirements of the law listed above.[60] This review process is commonly referred to as "examination."[61] The exchange of documents between the PTO and the patent counsel is broadly known as "prosecution."[62]

If the examiner believes that all requirements for a patent are met, then a "notice of allowance" is issued to the applicant.[63] Finally, a patent is issued once the applicant pays an "issuance fee." Following this, the entire contents of the patent application ("the file wrapper" or "prosecution history" [64]), along with a copy of the issued patent and all future documents pertaining to the patent are made available to the public.

"As part of the patent prosecution, all applications filed on or

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[60] Patent Examiner Qualifications, United States Patent and Trademark Office, http://www.uspto.gov/go/ac/ahrpa/ohr/jobs/qualifications.htm (last visited Apr. 10, 2007).

[61] *See* 35 U.S.C. § 131 (2000).

[62] BLACK'S LAW DICTIONARY 1258 (8th ed. 2004).

[63] 35 U.S.C. § 151 (2000).

[64] *See* HERBERT F. SCHWARTZ,PATENT LAW AND PRACTICE 18 (4th ed. 2003).

after November 29, 1999 are published eighteen months after filing (up to that point they are kept confidential), unless the applicant opts out and foregoes foreign . . . filing."[65] In effect, this implies that generally a patent application as filed will eventually appear in the public domain (whether or not it is patented) and will be available to competitors. The entire patent examination process, starting with the filing of the patent application to its final allowance or final rejection, may take anywhere from one to five years or longer.[66] This depends upon variables such as the specific technology area within the PTO where the patent is being reviewed by the patent examiner and the time to process the paperwork that accompanies the patent application by the PTO clerical staff.

Since the patent term commences from the date the patent is issued and ends twenty years after the date the application is filed,[67] most commercially valuable nanomedicine inventions are, in reality, in the marketplace prior to the actual patent grant date (unless regulatory approval is sought). Generally, it is impossible to predict future commercial success or commercial viability of an issued patent, even by its inventors. In part, this is due to the fact that most patents are filed at the PTO without any clear idea of whether the invention is commercially valuable. For example, in nanomedicine, patent applications are continuously being filed on a large number of drugs, therapies, and devices even before it is known that they will be ruled safe and effective by the FDA. If litigation rates (which range from 1.5%-2% of the issued patents) are any indicator of commercial value, then only a fraction of patents are commercially significant. Although obtaining a patent does not ensure commercial success, economists view patenting as an indicator of scientific activity.[68] They argue that this is the basis for providing a nation with a competitive advantage, fueling its

[65] 35 U.S.C. § 212 (2000). *See also*, Raj Bawa, *Nanotechnology Patenting in the U.S.*, 1 NANOTECHNOLOGY L. & BUS. 31, 46 (2004).

[66] *See* FRED K. CARR, ESSENTIALS OF THE PATENT, 107-31, (1981) (detailing the patent examination process).

[67] 35 U.S.C. § 154 (2000).

[68] *See* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation,* 76 CAL. L. REV. 803, 807–08, 845 (1988) (describing the patent system's effect on scientific invention and innovation and how this is relied upon by economists).

economy.[69]

In recent years, however, patents have also become the subject of much debate and controversy. In fact, there are plenty of anti-patent players in the field who feel that patent laws (and most international treaties) are unfairly providing an economic advantage to some over others.[70] It has even been suggested that patent laws and intellectual property (IP) are the products of a new form of Western colonialism designed to deny the developing world access to common goods.[71] Issues like biopiracy and IP theft have been proffered as reasons for the unavailability of essential drugs to the poorest and neediest people in the world.[72] Not surprisingly, those in the developing world support patent protection, but prefer a regime that suits their own national interests.[73] In this regard, future struggles over patents on the international stage are almost certain to focus on drug patents where multinational drug patents are revoked or challenged.

Note that the PTO does not police or monitor patent

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[69] *See* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 8 (2004) (arguing that a properly functioning patent system encourages companies to fund innovation that benefits the modern economy).

[70] *See generally* Michelle McGrath, *The Patent Provisions in TRIPS: Protecting Reasonable Remuneration for Services Rendered - or the Latest Development in Western Colonialism*, 18 EUR. INTELL. PROP. REV. 398, 398–403 (1996) (discussing how third world countries are negatively impacted by the implementation of international treaties involving intellectual property).

[71] *See id*. at 399 (predicting that Trade-Related Aspects of Intellectual Property Rights (TRIPs) in the General Agreement for Trade and Tariffs (GATT) will cause less developed countries to become more dependent on developed countries, because less developed countries will have to pay "monopoly prices" for products patented by developed countries); *see also* Vandana Shiva, *North-South Conflicts in Intellectual Property Rights*, 12 PEACE REV. 501, 502 (2000), *available at* http://www.biotech-info.net/north_south.pdf (noting that "patents generated by the General Agreement for Trade and Tariffs (GATT) and the World Trade Organization (WTO) [ ] are often viewed as tools of recolonization by the Third World . . . " and arguing that the true goal of an international intellectual property regime is for Western nations to gain "control over the global economy").

[72] *See* Sivashree Sundaram, Note, *Battling Bills, Beans & Biopiracy* 15 ALB. L.J. SCI. & TECH. 545, 554-56 (2005) (describing biopiracy, which is the term for U.S. companies patenting plants or plant-derived substances that are native to other countries, where the plants may have been used for their medicinal purposes).

[73] *See* Shiva, *supra* note 71, at 506 ("As a Third World country, India's interest lies in working with other developing countries to change the IPR systems being globalized through TRIPs, [and] claiming that TRIPs is biased in favor of rich industrialized countries and global corporations").

infringement nor does it enforce issued patents against potential infringers. It is solely up to the patentee to protect or enforce the patent, all at the patentee's own cost.[74] The patentee may enlist the U.S. Government's help via the court system to prevent patent infringement. However, PTO decisions are subject to review by the courts, including the Court of Appeals for the Federal Circuit (CAFC), and rarely, the U.S. Supreme Court.[75] Sometimes Congress intervenes and changes the law governing patents. The CAFC was created by the U.S. Congress in 1982 with the aim of creating uniformity in the patent law,[76] especially with respect to unpredictable, evolving technologies like biotechnology and nanotechnology. In reality, it has sometimes failed in this role by rendering inconsistent and contradictory patent decisions.[77]

If a court deems a patent to be invalid, the patent holder is unable to enforce it against any party.[78] However, suing an alleged infringer is risky business because when a patent holder sues an alleged infringer, there is a fifty per cent risk that his own patent will be found to be invalid.

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[74] Scott R. Boalick, Note, *The Dedication Rule and the Doctrine of Equivalents: A Proposal for Reconciliation*, 87 GEO. L.J. 2363**,** 2369 (1999) ("A patent is not self-enforcing; rather, a patent holder must bring suit against an alleged infringer." (*citing* SAMUEL C. MILLER III & JOEL M. FREED, PATENT, TRADEMARK AND TRADE SECRET LAW 66 (1997))(on file with author)).

[75] 28 U.S.C. § 1295(a)(4) (2000) (granting the United States Court of Appeals for the Federal Circuit "exclusive jurisdiction . . . of an appeal from a decision of . . . the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office with respect to patent applications and interferences . . . ."); John H. Barton, *Non-Obviousness*, 43 IDEA 475, 489 (2003) ("[t]he Supreme Court rarely intervenes in patent cases, leaving many of the issues to the CAFC").

[76] S. Rep. No. 97-275, at 5 (1981), *as reprinted in* 1982 U.S.C.C.A.N. 11, 15.

[77] *See*, *e.g.*, Optical Disc Corp. v. Del Mar Avionics, 208 F.3d 1324, 1335–37 (Fed. Cir. 2000) (holding that a difference in a shape of an invention's component could be an infringement under the doctrine of equivalents and remanding the case to determine whether the difference in shape insubstantially changed the form the invention); Tronzo v. Biomet, Inc., 156 F.3d 1154, 1160 (Fed. Cir. 1998) (holding that the shape of a component of a particular invention, as a matter of law, did not infringe on prior claims under the doctrine of equivalents); *see also* AMANDA MOGER, DARBY & DARBY, IS PATENT LAW PREDICTABILITY A THING OF THE PAST? (June 2001), http://www.darbylaw.com/news/news_article.asp?id=1695 (asserting that the CAFC produced opposing decisions regarding the doctrine of equivalents).

[78] *See* JAFFE & LERNER, *supra* note 69, at 32 (explaining that the defendant in a patent infringement suit may defeat the claim by showing that the patent is not valid).

Based on my review of seminal CAFC patent decisions from the past decade or so, it is my firm conclusion that the CAFC has fostered the following: (a) expanded what can be patented under the patent statues; (b) lowered the threshold to obtain a U.S. patent; and (c) tilted its decisions in favor of patent holders. Clearly, this stance has resulted in stronger patent protections for patent holders. As a result, since the creation of the CAFC, the number of patents granted has increased at an annual rate of 5.7% as compared to less than 1% from 1930-1982.[79] According to some experts, if this trend continues, it could stifle competition and limit access to some inventions.[80] Moreover, this is contrary to the *quid pro quo* discussed earlier: the balance between the patent holder's limited-time monopoly on the invention's use on the one hand and the public's interest in accessing these inventions on the other is disturbed. Certainly, this could be the very reason why the Supreme Court is increasingly stepping in to hear more and more patent appeals of CAFC decisions. It is important to note that the Supreme Court, which has rarely reviewed patent decisions in the past,[81] has heard five important patent appeals of CAFC decisions in the last three years alone, reversing all of them.[82] By these and other recent decisions, the Supreme Court may be trying to reestablish the balance between the patent holder's and the public's interest, a certain flexibility that it may have viewed as eroding under the CAFC. It is critical that the CAFC refocus its efforts to provide greater clarity to patent law and render patent decisions that are more consistent. After all, this is its true mission.[83]

One highly controversial but important statistic worth mentioning here is the patent grant rate, *i.e.*, the patent

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[79] *Id*. at 11.

[80] *Id*. at 4.

[81] *See* Robert C. Scheinfeld & Parker H. Bagley, *The Roberts Supreme Court Takes on Patent Cases*, 236 N.Y. L.J. 3 (2006) (explaining that although the Supreme Court rarely hears patent cases, the Roberts Court has already confronted numerous important patent issues).

[82] Medimmune, Inc., v. Genentech, Inc., 127 S. Ct. 764, 777 (2007); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 208 (2005); Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc., 126A S. Ct. 980, 989 (2006); Ebay Inc. v. Mercexchange, L.L.C., 126B S. Ct. 1837, 1841 (2006); Illinois Tool Works Inc. v. Independent Ink, Inc., 126A S. Ct. 1281, 1293 (2006).

[83] *See* JAFFE & LERNER, *supra* note 69, at 10; s*ee also* S. Rep. No. 97-275 (explaining that the purpose of creating the CAFC was to achieve uniformity and consistency in the area of patent law).

application allowance rate. Since the PTO is often not very forthcoming in providing accurate patent statistics and data on this issue,[84] several legal scholars have published studies to gauge this figure.[85] One widely cited estimate places the average PTO grant rate at 77% to 95% of filed patent applications for the years 1981 to 2005.[86] However, I agree with some legal scholars who consider this estimate to be artificially high as it is "based on an inappropriate legal framework and flawed [numbers]."[87] In any case, it is immaterial as to what the exact figures are; the crux of the matter is that the PTO grant rates are extremely high and this reflects a less rigorous review of patent applications as compared to the other major patent offices. These high allowance rates are yet another reason for the grant of poor quality patents.[88] As a side note, it should be pointed out that the time

[84] *See* Harold Wegner, *The USPTO's 54% Allowance Rate*, IPFRONTLINE.COM, Dec. 30, 2006, http://www.ipfrontline.com/depts/article.asp?id=13796&deptid=5 (stating that statistics either have not been released or are not readily accessible).

[85] *See, e.g.*, Lawrence B. Ebert, *Comment on "Patent Grant Rates at the United States Patent and Trademark Office",* 4 CHI.-KENT J. INTELL. PROP. 186, 186-87 (2005), *available at* http://jip.kentlaw.edu/archives.asp?vol=4&iss=2 (follow "Comment on 'Patent Grant Rates at the United States Patent and Trademark Office'" hyperlink) (comparing two major studies that arrived at different figures for the USPTO grant rate).

[86] *See, e.g.*, Cecil D. Quillen, Jr. & Ogden H. Webster, *Continuing Patent Applications and the U.S. Patent and Trademark Office – Updated*, FED. CIR. B.J. 635, 661 (2006) ("[F]or the 1981-2005 time period, the lower bound estimate for USPTO Grant Rates corrected for refilled continuing applications is [seventy seven percent] and the upper bound estimate is [ninety five percent].").

[87] Lawrence B. Ebert, *On Patent Quality and Patent Reform*, 88 J. PAT & TRADEMARK OFF. SOC'Y 1068, 1076 (2006).

[88] In light of all this discussion regarding patent allowance rates and patent quality, it is rather interesting to note the PTO's recent announcement of a fifty four percent allowance rate for the past fiscal year (October 1, 2005-September 30, 2006). USPTO, PATENT PUBLIC ADVISORY COMMITTEE ANNUAL REPORT 5, n.11 (2006), *available at* http://www.uspto.gov/web/offices/com/advisory/reports/ppac_2006annualrpt.pdf. In this regard, it is further worth noting that while the number of patent applications has continued to increase, creating a steady backlog, the percentage of issued patents out of patent applications has declined in recent years, most notably in 2005. *Id*. at 5, (stating "[t]he overall allowance rate dropped from 63% in fiscal year 2004 to 59% in fiscal year 2005"). Do these figures imply a vast improvement in patent quality over the earlier years when allowance rates were much higher? Most experts would disagree. *See*, *e.g.*, Wegner, *supra* note 84 (stating the likely result of the current lower allowance rates will be a backlog in the system that will be met with a more lax standard in the future). It is possible that numerous high profile patent cases like the recent Blackberry case, NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282

taken for one million patents to be granted has greatly declined since the grant of U.S. patent No. 1 in 1836.[89]

VI. SIGNIFICANCE OF PATENTS

Patents are critical to the nanotechnology "revolution." When investors or companies consider the merits of their investment, patent issues are one of the most important items they review. For example, "[t]here is ample evidence that companies, start-ups, and research universities of all sizes are ascribing greater value and importance to patents. [Increasingly], they are willing to risk a larger part of their budgets to acquire, exercise, and defend patents."[90] The process of converting basic research in nanoscience into commercially viable products is likely to be long and difficult. Because development of nanotech-related technologies is extremely research-intensive, without the market exclusivity offered by a patent, development of these products and their commercial viability in the marketplace would be significantly hampered. Patents are especially important for start-ups and smaller companies because they may help in negotiations over infringement during competitive posturing with larger corporations. "In fact, patents may also protect the clients of a patent owner because they may prevent a competitor from infringing or replicating the client's products made under license from the patentee."[91] Furthermore, patents provide inventors "credibility . . . with [their] backers, shareholders, and venture capitalists – groups that may not fully understand the

(Fed. Cir. 2005) (upholding, in part, a judgment of infringement against defendant who incorporated technology that integrates e-mail with wireless networks into the "Blackberry," a handheld device that can receive data and access the internet), have over-sensitized PTO upper management, who are now actively engaged in artificially suppressing the high patent grant rate. *See* Wegner, *supra* note 84 (noting that the PTO now requires the patent examiner to obtain agreement from two supervisors as to the patent's validity before the application is allowed). If this is indeed the case, all this tinkering with numbers will have disastrous consequences for the whole innovation process. Moreover, it is clearly counter to the basic tenet of the US patent system: "[t]o promote the Progress of Science and useful Arts . . . ." U.S. CONST. art. I, § 8, cl. 8.

[89] Press Release, USPTO, USPTO Issues 7 Millionth Patent (Feb. 14, 2006), *available at* http://www.uspto.gov/web/offices/com/speeches/06-09.htm.

[90] *Bionanotechnology Patenting*, *supra* note 9, at 29-5.

[91] *Id*. at 29-11.

science behind the technology."[92]

Generally, patents precede funding from a venture capital firm.[93] For a start-up company, patents are not only a means of attracting investment, but also "validating the company's foundational technology . . . ."[94] Therefore, "start-up companies are more aggressively seeking patents as a source of significant revenue. They cite the potential for licensing patents and the power to control emerging sectors of nanotechnology as major reasons for seeking patents on nanotech-related technologies."[95] Additionally, "[f]ew venture capitalists are likely to support a start-up that relies on trade secrets [alone]."[96] In sum, investors are unlikely to invest in a start-up that has failed to construct adequate defenses around its IP via valid, enforceable patents.

A company seeking a dominant position in a particular sector of nanotechnology may wish to review patent citations (i.e., patents cited in other patents). Patent citations can serve as a useful indictor of licensing potential because patents that are repeatedly cited are generally considered more commercially valuable.[97] Approximately "one-quarter of all patents receive no citations, and a mere 0.01% earn more than 100 citations . . . ."[98] According to one study, "a patent mentioned [fourteen] times by other patents is worth, on average, 100 times as much as a patent cited only 8 times."[99]

Millions of dollars may be lost if a company fails to take the necessary steps to protect its patent assets. Securing valid defensible patent protection is also vital to the long-term viability of virtually any company, whether nanotechnology is the platform technology involved or not. "Often, loss of these critical

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[92] *Id*.

[93] *See id*. (explaining how patents give nanotechnology inventors credibility with their financial backers and asserting that venture capitalists are unlikely "to support a start-up that relies on trade secrets instead of patents.").

[94] *Id*.

[95] *Patent Land Grab*, *supra* note 15, 346, 347 (2005) (citing Antonio Regaldo, *Nanotechnology Patents Surge As Companies Vie to Stake Claim*, WALL ST. J., June 18, 2004, at A1).

[96] *Bionanotechnology Patenting*, *supra* note 9, at 29-11.

[97] *See* Stewart McKie, *Innovation Asset Management: Don't Bottle Up Creativity*, INTELLIGENT ENTERPRISE, Dec. 1, 2006, http://www.intelligententerprise.com/showArticle.jhtml?articleID=194500328 ("Citations are a key measure of a patent's 'success' in the market").

[98] Christopher Farrell*, Follow the Patents*, BUS. WK., Jan. 8, 2007, at 78.

[99] *Id*.

assets is a result of the researcher's excitement with his [or her] work and [general] ignorance about intellectual property."[100] In fact, experts agree that "IP awareness" (i.e., the knowledge that patents are intangible property that can be obtained and lost) is central to any business plan or strategy.[101] Further, "it is essential that managers and patent practitioners implement certain proactive measures to 'box out' the competition. In other words, taking the correct preventive steps is critical to realizing the full commercial potential of a bionanotechnology invention."[102] Because nanotechnology interfaces with diverse fields such as biology, physics, chemistry, engineering, medicine, and computer science, filing a patent application (or conducting a patent search) in this field may require expertise in these diverse disciplines. Hence, employing qualified patent counsel (a patent agent, patent attorney or a multidisciplinary team of lawyers), who understands both the legal and technical complexities, is a critical first step in obtaining quality patents. Additionally, issued patents and other prior art should be carefully evaluated and effective patent-drafting strategies devised accordingly.

VII. NANOTECHNOLOGY PATENT PROLIFERATION AND PTO PROBLEMS

Federal agencies continue to grapple with nanotechnology.[103] The U.S. Patent and trademark Office (PTO) is no exception. In fact, "[f]or more than a decade, all the major patent offices of the world have faced an onslaught of [nanoscience and nanotech-related] patent applications."[104] At the PTO, the situation is likely to worsen as more applications are filed and pendency rates further skyrocket. As companies develop products and processes and begin to seek commercial applications for their

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[100] *Bionanotechnology Patenting*, *supra* note 9, at 29-8.

[101] David Forman, *IP Storm Clouds Build on Horizon*, SMALL TIMES, May/June 2004, at 22.

[102] *Bionanotechnology Patenting*, *supra* note 9, at 29-8.

[103] *See* Rick Weiss, *Nanotechnology Regulation Needed, Critics Say*, WASH. POST, Dec. 5, 2005, at A08, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2005/12/04/AR2005120400729.html (suggesting that most federal agencies have not created nanotech-specific safety regulations and discussing the EPA's nanotech program, with which companies that manufacture nanotech products may voluntarily choose to comply).

[104] Raj Bawa, *Patenting Nanomedicine: A Catalyst for Commercialization?*, SMALL TIMES, Nov./Dec. 2005 at 16 [hereinafter *Patenting Nanomedicine*].

inventions, securing valid and defensible patent protection will be vital to their long-term survival. In the decades to come, with certain areas of nanotechnology further maturing and promised breakthroughs accruing, patents will generate licensing revenue, provide leverage in deals and mergers, and reduce the likelihood of infringement. The development of nanotech-related products, which is extremely research-intensive, will be significantly hampered in the absence of the market exclusivity offered by a patent.

Due to the potential market value of [nanotech-related] products, [every player in the international race for technological dominance –] researchers, executives and patent lawyers" – view the collection and exploitation of patents as critical.[105] In fact, these players are making an effort to obtain the broadest patent protection possible for "new nanoscale polymers," devices and systems, often claiming wide applications.[106] Therefore, "[a] sort of 'patent land grab' [Figure 1 (a)-(c)] is in full swing by patent prospectors as startups, [universities] and corporations compete [to secure broad patents in nanomedicine during these critical early days]."[107] "This patent 'land grab mentality' is also fueled by the relative lack of products and processes in the marketplace . . . ."[108] Companies feel that to "demonstrate confidence" and sway venture capitalists they must generate or claim IP.[109] Some companies also feel pushed into claiming as much IP real-estate as possible due to fear that, if they lag behind in this effort, someone else will claim the broadest IP.[110] Similarly, academic researchers feel this compulsion to file for nano-patents in order to bolster their reputation and *curriculum vitae*.[111] Moreover, most inventors have quickly realized the opportunities of a disorganized PTO during these early days when they can indeed

[105] *Id*.
[106] *Id*.
[107] *Id*.
[108] Sean O'Neill et al., *Broad Claiming in Nanotechnology Patents: Is Litigation Inevitable?*, 4 NANOTECHNOLOGY L. & BUS. 595, 597 (2007).
[109] *Id*.
[110] *Id*.
[111] *See* Ruben Serrato, Kirk Hermann & Christopher Douglas, *The Nanotech Intellectual Property Landscape*, 2 NANOTECHNOLOGY L. & BUS. 150, 152 (2005), *available at* http://www.foley.com/files/tbl_s31Publications/FileUpload137/2721/viewcontent.pdf ("In the scientific community, patents can bolster a researcher's reputation and enhance his or her resume.").

secure broad patents on valuable technologies with relative ease.[112]

Certain general trends are being reported for nano-patents. With nanotechnology maturing further, the number of claims in the patent applications and the amount of scientific literature that is cited during patent prosecution is on the rise [Figure 2]. This is significant because scientific publications are the most accurate indicator of scientific activity and productivity.[113] Another trend observed is that nanotechnology patent owners are eyeing commercial potential and therefore maintaining more of their patents [Figure 3].

The overburdened and inefficient PTO "has yet to implement a [solid] plan to handle the soaring number of nanotechnology patent applications being filed."[114] This has resulted in additional time to review patent applications[115] (i.e., an increase in patent pendency) and concerns about the validity and enforceability of numerous issued patents (which reflects a decrease in patent quality).[116] A recent report puts the average nanotechnology patent pendency at four years [Figure 4], a period that is simply too long for certain nanotechnologies that peak and then become obsolete in a few short years.

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[112] *See* Joff Wild, *Patent Challenges for Nanotech Investors*, IPFRONTLINE.COM, Nov. 15, 2004, http://www.ipfrontline.com/printtemplate.asp?id=1487 (discussing the rush to obtain broad patents in nanotechnology and its implications).

[113] Vesna Ilakovac et al., *Reliability of Disclosure Forms of Authors' Contributions*, 176 CAN. MED. ASS'N J. 41, 41, *available at* http://www.cmaj.ca/cgi/reprint/176/1/41 (citing Linda Pololi Sharon Knight & Kathleen Dunn. *Facilitating Scholarly Writing in Academic Medicine*, 19 J. GEN. INTERNAL MED. 64, *available at* http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=14748862#b7) (asserting that despite its problems, "[a]uthorship of scientific articles is the main measure of research productivity . . . ").

[114] Raj Bawa, *Nanotechnology Patenting in the US*, 1 NANOTECHNOLOGY L. & BUS. 31, 47 (2004), *available at* http://www.nanolabweb.com/ (follow "Intellectual Property" hyperlink under "Browse Articles by Topic"; then follow "View Abstract" hyperlink under "Nanotechnology Patenting in the US").

[115] *See id*. at 5, n.16 (describing the backlog of patent applications and the increased PTO processing time for those applications).

[116] *See Bionanotechnology Patenting*, *supra* note 9, at 29-14, 29-15, n. 38 (*citing* FTC, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5 (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf) (discussing the issuance of poor quality patents as a result of several problems that the PTO is experiencing).

Furthermore, surprisingly broad nano-patents continue to be issued by the PTO.[117] Obviously, this is partly the result of court decisions in the past two decades that have made it easier to secure broad patents.[118] "[L]aws have also tilted the table in favor of patent holders, no matter how broad or tenuous their claims."[119] As a result, the PTO faces an uphill task as its attempts to handle the enormous backlog in applications filed. It also faces a torrent of improperly granted patents, many of which are likely to be "re-examined."[120]

The entire U.S. patent system is under enormous scrutiny and strain. Various examination problems continue to haunt the PTO.[121] Some shortcomings specific to nanotechnology patent examination beset the PTO:

At present, the agency lacks a dedicated examining group (called the "Technology Center" or TC) to handle applications on

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[117] *Bionanotechnology Patenting*, *supra* note 9, at 29-11.

[118] *See* Adam B. Jaffe & Josh Lerner, *Patent Prescription*, IEEE Spectrum, Dec. 2004, *available at* http://www.spectrum.ieee.org/dec04/3845 (asserting that the decisions of the CAFC have "significantly broadened and strengthened the rights of patent holders.").

[119] *Bionanotechnology Patenting*, *supra* note 9, at 29-11.

[120] *See* Dan McDonald, *Fighting the Modern Patent Wars,* 14 INTELL. PROP. TODAY 7, 7 (2007), *available at* http://www.iptoday.com/pdf/2007/1/McDonald-Jan2007.pdf (relating criticism of the PTO for improperly granting patents and explaining that Congress is anticipating patents challenges and attempting to address this situation).

[121] One patent expert recently summarized the current crisis at the PTO as follows: "The U.S. Patent and Trademark Office is under siege for issuing patents that should never have [sic] issued, and for excessive delays. Congress is considering changes such as a new opposition system for challenging patents when they emerge from examination." *Id*. A law professor summarizes the blunter criticism found in *Innovation and Its Discontents: How Out Broken Patent System is Endangering Innovation and Progress*, as follows:

> Why are so many bad patents being issued? . . . Under our current system, granting an application with little scrutiny takes less time than subjecting it to rigorous review. . . . The examiners are unable to perform more than a cursory search of their own [due to time constraints and lack of expertise]. . . . Third parties -- competitors and consumers -- are generally excluded from the patent examination process, even though these parties have the greatest incentive to discover the prior art and disclose it to the Patent Office in order to prevent bad patents from being issued.

Mary LaFrance, *Patent Medicine: 'Innovation and Its Discontents' Diagnoses a Broken System*, THE PRESS REGISTER, Jan. 7, 2007, http://www.al.com/entertainment/mobileregister/index.ssf?/base/entertainment/116816493484700.xml&coll=3 (reviewing ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS (2004)).

nanotechnology.[122] Few examiners have experience in this rapidly evolving field of nanotechnology.[123] Since "nanotechnology is interdisciplinary in nature, patent applications that are searched, examined and prosecuted in one center could and should be examined more effectively by a coordinated review in more than one [TC]."[124] In reality, applications are being dealt with differently within each center.[125] This approach results in non-uniform examination of applications because examiners in different TCs review patent applications in light of the case law and prior art unique to their own TC.[126]

Most patents may not receive adequate examination during prosecution due to the patent examiner's inability to locate applicable prior art, especially non-patent prior art.[127] Therefore, as discussed in detail earlier, it is accurate to conclude that patent examiners are basing decisions about the grant of a nanopatent on limited information.[128]

The PTO continues to be under-staffed in numerous TCs and it is plagued by high attrition.[129] The agency's inability to attract and retain a talented pool of patent examiners is creating havoc. Each year, at hearings on Capitol Hill and in its annual report, the PTO brass proudly touts hiring over 1,200 new patent examiners to alleviate the backlog that is clogging the patent

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[122] *Bionanotechnology Patenting*, *supra* note 9, at 29-13.

[123] Drew Harris, et. al., *Strategies For Resolving Patent Disputes Over Nanoparticle Drug Delivery Systems*, 1 NANOTECHNOLOGY L & Bus. 1, 5.

[124] *Bionanotechnology Patenting*, *supra* note 9, at 29-13.

[125] *See Bionanotechnology Patenting*, *supra* note 9, at 29-13 (suggesting that reviews of applications for nanotechnology-related inventions that are completed independently by a single TC are less effective than reviews completed by multiple, collaborating TCs, because each TC might find different information relating to their specialized areas).

[126] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL COMMITTEES, INTELLECTUAL PROPERTY: USPTO HAS MADE PROGRESS IN HIRING EXAMINERS, BUT CHALLENGES TO RETENTION REMAIN, NO. GAO-05-720, at 7 (2005), *available at* http://www.gao.gov/new.items/d05720.pdf (explaining that each of the PTO's eight TCs specializes in a particular area of science or engineering) [hereinafter "Retention Report"].

[127] Beth Simone Noveck, *"Peer to Patent": Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J. L. & TECH. 123, 135 (2006), *available at* http://jolt.law.harvard.edu/articles/pdf/v20/20HarvJLTech123.pdf (describing how patent examiners generally lack the ability to search non-patent prior art).

[128] *See* discussion, *supra* Part III.

[129] *Nanotechnology Patenting in the US*, *supra* note 114, at 47–48, fig. 7.

system.[130] However, it fails to focus on the critical issue of "brain drain" resulting from an exodus of so many experienced patent examiners. It would be wise for PTO Commissioners to focus on retaining some of its employees and not putting all its efforts on hiring new ones. Some experts believe that these attrition rates are likely to be further exacerbated by decreasing morale and work conditions, including poorly designed quality initiatives and inefficient electronic search software.[131] According to many experts, patent examiners are underpaid (relative to law firm salaries) and overworked (as compared to their colleagues at the European Patent Office).[132] They also have to review applications under unreasonable time pressures and skyrocketing patent pendency.[133] Arguably, the internal quality review process that monitors quality of patents that have been allowed by patent examiners is fraught with a general lack of legal and scientific expertise on the part of reviewer.

The PTO's funding problems are legendary: "Congress's long-standing practice of 'diverting' [PTO] user fees collected from patent applicants to the general budget" has always caused much consternation.[134] Naturally, stopping this practice would alleviate some problems at the agency. In February 2006, a bill

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[130] USPTO, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2006 4 (2005) *available at* http://www.uspto.gov/web/offices/com/annual/2006/2006annualreport.pdf. Many reports have highlighted the fact that the federal government is "vulnerable to 'brain drain' both because baby boomers are retiring and because their potential replacements, most notably graduate students, often don't view the government as their first choice of employer." Corinne A. Marasco, *Overlooked Opportunities in Government*, 85 CHEMICAL & ENGINEERING NEWS 47, 47-48 (2007), *available at* http://pubs.acs.org/cen/employment/85/8511employment.html.

[131] *See* RETENTION REPORT, *supra* note 126 (stating that the USPTO faces challenges in retaining employees, including low morale and an ineffective reward system).

[132] Hal R. Varian, *A Patent That Protects a Better Mousetrap Spurs Innovation. But What About One for a New Way to Amuse a Cat?*, N.Y. Times, Oct. 21, 2004, at C2; *see also* U.S. DEPT. OF LABOR, BUREAU OF LABOR STATISTICS, *Lawyers*, *in* OCCUPATIONAL OUTLOOK HANDBOOK (2007), http://www.bls.gov/oco/pdf/ocos053.pdf ("In May 2004, the median annual earnings of all lawyers were $94,930").

[133] *See Nanotechnology Patenting in the U.S.*, *supra* note 114, at 35, n. 16 (describing the amount of backlogged patent applications and the additional time the PTO must expend to process this large number of applications).

[134] Raj Bawa, *Nanotechnology Patents and the U.S. Patent Office*, IPFRONTLINE,COM, May 18, 2004, http://www.ipfrontline.com/depts/article.asp?id=708&deptid=5.

was signed by the President that allows the PTO to spend all of its projected collected fees, thereby preventing funds from being diverted to other government programs.[135]

"[E]ven today with all the quality initiatives underway at the agency, examiners are still largely rewarded on the quantity of their work, not quality."[136] Hence, as borne out in the annual PTO statistics each fiscal year, quality continues to take a back seat.[137]

The PTO has failed to effectively engage outside legal or technology experts. For example, "[o]nly a handful of experts from industry or academia have lectured on nanotechnology at the PTO."[138] This reluctance to use outside expertise has further added to the information deficit. It is clear that the PTO lacks internal expertise in nanotechnology and its isolationist policy only compounds the problem. Moreover, patent examiners are not required to have advanced degrees in science or engineering.[139] Even if they have such credentials (e.g., PhD, JD, PharmD, etc.), they are often "overruled" by those with much lesser legal and/or scientific expertise. In other words, possessing advanced degrees or advanced training, by and large, go unrecognized at the PTO.

"[Few] training modules or examination guidelines have been developed to educate patent examiners in the complexities and subtleties of nanotechnology."[140] Similarly, no written guidelines specific to nanotechnology are available for patent practitioners.

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135 EXECUTIVE OFFICE OF THE PRESIDENT OF THE U.S., BUDGET OF THE UNITED STATES GOVERNMENT: FISCAL YEAR 2007 2, 54 (Office of Management and Publication 2006) http://www.gpoaccess.gov/usbudget/fy07/pdf/budget/commerce.pdf ("The President's Budget provides PTO full access to its fees . . .").

136 *Bionanotechnology Patenting*, *supra* note 9, at 29-15, n. 38.

137 *See Nanotechnology Patenting in the US*, *supra* note 114, 49, n.48 (citing Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf) ("Many, including the Federal Trade Commission . . . , believe that the PTO is often issuing patents of poor quality.").

138 *Nanotechnology Patenting in the US*, *supra* note 115, at 49.

139 *See* U.S. Patent and Trademark Office, Patent Examiner Qualifications, http://www.uspto.gov/web/offices/ac/ahrpa/ohr/jobs/qualifications.htm (last visited May 27, 2007) (setting forth degree requirements for the position of patent examiner in different areas of science or engineering and explaining that although no advanced degree is required for a lower level position as a patent examiner, some graduate work is required for higher levels).

140 *Bionanotechnology Patenting*, *supra* note 9, at 29-14.

Given all these challenges, it is hard to predict with certainty how all this will play out with respect to nanopatenting or commercialization. We will all have to wait and see whether the nanotechnology industry thrives like the information technology industry, or becomes burdened like the radio patent deadlock.[141] Congress is continuing patent reform hearings in an effort to quell questionable patents as well as to provide adequate safeguards against abuses to the patent system.[142]

VIII. CONCLUSIONS, CAUTIONS AND RECOMMENDATIONS

Currently, there are too many players holding too many nanotech-related patents; this has created the current fragmented, messy patent landscape.[143] Most experts agree that this patent landscape is already producing "patent thickets"[144]

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[141] *See* Ted Sabety, *Nanotech Innovation and the Patent Thicket: Which IP Policies Promote Growth?*, 1 NANOTECHNOLOGY L. & BUS. 262, 263, 272–75 (2004) (comparing the nanotechnology industry to the radio industry and examining patent deadlock in the radio industry).

[142] *See* U.S. Senate Comm. on the Judiciary, Notice of Committee Hearing, Patent Reform: The Future of American Innovation, http://judiciary.senate.gov/hearing.cfm?id=2903 (last visited May 28, 2007) (announcing the upcoming full Senate Judiciary Committee hearing on patent reform); *Process Patents*, *Senate Judiciary Committee Hearing*, 110th Cong. (2007), *available at* http://judiciary.senate.gov/member_statement.cfm?id=2735&wit_id=2629 (statement of Senator Patrick Leahy, Chairman, Senate Judiciary Committee) (introducing the debate over "what defenses should be available to a party accused of importing products manufactured abroad by infringing a U.S. process patent" in a previous hearing before the Senate Judiciary Committee); *see also* Luke O'Brien, *Congress Tackles Patent Reform,* WIRED NEWS, Feb. 15, 2007, http://www.wired.com/news/technology/0,72743-0.html (discussing a Congressional hearing focused on reforming the patent system and the findings, which included a list of problems, such as the quality of patents and how the weak patent system is abused).

[143] *See* Press Release, Lux Research & Foley & Lardner LLP, Nanotechnology Gold Rush Yields Crowded, Entangled Patents (Apr. 21 2005), http://www.luxresearchinc.com/press/RELEASE_IPreport.pdf (discussing a review of present nanotechnology patents completed by Lux Research and Foley & Lardner LLP that suggests nanotechnology claims are crowded and overlapping and "the patent landscape . . . is complex and fragmented.").

[144] Patent thickets are broadly defined in academic discourse as "a 'dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.'" Richard Raysman & Peter Brown, *Patent Cross-Licensing in the Computer and Software Industry*, 233 N.Y. L. J., Jan. 11, 2005, at 3, 6 (quoting Carl Shapiro, *Navigating the Patent Thicket: Cross-Licenses, Patent Pools, and Standard Settings*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam Jaffe et al. eds., 2001)). Such patent thickets, a result of multiple blocking patents, naturally discourage

that have the potential to cause protracted legal battles.[145] This is obviously an undesirable result and could easily freeze nanotechnology development in its tracks. It poses the biggest threat to commercialization.[146] Therefore, business planners and patent practitioners should steer company researchers away from such potential patent thickets. For instance, "[t]hey may also need to analyze the patent landscape to gauge the 'white space' opportunities (no overlapping patents) prior to R&D efforts, patent filing, or commercialization activities."[147] Classically, such an analysis into the number and quality of patents issued can highlight a particular technology trend, areas of high/low commercialization potential, and areas that indicate a high risk of market entry. To analyze the perceived patent thicket in any nanotech-related technology, a detailed legal review of the claim set from the patents in the thicket may be necessary before decisions regarding patent filings or substantial investment on commercialization are undertaken.

Clearly, this proliferation of unduly broad patents and the resulting patent thickets will require litigation to sort out, especially if sectors of nanotechnology become financially lucrative. At the present time, it seems that companies are avoiding costly court battles. In fact, there is hardly any nanotechnology patent litigation underway in the US.[148] Companies sometimes avoid costly litigation to prevent exposing their own patents, some of which may be based on a poor review at the PTO and, thus, whose validity may be questionable. In any case, I believe that "expensive litigation is as inevitable as it

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and stifle innovation and "[c]laims in such patent thickets have been characterized as 'often broad, overlapping and conflicting . . . '"). *Patent Land Grab*, *supra* note 15, at 346, 348 (*quoting* ETC GROUP, NANOTECH'S "SECOND NATURE" PATENTS: IMPLICATIONS FOR THE GLOBAL SOUTH (2005), *available at* http://www.etcgroup.org/en/materials/publications.html?keyword=FAO (follow "Download PDF" hyperlink under "Special Report – Nanotech's "Second Nature" Patents: Implications for the Global South)).

[145] *See Patenting Nanomedicine*, *supra* note 105, at 16 (predicting that the issuance of overly broad nanomedicine patents will result in litigation).

[146] *See id*. (suggesting that companies will not commercialize nanomedicine products, because they find the uncertainty of broad, possibly blocking patents too risky).

[147] *Patent Land Grab*, *supra* note 15, at 347–49.

[148] Andrew S. Baluch et al., *Issues Facing Nanotech Companies Going Public: A Recap of an Executive Roundtable*, 3 NANOTECHNOLOGY L. & BUS. 351, 355 (2006).

was with the biotechnology industry, where extensive patent litigation resulted once the products became commercially successful."[149] The reason for this is simple: at this stage, royalties may be collected from potential infringers. When this comes about, in most patent battles, the larger entity with the deeper pockets will prevail even if the brightest innovative stars are on the other side. This situation is all too familiar to business sectors. It leads to higher costs for consumers (if and when products are commercialized), while deterring the innovation process itself.

Ultimately, companies introducing new products to the market will face considerable uncertainty regarding the validity of broad and potentially overlapping patents held by others. This is already happening in various sectors of nanotechnology, most notably in the carbon nanotube arena.[150] The ongoing land grab will definitely worsen the problem for companies striving to develop commercially viable products. In fact, start-ups may soon find themselves in patent disputes with large, established companies, as well as between themselves. Start-ups may also become attractive acquisition targets for larger companies because "takeover is generally a cost-effective alternative to litigation."[151]

It is possible that companies may need to acquire costly licenses for patents from other companies in order to establish themselves. It is also possible that companies may use their patents to exclude rather than license out. Furthermore, those who do license them may do so at an unreasonably high cost. However, I hope that none of these scenarios will come about. Instead, I hope that a more harmonious atmosphere will prevail where cross-licensing agreements by start-ups and large corporations alike will become the norm. In my view, liberal patent licensing is another particularly effective strategy to maneuver the patent thicket at this stage in the development of nanotechnology, especially since the enforceability of so many patents is questionable. It should be noted, however, that "when the total number of owners of conflicting intellectual property is

149 *Patent Land Grab, supra* note 15, at 348.

150 *See* Drew Harris & Raj Bawa, *The Carbon Nanotube Patent Landscape in Nanomedicine – An Expert Opinion*, 17(9) Expert Opinion on Therapeutic Patents 1165-1174 (2007).

151 *Patent Land Grab*, *supra* note 15, at 349.

relatively small, cross-licensing has been the answer. However, when the number of owners of conflicting IP is relatively large, the transaction costs of cross-licensing may be too great [for it to be effective]."[152] Also, critics consider that cross-licensing, as a settlement of a patent dispute, may not serve the public interest since cross-licensing (as compared to litigation) limits competition when it is between competitors.[153]

Given this backdrop, it is almost certain that the enforceability of U.S. nanopatents (like e-commerce patents previously) will be a major problem in the future. Furthermore, due to the substantial annual increase in costs associated with maintaining and enforcing issued patents,[154] enforceability may be a problem when the patent holder lacks the resources to maintain or enforce the patent against potential infringers. Numerous influential entities, ranging from government to non-government organizations, have recently produced authoritative reports critical of the PTO and the US patent system.[155] They all call for urgently needed reforms to be undertaken at the PTO in order to

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[152] *Id*.

[153] *See* Joel I. Klein, Acting Assistant Attorney Gen., Antitrust Div., U.S. Dep't of Justice, Address before the American Intellectual Property Law Association: Cross-Licensing and Antitrust Law (May 2, 1997), *available at* http://www.usdoj.gov/atr/public/speeches/1118.pdf (explaining the anticompetitive effects of cross-licensing between competitors).

[154] *See* U.S. PATENT AND TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2006 ch. 3.6.6 (2006), *available at* http://www.uspto.gov/web/offices/com/annual/2006/30606_earnedrev.html (stating that between 2005 and 2006, the PTO saw a $74.8 million increase in the maintenance fees collected).

[155] *See generally*, FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available* at www.ftc.gov/os/2003/10/innovationrptsummary.pdf (concluding that the patent system should be changed to improve competition and making recommendations for change); A PATENT SYSTEM FOR THE 21ST CENTURY (Stephen A. Merrill, Richard C. Levin & Mark B. Myers eds., 2004), *available* at http://books.nap.edu/html/patentsystem/ (identifying seven criteria for evaluating the patent system, examining the system based on these criteria, and making recommendations for improvements) *available at* http://www.gao.gov/new.items/d051008t.pdf; NAT'L ACAD. OF PUB. ADMIN. FOR THE U.S. CONG. AND THE U.S. PATENT AND TRADEMARK OFFICE, US PATENT AND TRADEMARK OFFICE: TRANSFORMING TO MEET THE CHALLENGES OF THE 21ST CENTURY (2005), *available at* http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Comments2/Patent_and_Trademark_Office/20055/NAPAFullReport.pdf (assessing the weaknesses of the PTO as a "complex 'knowledge worker' agency" and making recommendations for improvements).

ensure a better balance between innovation and competition.[156] Without these reforms, the cursory patent examination that is currently in place, coupled with patent proliferation and patent pendency (that is approaching one million[157]) will continue and issuance of too many invalid and unenforceable nanopatents will become the norm. This will continue to generate a crowded, entangled patent landscape with few open-space opportunities for commercialization. For many companies, navigating this minefield will be an unattractive option.

Ownership of technology in the form of patents is one thing; deriving sufficient economic value therefrom is a different issue. Obtaining undeserving patents and profiting from the threat of litigation rather than providing beneficial nanoproducts runs counter to the foundations of our patent system. Therefore, if the current dense patent landscape becomes more entangled and the patent thicket problem worsens, it may prove to be *the* major bottleneck to viable commercialization, negatively impacting the

[156] *See* FED. TRADE COMM'N, *supra* note 155, at 9–10 (stating that competition can stimulate innovation); A PATENT SYSTEM FOR THE 21ST CENTURY, *supra* note 155, at 1–2 (describing how the patent system has encouraged competition since the 1980s and explaining that now the patent system is facing difficulties, which may be affecting innovation); NAT'L ACAD. OF PUBL. ADMIN. FOR THE U.S. CONG. AND THE U.S. PATENT AND TRADEMARK OFFICE, *supra* note 155, at xxii–xxiv (discussing PTO's strategy for maintaining patent quality, which relates to competition and innovation, and possible changes that could be made).

[157] *Bionanotechnology Patenting*, *supra* note 9, at 29-14.

entire nanotechnology revolution. For investors, competing in this high-stakes patent game may prove too costly.

IX. APPENDIX AND FIGURES

I wish to thank Nanowerk News for kindly providing Figure 1(b). I thank Lux Capital, Inc. (New York, New York) and Foley & Lardner (Washington, DC) for kindly providing the remaining figures.

Figure 1(a): U.S. Nanotechnology Patent Explosion

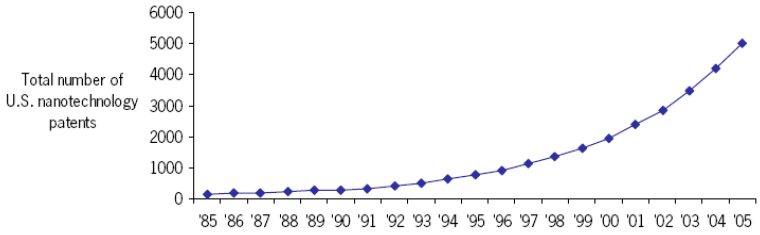


Figure 1(b): Annual Nanomaterials-Related U.S. Patents Issued

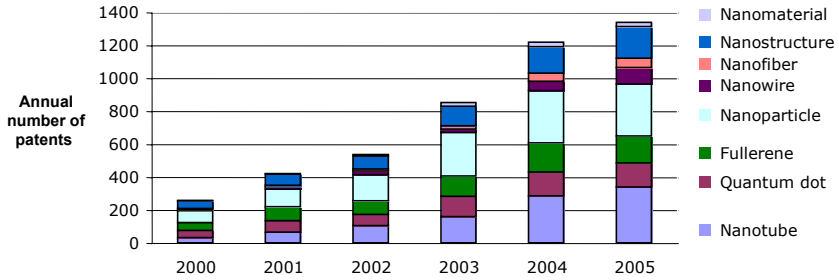


Figure 1(c): Rising Patent Applications and Scientific Publications for Nanotechnology

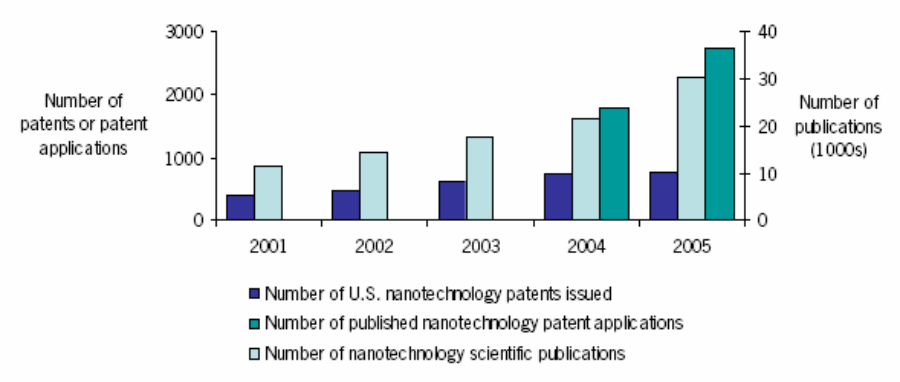


Figure 2: Trends in Nanotechnology Patent Claims and Cited References

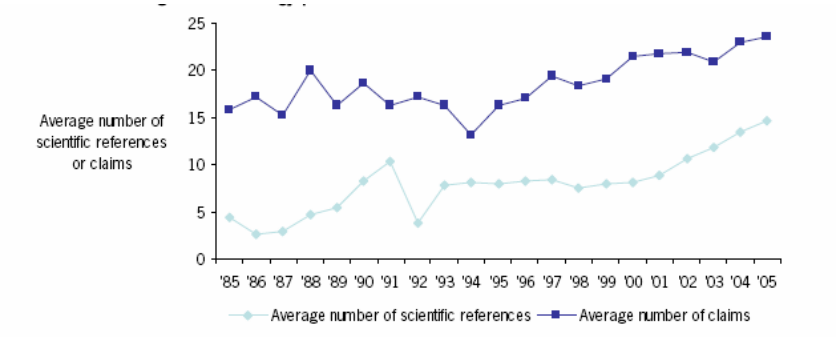


Figure 3: Owners Maintaining Nanotechnology Patents

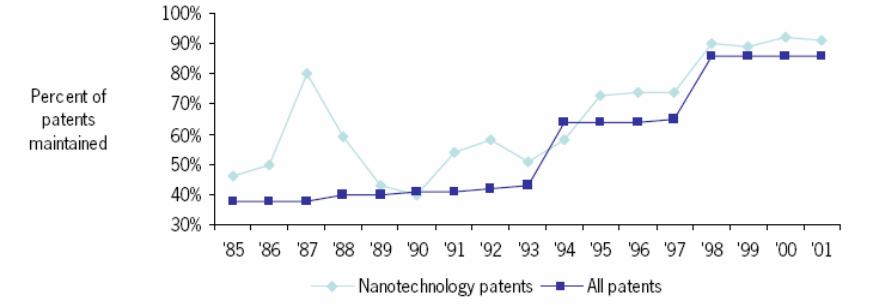
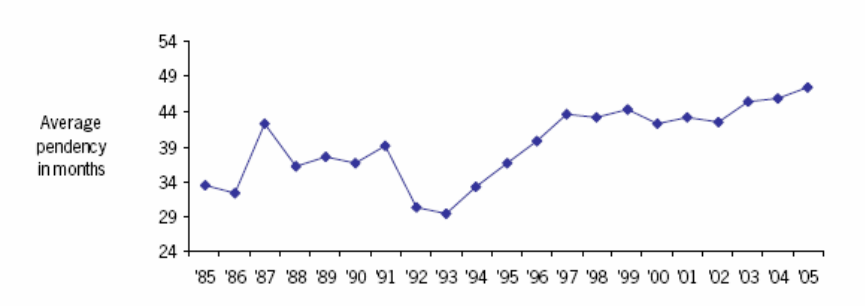


Figure 4: Nanotechnology Patent Pendency


Average pendency in months
54
49
44
39
34
29
24
'85 '86 '87 '88 '89 '90 '91 '92 '93 '94 '95 '96 '97 '98 '99 '00 '01 '02 '03 '04 '05