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Nanotechnology Patenting in the US

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ABSTRACT

Patents are the strongest form of intellectual property protection and are essential to the growth of a nanotechnology company. Similar to their importance to the development of the biotechnology and information technology industries, patents will also play a critical role in the success of the global nanotechnology revolution. In fact, patents are already shaping the nascent and rapidly evolving field of nanoscience and small technologies. As companies develop the products and processes of nanotechnology, and begin to seek commercial applications for their inventions, securing valid and defensible patent protection will be vital to their long-term survival. In this article, Dr. Raj Bawa presents key patent strategies for a small tech inventor. He first provides an overview of the business of patenting. He then engages in a detailed analysis of nanotechnology patent issues. Specifically, he discusses: searching nanotechnology patents, the importance of nanotech patents in the media, nanotech patent trends, strategies involved in patenting, the costs of obtaining nanotech patents, foreign patenting, the future of patents in nanobusiness and challenges facing the PTO.

I. THE BUSINESS OF PATENTING: AN OVERVIEW

Ralph Waldo Emerson in an 1871 lecture said, "If a man can . . . make a better mousetrap, though he builds his house in the woods, the world will make a beaten path to his door." Some inventors misconstrue Emerson's dictum and expect that simply obtaining a patent will guarantee success. Others realize that obtaining a patent does not automatically ensure commercial reward. Still others find that patents sometimes cost much more than they are worth. Detractors complain that legal monopolies hinder free market competition. They argue that a climate of excessive ownership and secrecy has a chilling effect on research and restricts free communication between researchers. So, does the US patent system add "the fuel of interest to the fire of genius," as Abraham Lincoln observed?[1] All

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1 From a speech given in Springfield, Illinois on February 5, 1859.

controversy aside, one thing is clear: a patent is not a "hunting license";[2] it is merely a "no trespassing signpost" that clearly marks the boundaries of the invention.

1. Intellectual Property

Intellectual property, a product or creation of the human mind, is an intangible asset representing humankind's only truly inexhaustible resource. Modern intellectual property consists of patents, trademarks, copyrights and trade secrets.[3] 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 changing from tangible to intangible. Intangible assets as a portion of corporate market capital are steadily rising. Patent protection is the incentive for industry to invest in research and development programs that produce innovation. Clearly, without such protection, many companies would avoid costly R&D and society would be deprived of the many useful benefits thereof. Patents are the most complex, tightly regulated and expensive forms of intellectual property. However, they offer protection for the broad design concept behind an invention in addition to the tangible form of the invention itself.

2. What Is a Patent?

A US patent is a legal document granted by the federal government 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 US for up to 20 years from the filing date.[4] A US patent provides protection only in the US, its territories and its possessions for the life of the patent.

The rationale behind patent law is simple. An inventor is encouraged to apply for a patent by a promise from the US government of a limited legal monopoly for the invention. This promise of limited monopoly rights justifies the development costs and assures a reasonable return on profit. In exchange, the inventor publicly discloses the new technology that might have otherwise remained secret (the "immediate benefit" to the public) and allows the public to freely use, make, sell, or import the invention once the patent expires (the "delayed benefit"). Hence, the new technology that is brought to light encourages further 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 spurs American industry and stimulates commerce (the "long-term benefit").[5]

3. Historical Background

The first patent statute was promulgated in Venice, Italy in 1474. Immigrants from England brought the concept of patents to the New World and patents were granted within the colonies,

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[2] Brenner v. Manson, 383 U.S. 519, 536 (1966).

[3] In the case of nanotechnology, maskworks may be added to this list. If chip layout information is novel in design, it can be protected to prevent unauthorized copying. The PTO issues three types of patents: (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"; and (c) design patents for "any new, original and ornamental design for an article of manufacture." Note that this paper will focus solely on US utility patents.

[4] Similarly, if the invention is a process, then the product(s) made by that process cannot be imported into the US.

[5] Although obtaining a patent does not ensure commercial success, economists view patenting as an indicator of scientific activity. They argue that this in turn is the basis for providing a nation with a competitive advantage, fueling its economy. *See, e.g.,* Roger W. Ferguson, Jr., *Patent Policy in a Broader Context,* Remarks at 2003 Financial Markets Conference of the Federal Reserve Bank of Atlanta (April 5, 2003), *at* http://www.federalreserve.gov/boarddocs/speeches/2003/20030407/default.htm.

although no uniform patent system was yet in place. For example, the Massachusetts Bay Colony granted the first patent on the American continent in 1641 for a new method of making salt.

The Founding Fathers incorporated the concept of patents into the Constitution under Article 1, Section 8, Clause 8, whereby Congress has the authority "[t]o promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[6] President Washington signed the first US Patent Act on April 10, 1790. Title 35 of the *United States Code* codified the Patent Act of 1952, the Act currently in use. Since the granting of the first US patent in 1790, more than 6.6 million patents have been issued by the Patent and Trademark Office ("PTO"),[7] a bureau of the US Department of Commerce. On September 30, 2003, the PTO workforce was comprised of 6,723 federal employees, including 3,637 patent examiners and 355 trademark examining attorneys. In addition, PTO had approximately 4,300 contract employees. In 1790, the PTO issued only three patents. For the past few fiscal years the agency has received over 350,000 patent applications.[8] It issued 171,500 patents in fiscal year 2003.[9]

Traditionally, patents and inventions of commercial interest have been viewed as the domain of industry while basic science and research have been viewed as the concern of academia.[10] This

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[6] This language provides the constitutional basis for the US copyright system as well.

[7] The PTO website (http://uspto.gov) lists all the patents issued since 1790, although some records were lost in an 1836 fire. In 2003, for the eleventh consecutive year, IBM has garnered more US patents than any corporation in the world. It generated $10 billion in licensing fees over the period 1992-2002. It may be of interest to note that IBM has an open licensing policy, offering nonexclusive licenses to anyone who can afford them. Compare this to US academic institutions that usually offer exclusive licensing deals to companies for access to their technology, including nanotechnology. Some experts believe that such exclusive licenses stymie innovation and run counter to the intent of the Bayh-Dole Act of 1980, the act that allows academic institutions to license federally funded research and has propelled them into the world of commercialization of inventions. Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-212. *See generally* DEREK BOK, UNIVERSITIES IN THE MARKETPLACE: COMMERCIALIZATION OF HIGHER EDUCATION (2003). According to Information Holdings, Inc., licensing revenues through US patents increased from $15 billion in 1990 to $115 billion in 1999. *See* Mary Jane Credeur, *Spinoff Targets Unused Patents*, ATLANTA BUSINESS CHRONICLE, July 28, 2003, *at* http://atlanta.bizjournals.com/atlanta/stories/2003/07/28/story5.html.

[8] *See* http://www.uspto.gov/web/offices/com/annual/2003/060402_table2.html. The number of patent applications filed has been increasing, on average, by over 10% per year since 1996.

[9] Nearly 90% of the world's patents are issued through the three main Patent Offices: the US, Europe and Japan. According to PTO data (http://www.uspto.gov/web/offices/com/annual/2003/060406_table6.html), each fiscal year (October 1-September 30), the US Patent Office grants more patents (excluding design, plant or reissue patents) than the European Patent Office or the Japanese Patent Office. Note that since many patent applications remain under review at the PTO for more than one fiscal year, these annual patent figures do not represent a valid comparison. The US has been the major foreign patenting system employed by foreign inventors. The primary reason for this is that the US economy is particularly attractive to foreign innovators due to its large size and technologically advanced nature. Another important statistic worth mentioning is the PTO grant rate, i.e., the patent application acceptance or allowance rate. The PTO grant rate may be as high as 97% (taking into account continuing patent applications). *See* Note, *Stopping Madness at the PTO: Improving Patent Administration Through Prosecution History Estoppel*, 116 HARV. L. REV. 2164, 2165 (2003). Since the acceptance rates for the European, German and Japanese Patent Offices are substantially lower, some patent experts claim that this indicates a less rigorous examination at the PTO.

[10] There has been an upsurge of patents granted to US universities. This has contributed to an increase in the number of university-related startups as well as an increase in income generated via patent licensing. According to recent data on US university patents, the University of California tops the list for the tenth consecutive year as the university receiving the most US utility patents during calendar year 2003. *See Top 10 Universities Receiving Patents in 2003, at* http://www.uspto.gov/main/homepagenews/bak2004feb09.htm. In 2002, 13 of the top 25 US universities saw a 50% or more increase in patents granted as compared to 1997. In fact, during this five year period, six universities have seen a 100% increase in patents granted in 2002 as compared to 1997. *See* Tracy Staedter, *Academic Patent Binge*, TECHNOLOGY REVIEW (Dec. 2003/Jan. 2004), at 24. An interesting trend is emerging with respect to Asian nanotechnology companies: they are funding US research and striking deals for patents from US universities. According to survey data for the fiscal year 2001 (ending June 30, 2001) published by the Association of University Technology Managers (AUTM), US and Canadian universities, teaching hospitals and research institutions generated nearly $1.07 billion in royalties and fees from discoveries licensed to companies in fiscal year 2001 (it was $699

separation has now blurred. In the early days of the patent system, an inventor worked alone in a basement or attic, patented the invention and commercialized the product. Today's inventor is likely to work for a corporation and, if he or she builds a better mousetrap, he or she will likely remain anonymous and reap limited rewards. Although this was certainly not the original plan of the framers of the patent laws in 1790, the change is a result of the Industrial Revolution in the last century coupled with the growth of powerful corporations that control various technologies.

4. Criteria for Patentable Inventions

As defined by the Constitution, US patents are granted to chemical compositions; machines; industrial or chemical processes; manufactured articles; ornamental designs of an article of manufacture; and asexually reproduced non-tuber plant varieties. Patentable inventions need not be pioneering breakthroughs. Improvements of existing inventions or unique combinations/arrangements of old formulations or components may also be patented. In fact, the majority of inventions are improvements on existing technologies. However, not every innovation is patentable. For example, abstract ideas, laws of nature,[11] works of art, mathematical algorithms and unique symbols and writings cannot be patented. To be patentable, an invention (or more accurately, the patent specification) must meet the following criteria:[12]

- it must be novel (i.e., sufficiently new and unlike anything that has been previously patented, marketed, practiced, publicized, or published);
- it must 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);
- it must have utility (i.e., the invention has some use and it actually works or accomplishes a useful task);[13]
- it must be adequately described to the public in order to demonstrate "possession" of the invention at the time of filing;
- it must 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);

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million in 1997). Columbia University leads the pack by having the highest licensing income in the country at $129.9 million, with 90% generated from pharmaceutical patents. In fact, the top ten income-generating universities collectively took in close to $511 million, with the majority of revenue derived from biopatents. *See* L. Pressman, *AUTM Licensing Survey: FY 2001*, *available at* http://www.autm.net. Three biotechnology patents that expired in 2000 brought Columbia University close to $300 million in royalties and licensing fees. *See* Gary Stix, *Working the System II,* 290 SCIENTIFIC AMERICAN 41 (March 2004).

[11] Laws of the universe or discoveries in the natural world, even if revolutionary, cannot be patented. For instance, Einstein's Law of Relativity cannot be considered anyone's intellectual property.

[12] If the inventor is unable to fulfill any one of these requirements of patentability, the inventor may need to amend his application via incorporation of additional subject matter. However, addition of this "new matter" into the patent application will cause the inventor to loose the original filing date, something that may cause the inventor to lose the right to obtain a patent due to statutory time bars.

[13] Perpetual motion machines, time machines and a random configuration of gears lack utility, and therefore, are unpatentable. Note that inventions that may be perceived as being immoral or illegal also fall under this clause. A hypothetical example is an aerosol formulation comprising toxic nanoparticles and lacking any known beneficial use. Although patent statutes are technology-neutral, emerging areas such as biotechnology and nanotechnology may face PTO scrutiny in particular with respect to utility.

- it must enable a person with knowledge in the field related to the invention to use the invention;
- it must be described in clear, unambiguous and definite terms; and
- it must set forth the best mode of making and/or using the invention contemplated by the inventor at the time of filing of the patent application.

5. The Patent Process

Obtaining a US patent for an invention is often a long, expensive and tedious process that generally involves the inventor, patent counsel[14] and PTO staff. Some inventors attempt to work through the patent process themselves ("*pro se* inventors"). In order to proceed efficiently through the patent process, the inventor and patent counsel should assess the commercial feasibility and enforceability of the invention prior to preparing and filing a patent application (see section II(4)). Following this, the inventor should conduct a thorough literature search and review, an exercise referred to as a "prior art" search. This critical step helps shape the patent application so that the described invention fulfills all the criteria for patentability discussed earlier (see section I(4)). It may also save the inventor from spending time and resources on an invention that is unpatentable (e.g., not novel or being obvious). The next step may involve making and testing the invention under actual conditions of use. Once the application is filed with the PTO,[15] it is given an application number and processed. Following this, it is assigned to a patent examiner who conducts a thorough review to evaluate the issues of patentability, a process known as "patent examination."[16]

Until recently, patent examiners searched for prior art in "shoes," a term used to define shallow metal or wooden containers arranged in file cabinets used to house patent documents. The name harks back to Thomas Jefferson, the father of the US patent system and the first head of the Patent Office, who stored his patent documents in shoeboxes. Nowadays, examiners search electronic databases by computer, the digital equivalent of searching the shoes.

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[14] In the US, there are two main types of patent counsels: patent agents and patent attorneys. They both must have a technical background. Both are registered and licensed to practice before the PTO, having fulfilled its qualifications (i.e., their professional credentials have been reviewed by the PTO and they have passed the agency's patent bar examination). Patent attorneys are lawyers who can also litigate patent cases in court and prepare/negotiate licenses.

[15] As part of the application process, all patent applications filed on or after November 29, 1999 are published eighteen months after filing (up to that point they are confidential), unless the applicant opts out and foregoes foreign filing. This means that an application will eventually appear in the public domain and be available to competitors, whether or not it is patented. The entire application process, starting with the filing of a patent application to the final allowance of the application, may take from 1-5 years. Since the patent term commences from the date of filing and ends after 20 years, most viable inventions are in reality commercialized prior to the actual patent grant date (unless regulatory approval is sought). According to a report in the *Atlanta Business Chronicle*, as many as 75% of patents are never used or licensed by the companies that own them. *See* Credeur, *supra* note 7. In the future, these unused patents could be purchased by businesses, combined with similar or complementary ones from other companies, and licensed or resold as a "patent cluster" to third parties.

[16] Since there is a backlog of almost half a million patent applications, the average time to process an application at present is over two years, well off the PTO's target of eighteen months. However, the Director of the PTO in October 2003 warned that if the present trend continues, the agency expects the backlog of unexamined patent applications to skyrocket to more than one million by 2008 (it was 70,000 in the mid-1980s). This implies an average pendency of 3-5 years (or longer) for patent approvals. This would translate into an unacceptable drag on the innovation and commercialization of technology. In an effort to make the patent process paperless, the PTO recently announced that by October 2004 inventors would be able to access online all documents and patent records that accompany the patent application. This development would potentially save time and resources for inventors. This modernization is part of the agency's 21st Century Strategic Plan (an ambitious effort to overhaul the PTO), which aims to streamline the application procedures and speed the review process. Furthermore, in an effort to make the application process more simple and efficient, as of June 30, 2003, all new incoming patent applications (along with about half a million pending applications) are being processed electronically.

Through correspondence with the examiner, interviews and amendments to the application, the inventor seeks an "allowance," a finding that the invention is patentable that results in the grant of a US patent. However, obtaining a US patent does not automatically entitle an inventor to publicly practice his or her invention (i.e., commercialize the invention). Often, appropriate federal regulatory approval is required. For instance, one may need FDA approval to commercialize a pharmaceutical invention or EPA permission to commercialize a pesticide invention.[17] Note that the PTO does not police patent infringement nor does it enforce issued patents. It is solely up to the patentee to enforce the patent and enlist the US government's help via the courts to prevent patent infringement. However, PTO decisions are subject to review by the courts, including the Court of Appeals for the Federal Circuit, and rarely, the US Supreme Court. Sometimes Congress intervenes and changes the laws governing patents.

6. Evolution of Patent Laws: The Biotechnology Example

Patent law is a subtle and esoteric area of law that has evolved in response to technological change. Naturally, it has been modified numerous times since 1790 due to new interpretations of existing laws by the PTO and by the courts or by creation of new laws by Congress, often in response to new technology. For instance, the landmark 1980 Supreme Court's 5-4 decision in *Diamond v. Chakrabarty*[18] allowed genetically altered life forms to be granted a US patent for the first time. A boom in the biotechnology industry followed this ruling, largely due to the intellectual property protection now available to inventions of modified life forms. This decision as well as subsequent actions by Congress and the executive branch have provided the biotechnology industry an economic stimulus to develop new "man-made" microorganisms, animals, plants and cells.

Following this, a subsequent 1987 Supreme Court decision extended patent protection to genetically altered animals. The first animal patent (Harvard Oncomouse) was granted in 1988.[19] Now, the door is open to a host of biotechnological creations ("transgenics"), ranging from goats that produce human proteins in their milk to plants that produce their own pesticides. The PTO presently views altered or genetically engineered organisms to be "non-naturally occurring" and "a product of human ingenuity" and thus, patentable. Despite this, the patenting of genetically engineered life forms, especially plants and animals, remains one of the most contentious moral, regulatory, ethical and legal issues of our time. Adding to this is the fact that decisions regarding patentability (both at the PTO and the courts) are often confusing, contradictory and abstruse. In addition, the PTO and the courts are often slow to resolve critical issues pertaining to patent law, frequently relying on old case law that offers limited guidance today.

7. The Future of Innovation

Present-day technological challenges will be tomorrow's patents. In this new millennium, patents will play a key role in stimulating technological innovation. Who knows what direction technology will take in the future? Consider that the one-millionth patent, issued in 1911, was for a new car tire and then compare that to the six millionth patent, issued in 1999 for a handheld

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[17] Nanobiotechnology-related products, such as nanotherapeutic drug-delivery devices and nanosensors, may require FDA approval. Some experts predict that when companies do finally seek FDA approval, a significant delay in processing may result, as regulators assess for the first time the benefits and risks of these new technologies. In fact, the FDA plans to rely on existing regulations to evaluate nano-related innovations.

[18] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[19] *See generally* Michele Simkin, *Squeak Squeak: Patenting of the Harvard Mouse and Where We Go From Here,* 11 INTELLECTUAL PROPERTY TODAY 18 (2004).

computer. One thing is certain: American inventiveness and a strong patent system are crucial for a robust economy and are keys to current and future US competitiveness.

II. NANOTECHNOLOGY PATENTS AND CHALLENGES

The time for nanotechnology[20] has come and a classic technological revolution is unfolding. According to the National Science Foundation, by 2015 the annual global market for nano-related goods and services will top $1 trillion, making it one of the fastest growing industries in history.[21] If these figures prove to be accurate, nanotechnology will become a larger economic force than the combined telecommunications and information technology industries at the beginning of the technology boom of the late 1990s.

However, history has shown that forecasting technological advances is fraught with difficulty and, consequently, devising policies for them almost impossible. Many products that will be developed early on may remain within existing markets or established sectors, and thus, may not be marketed as nanoproducts. Although the process of converting basic research in nanoscience into viable market products will be long and difficult, governments across the globe are impressed by nanotechnology's potential and are staking their claims and doling out billions of dollars, euros and yen for research. In 2002, worldwide government funding of research and development in nanotechnology exceeded $2 billion, with the US government alone spending $604 million (it increased to $774 million in 2003). In fact, funding from the US government has surged almost sevenfold in the last six years, starting at $116 million in 1997 to a budgeted $847 for 2004. Although the US accounts for almost a third of global nanotechnology spending, about 40 countries have set up similar initiatives. In December 2003, the US Congress passed the National Nanotechnology Initiative (NNI) of 2000 into law and recommended appropriating $3.7 billion for the next four years for the creation of the National Nanotechnology Coordination Office along with funding for various federal nanotechnology initiatives and programs. The European Union has earmarked $1 billion from 2002 to 2006, while Japan has increased funding from $120 million in 1997 to nearly $750 million in 2002. Note that it is impossible to accurately determine the total funding in nanotechnology since these figures do not include private funding.

Some additional statistics from *Nanotech Report 2003*[22] are summarized below:

- Public and private companies will spend close to $3 billion worldwide on nanotechnology R&D in 2003.
- The US government has appropriated $2 billion for nanotechnology since 2000, putting it on track to be the largest US government funded science initiative since the Apollo Mission.
- Presently, more than 700 companies are involved in nanotechnology.

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[20] However, there is confusion and disagreement on the definition of nanotechnology. This is because nanotechnology is an umbrella term used to define the products and processes at the nano/micro scale that have resulted from the convergence of the physical, chemical and life sciences. The US National Nanotechnology Initiative arbitrarily defines it as "anything involving structures less than 100 nm in size." However, this definition excludes numerous devices and materials of micron dimensions, a scale that is included within the definition of nanotechnology by many nanoscientists. The author recommends the phrase "small technology" as a substitute for the term "nanotechnology," and further, to define it as "devices and materials in the nano- and microscale."

[21] One recent report estimates that 800,000 US workers will be needed to support this prediction. *See Lux Capital Releases Key Findings from "The Nanotech Report 2003," available at* http://nanotech-now.com/Lux-Capital-release-06232003.htm [hereinafter "Nanotech Report 2003"]. However, according to NSF estimates there are presently only 40,000 US workers with skills in nanotechnology. *Id.*

[22] *Id*.

- 40,000 US scientists are currently capable of working in nanotechnology.
- In the past four years, more than 1,700 small tech jobs have been created from venture capital funding.
- $900 million in venture capital funding has gone to nanotechnology startups since 1999, with $386 million invested in 2002.

Despite an overall decline in total venture capital from 2001 to 2002, venture investments in nanotechnology have increased (251% in electronics, 211% in industrial products and 313% in life sciences).

Critics question the wisdom of investing such large amounts for a technology that has generated few products, and charge that politicians have been cleverly sold unrealistic economic benefits of nanotechnology. In any case, we should not overestimate what can be achieved within the next five years nor underestimate what can be done by the year 2015. Time will tell if this technology will be a "disruptive technology" and revolutionize worldwide markets.

1. Searching Nanopatents[23]

Since nanotechnology by definition covers a broad class of materials and systems, searching for nanotechnology-related patents and publications is complicated relative to other technology areas. At present, global patent classification systems are neither sufficiently defined nor descriptive enough to accommodate many of the unique properties that nanotechnology inventions exhibit. There is no formal classification scheme for US nanotechnology patents. Additionally, the PTO lacks effective automation tools for nanotechnology "prior art" searching. The fundamental nature of nanotechnology is part of the challenge for effectively mapping the patent landscape. Many patent applications may result from a single nanotechnology invention; hence, a single patent may generate many products or markets.

Published patents that are truly nanotechnological in nature may not use any specific nano-related terminology. Often patents are written "not to be found" in order to keep potential competitors at a "knowledge" disadvantage. Conversely, there are business savvy inventors and assignees that might use key terms incorporating a nano prefix for the sake of marketing their invention or concept.

Therefore, part of the challenge in finding truly nanotechnology related patents is the judicious use of key terms and class codes while searching the patent databases. This searching, along with the additional filter of subject area expertise (which can be used to review patents for the problem being solved and the technology applied) is the most reliable way to find nanotechnology patents at the present time. A subject area expert can ultimately provide the judgment in determining whether a patent pertains to nanotechnology.

2. Media Hype

One thing is obvious: patents in nanotechnology are vitally important for nanoscience to realize its true potential and move beyond the hype (*Figure 1*). According to a SRI Consulting Business Intelligence study, hype in nanotechnology (as measured by the number of news articles) outpaced patents awarded for the past few years, in particular 1997-2002.[24] According to *Nanotech Report 2003*, mentions of "nanotechnology" in the media have increased twenty-fold, from approximately 200 in 1995 to more than 4,000 in 2002, suggesting levels of attention

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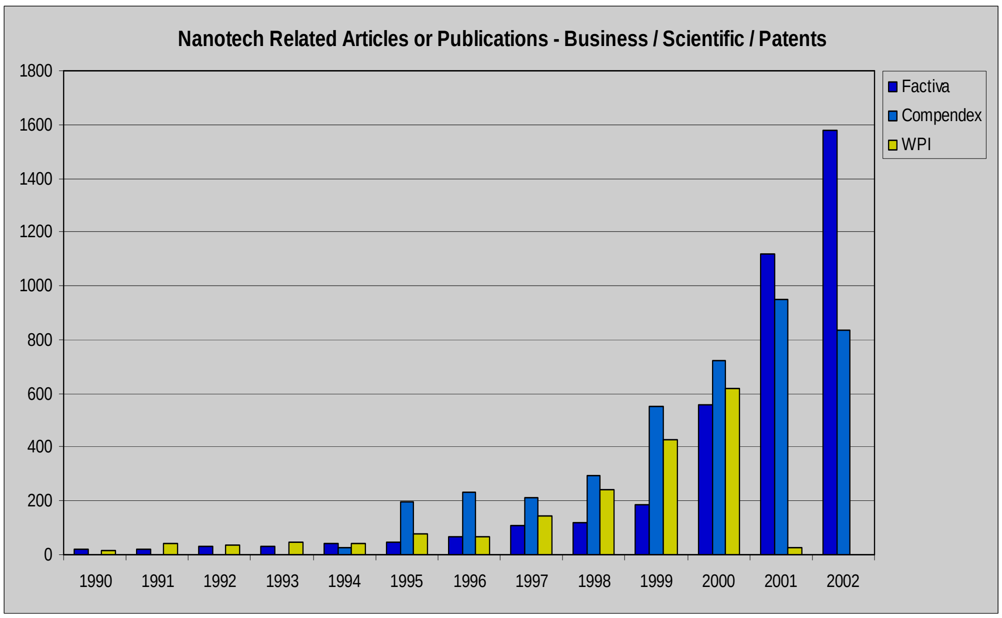
[23] Keith Walker (Director, IP Analytics, InteCap, Inc.) contributed to this subsection.
[24] *Beyond the Nanohype,* THE ECONOMIST, March 15, 2003, at 26.

comparable to the transition that occurred in 1993 heralding the information technology boom.[25] In fact, given the amount of research investment from government, corporate and private sources that is beginning to flow into nanotechnology research, the trend of patenting activity would be expected to continue to rise at an almost synchronous pace.

Figure 1: Nanotechnology Hype *(Courtesy of Keith Walker, InteCap, Inc.)*



Year	Factiva	Compendex	WPI
1990	21	0	14
1991	20	0	43
1992	30	0	36
1993	31	0	45
1994	40	28	39
1995	44	194	75
1996	68	232	66
1997	107	209	143
1998	117	292	241
1999	184	553	428
2000	556	724	617
2001	1117	950	28
2002	1578	837	1

[25] Nanotech Report 2003, *supra* note 21.

3. Patent Trends[26]

As stated earlier, patents add value to a company, providing it with a competitive advantage by virtue of excluding others from making, using, selling, offering for sale or importing the patented invention into the US. As we enter the "golden era" of nanotechnology in the next decade, with the field maturing and the promised breakthroughs accruing, patents can generate licensing revenue, provide advantages in deals and mergers, and reduce the likelihood of infringement. Since development of nanotechnology-related products is one of the most research-intensive industries in existence, without the market exclusivity offered by a US patent, development of these products and their introduction into the marketplace would be significantly hampered. Nanobusiness today is practiced mainly by three entities:

- universities, national laboratories and government agencies;
- large companies with significant R&D, manufacturing, marketing and distribution capabilities; and
- start-ups and spin-offs formed by academic researchers and scientists.

Although the full potential of nanotechnology has yet to be realized, patents granted in this field and applications containing the terms "nano" or "quantum" have shown an upward trend in the past five years. In fact, the number of nanotechnology-related patents has been on the rise for more than a decade (see *Figures 2-6*). According to *Nanotech Report 2003,* almost 3,000 patents were filed at the PTO since 1996, with IBM leading all nanopatent recipients.[27] Because the patent landscape is getting crowded, commercialization of a nanotechnology product should not be attempted without reviewing the patent literature.

Although there has been a dramatic rise in nanotechnology patent activity, most of the prior art exists in the form of journal publications and book articles. Web sites and pre-grant patent publications provide an additional resource. Various data sources and software tools can make a patent search more efficient and effective.

Some of the key data sources available for patent search and analysis include: Thomson Derwent (World Patents Index, Patents Citation Index); Thomson Delphion; various issuing authorities' websites (PTO, European Patent Office, Japanese Patent Office, etc.); IFI CLAIMS (US Patents/Citations, Current Patent Legal Status); assignee websites; INPADOC (family and legal status); Dialog (e.g., Dialindex); JAPIO (patent abstracts of Japan); engineering, technology and scientific (INSPEC, EiCompendex, SCISEARCH, CAS); and markets and business (Factiva or PROMT).

Some key software tools useful for patent analysis include Internet-based or enabled systems (Delphion, Derwent, MicroPatent, Government sites, Google, Dogpile, Vivisimo, Teleport Pro); text-mining tools (ClearForest, VantagePoint); and Microsoft Office (Pivot tables, charting, organizing data).

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[26] Patent data are often used to describe technology strengths and weaknesses of nations. In fact, patent data analysis can often reveal early trends in technology change that can subsequently be transformed into commercialization opportunities and market success.

[27] Nanotech Report 2003, *supra* note 21. Judging from the explosion of US nanopatents, it is clear that the PTO views a scale-down in physical dimensions patentable. In fact, current case law supports the proposition that a change in size can result in patentable subject matter because unique technical problems arise when physical dimensions are reduced.

The distinction between using patent filing activity[28] and patent publication activity is often overlooked when doing competitive assessment. *Figures 2* and *3* depict a patent priority filing trend and a patent publication trend, respectively. Patent priority filing activity more accurately reflects patent trends; the rationale being that the priority filing date is a more accurate indicator of patent activity, i.e., it is more indicative of when the inventive activity initially occurred. The patent filing activity for nanotechnology is based on patent family information obtained from Derwent World Patents Index. The search terms employed to construct this search were intentionally kept broad to accommodate the many aspects of small technology inventions. The results are also restricted in the sense that all of the filings have a US counterpart (patent publications having one or more of the same priority dates) within the family. The chart would look quite different without that restriction; it would be more dramatic and show a greater increase in filing activity.

(*See next two pages for Figures 2*-*6*)

[28] There can be a significant delay between the date of patent filing (date of patent application) and the date of patent issue (date of patent grant), in some cases years.

Figure 2: Nanotechnology Patent Priority Filings *(Courtesy of Keith Walker, InteCap, Inc.)*

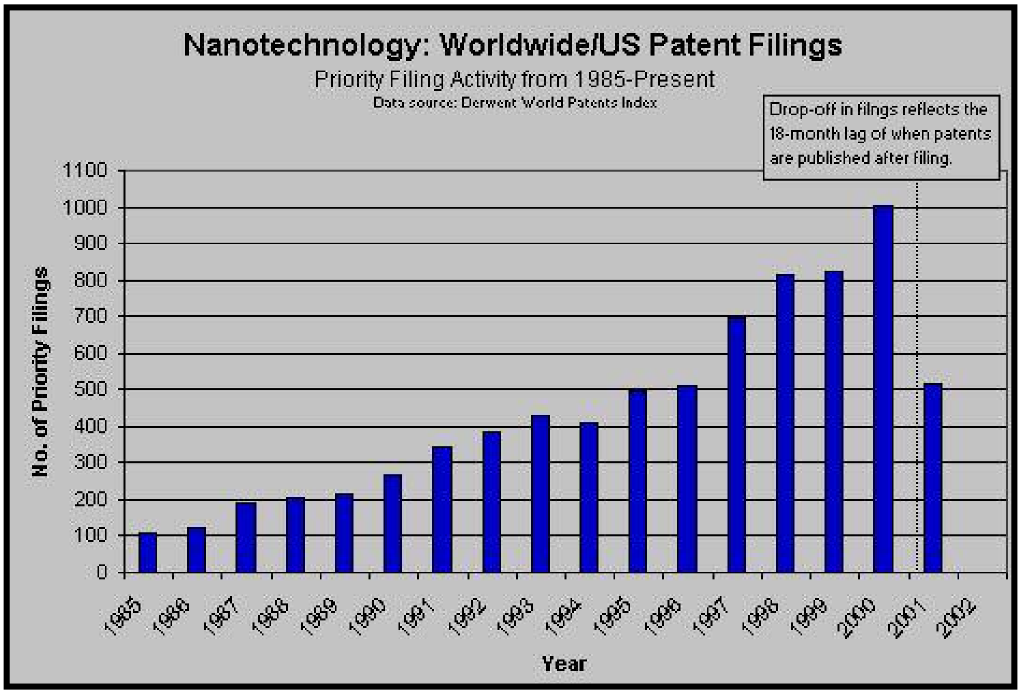


Figure 3: Nanotechnology Patent Publications *(Courtesy of Keith Walker, InteCap, Inc.)*

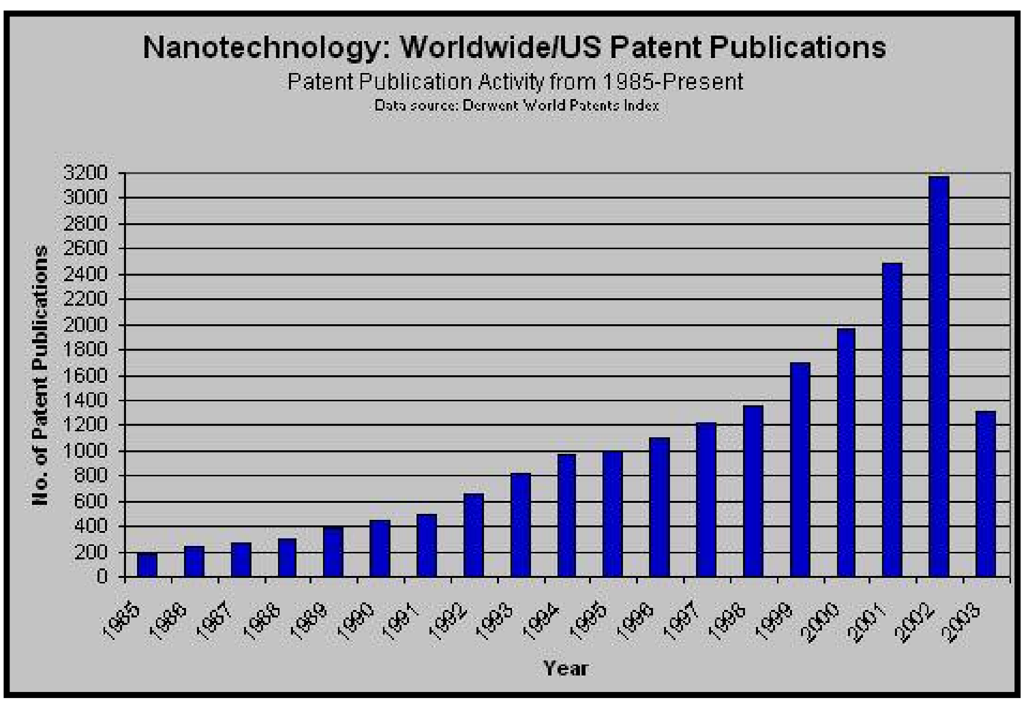


Figure 4: Global Priority Filings on Small Tech Drug Delivery and Therapeutics
(Courtesy of InteCap, Inc.)

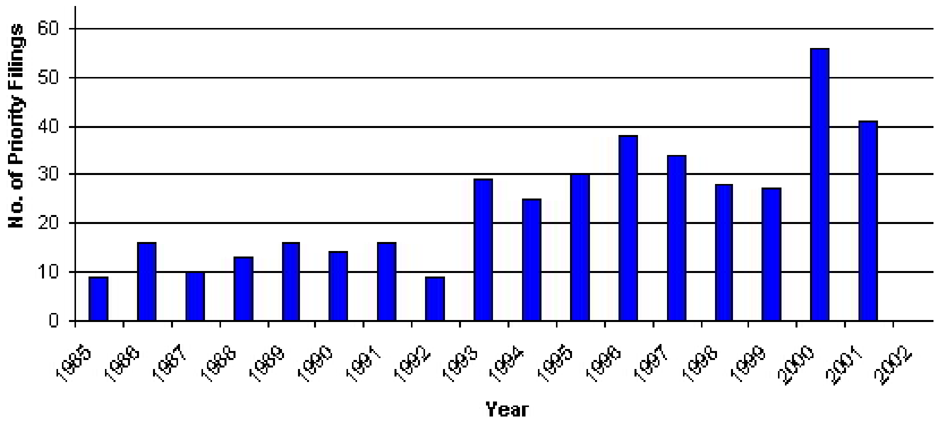


Figure 5: US Patents and Published Applications Containing the Word "Nanowire"
(Courtesy of Stephen Maebius, Foley & Lardner)

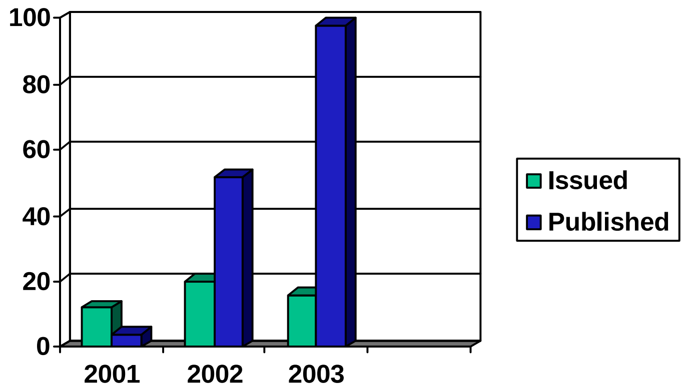
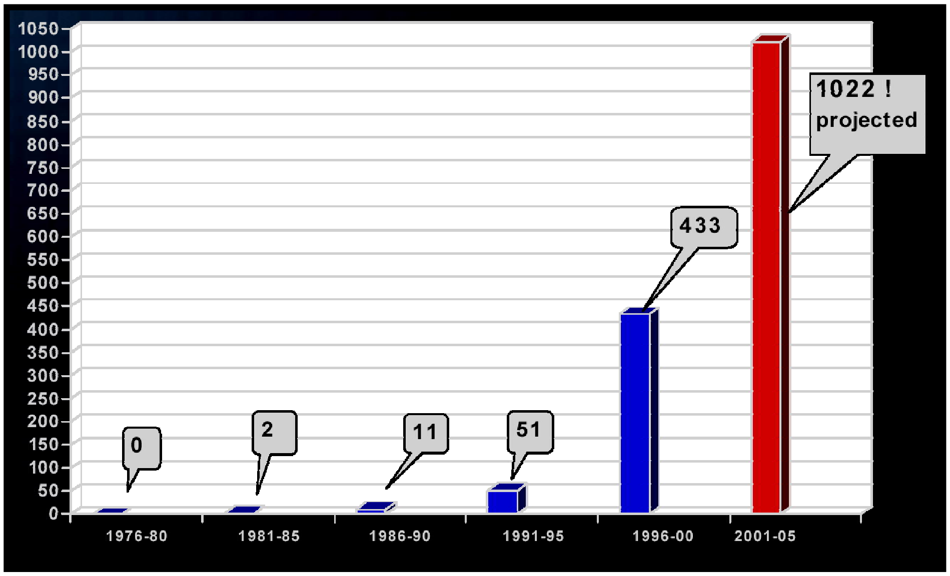


Figure 6: US Patent Filings on Dendrimers
(Courtesy of Dr. Rutt, Foley & Lardner)



4. Key Considerations and Strategies for Inventors

Because this emerging technology interfaces with fields such as biology, physics, chemistry, engineering and computer science, filing a patent application (or conducting a patent search) in nanotechnology may require expertise in these diverse disciplines. The quality and value of the issued nanotechnology patent[29] will largely determine its potential for commercialization, licensing opportunities, investor interest and enforceability. Hence, employing qualified patent counsel (a patent agent, patent attorney, or a multidisciplinary team of lawyers) who understand the legal and technical complexities of nanotechnology is a critical step in obtaining quality patents.[30]

In short, issued small tech patents should be carefully evaluated and effective patent-drafting strategies devised accordingly. Additionally, many complex marketing factors may also need to be carefully evaluated ("Inventor's Reality Checklist"):

- Does the invention offer a unique solution to a real problem?
- Does it offer a measurable improvement over previous attempts to solve the problem?
- Is it a stand-alone product or part of an existing product?
- Can it be easily manufactured or integrated into an existing product or system?
- How big is the potential market?
- Is the market growing or shrinking?
- Can the invention be expanded into new markets as they evolve?
- Will the invention become passé before a prototype is designed?
- Who are the prospective investors, partners or licensing agents in this field?
- What price will consumers put on its value?
- What are the estimates for commercialization and marking?
- What are the incentives for the consumer to buy the product?
- Is federal regulatory approval required?
- How long will it take to bring the product to market?

Taking the correct preventive steps is critical to realizing the full commercial potential of a new nanotechnology invention. Some essential considerations the inventor must be aware of to adequately protect his invention prior to filing for a patent are as follows:

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[29] The "patent quality or value" of an issued patent is relative and often measured in terms of other factors: the breadth and scope of the issued patent claims that affect others' freedom to operate; the number of potential competitors in that particular technology; licensing activity surrounding the issued patent; other intellectual property held by the patent-holder in that particular technology, including any blocking patents. On the other hand, "patent examination quality" is a complex concept. It generally refers to the ability of a patent examiner to make proper, timely decisions about the validity and scope of protection during the examination process that is consistent with the legal ruling a court would make after comprehensive review of the same application.

[30] A growing number of law firms see enormous opportunities in nanoscience and nanotechnology. Some law practices that have formed nanotechnology patent/intellectual property groups include Foley & Lardner; Sterne, Kessler, Goldstein & Fox; Finnegan, Henderson, Farbow, Garrett & Dunner; Bawa Biotechnology Consulting LLC; Brinks, Hofer, Gilson & Lione; Foster, Swift, Collins & Smith PC; Winstead, Sechrest & Minick PC; Bracewell & Paterson; Oppenheimer; and Burns, Doane, Swecker & Mathis.

(a) The inventor must refrain from publishing a description of, publicly presenting, submitting grant proposals for, or offering the invention for sale prior to filing a patent application. All of these activities create "prior art" against the inventor, which in turn may prevent the inventor from obtaining a patent, or prevent the inventor from realizing the full range of potential applications of the technology for which a patent is being sought.[31]

(b) When working in research teams, proper laboratory notes documenting the creative effort, maintaining confidentiality and securing communication among the teams, and filing for a patent promptly are essential so that some members of one group do not inadvertently disclose the invention of another group prematurely.

(c) Because the patent owner does not automatically have the right to practice his invention, it may be wise to conduct a "freedom-to-operate search" of the issued patent prior to investing and/or commercializing the patented product.

Once a company invents a nanoproduct or process, it may opt to commercialize it, license it, patent it, or sell its rights. Examples of some nanotechnology efforts and applications that can be protected via patents are:

Upstream Inventions:

- Manufacturing Methods (materials and tools)
- Computational Techniques

Downstream Inventions:

- Nanoelectronics (quantum dots)
- Sensors (carbon nanotube gas sensors, nanocantilever-based sensors)
- Aeronautics/Space Travel (durable, low-weight fullerenes)
- Environmental Clean-up/Sanitation (self-assembly monolayers, dendrimers)
- Nanobiotechnology/Nanomedicine (drug delivery via fullerenes, liposomes, nanoparticles, and nanoshells; prosthetics; surgical robots; and implantable smart devices)

5. Nanopatents and the Start-up

Patents are of great importance to start-ups and smaller nanotechnology companies as they may protect them from infringement by 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. Moreover, patents offer credibility to any nanotechnology inventor with its backers, shareholders and venture capitalists—groups that may not fully understand the science behind the technology.

As start-ups evolve and grow in size, protecting trade secrets in this information age may be difficult. Few venture capitalists are likely to support a start-up that relies on trade secrets instead of patents. For a start-up, patents are a means of validating the company's foundational technology in order to attract investment. Most experts agree that a start-up should focus on obtaining a broad intellectual property portfolio that includes both patents and trade secrets that cover clusters of an emerging sector in nanotechnology. Alternatively, the start-up may seek

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[31] According to current US patent law, the applicant has one year to file for an application from the date that invention is known of, used by others, or offered for sale. However, because this one-year grace period is not offered by foreign patent offices, an application should be filed as soon as possible after the completion date of the invention.

dominant (or pioneering) patent protection as a means of gaining an advantage.[32] The start-up (or any skilled inventor) should consider filing patents on their concepts to protect them from predatory inventors,[33] and later file on the details of these early concepts when those are worked out. A nanotechnology start-up should also consider patenting peripheral technology and non-related technology in addition to the base technology. This strategy may sustain it during times of economic down or provide it with additional revenue, through licensing or sale to other companies that are better positioned to take advantage of the technology. Either of these intellectual property strategies provides a market advantage to the start-up. Generally speaking, even after the dissolution of a poorly performing nanotechnology start-up, patents on its vital technologies can be sold to another company thereby providing some return for investors.

6. Soaring Costs of Obtaining a Patent

Obtaining and maintaining a patent is a costly process, with fees at every step. The basic patent filing fee can range from a few hundred US dollars to more than $1,000, depending on the size of the company and type of patent sought. The legal fees for a patent agent or attorney to draft and prosecute a nanopatent application are variable, averaging anywhere from $2,000 to $100,000. This is clearly the biggest expense in the application process. Add to this the cost of obtaining a professional patent search, the significance of which is often underestimated. Once the patent is issued, the applicant must pay an issue fee, followed by escalating maintenance fees throughout the patent's life. All of this may total over $100,000, a significant expenditure for any company, especially for a start-up. However, most companies view obtaining a patent as simply the cost of doing business.

It should be pointed out that in certain areas of nanotechnology, obtaining a patent on a short lived innovation may not be practical because the technology it covers may be obsolete by the time the patent issues. In other cases, the patented product may be too costly to produce and therefore not commercially viable. However, both of these scenarios are often hard to gauge prior to filing for a patent. These are just some of the challenges of critical importance that dog almost all nanotechnology start-ups today.

7. Obtaining a Foreign Patent

Filing a nanotechnology patent in a foreign country should be carefully considered and should largely depend upon commercial considerations. If there is an interest in expanding into foreign markets, then obtaining patents abroad should be seriously considered. In fact, even if the inventor does not plan to establish a market in a foreign country, obtaining a patent there could be critical in securing licensing deals (and discouraging unlicensed copying or use).

Most US inventors seeking foreign nanotechnology patents first file a US patent application (known as the "national stage" application) and follow it with a patent application under the Patent Cooperation Treaty (PCT). The PCT is a multilateral treaty established in 1978 among more than 120 nations that allows reciprocal patent rights among its signatory nations. In other words, it simplifies the patenting process when an inventor seeks to patent the same invention in more than one country.[34] Inventors have a one-year grace period after filing the national stage patent application before they must file in the foreign country under the PCT. Under PCT rules,

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[32] Dominating patents are those that are generally the first ones to issue and detail a novel technology. For example, NEC owns the dominant patents on carbon nanotube technology.

[33] Predatory inventors are individuals who patent every possible application around a novel, early technology. This approach could become common in certain sectors of nanotechnology.

[34] It should be emphasized that there is no "world patent."

inventors can specify the particular foreign countries where they intend to seek patent protection for their nanotechnology invention and may take 30 months (or more) from their original national stage application filing date in their home country to complete all foreign application requirements. This delay may provide the inventors with time to determine whether their nanotechnology invention is commercially viable and merits patenting in several countries, thereby sparing them substantial effort and expense.

Today, as part of the application process, all patent applications are published eighteen months after filing (up to that point they are confidential), unless the applicant opts out and foregoes foreign patent filing.[35] This implies that a nanotechnology application will generally appear in the public domain and be available to competitors, whether or not it is patented. The danger of steering clear of foreign patent filing is that a competitor could commercialize the invention in a foreign country and capture a valuable market share there. For example, an inventor who patents a new process of synthesizing a nanomaterial only in the US is giving away the technology to other countries since the patent may disclose the best method of producing this novel nanomaterial.

8. The Future of Nanobusiness

Nanotechnology will almost certainly develop as biotechnology has, through intensive research that produces novel products and processes. Largely, the present-day nanoenterprise mimics what the biotechnology start-ups of the early 1980s faced—namely, corporate partnerships, licensing,[36] and venture opportunities. Patents are central to all these activities. In fact, a sort of “patent land grab” is currently underway by nanotechnology “patent prospectors,” as startups and corporations compete to acquire broad patents in these critical early days.

Biotechnology and pharmaceutical industries are likely to be the big winners as they offer therapy or cures for numerous diseases. Medicine will intersect nanotechnology and evolve into nanomedicine, or nanobiotechnology. Cellular and molecular processes inherent to biotechnology will be used to manufacture tools and technologies for drug discovery, diagnostics, detection and therapeutics. Furthermore, disciplines like biotechnology, information technology and bioinformatics will merge with nanotechnology to create hybrid technologies. For example, nano-therapeutic drug-delivery devices could be on the horizon. In the years ahead, nanotechnology’s involvement in bio-diagnostics (e.g., implantable sensors that monitor and respond to changing health status) could grow to billions of dollars annually. According to *Nanotech Report 2003*, venture funds are preferentially going to nanobiotechnology, with 52% of the $900 million in venture capital funding for nanotechnology in the past four years going to nanobiotechnology startups.[37] The two major factors driving commercialization in nanobiotechnology are federal funding and an expiration of drug patents.[38]

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[35] Traditionally, applications filed at the PTO were kept secret until they matured into a patent. However, as a result of the American Inventors Protection Act (AIPA) of 1999, an application filed on or after November 29, 1999 loses its secret status if and when it is published.

[36] According to Stephen Maebius (Partner, Foley & Lardner, Washington, DC), many biotechnology start-ups sprouted in the early 1980s from broad university patents or groups of patents that were licensed to the start-up following an initial round of venture capital funding. The stimulus then was the Bayh-Dole Act of 1980 and the granting of the first US patent on a life form. Today, this trend continues with nanotechnology start-ups who have licensed university nanotechnology patents.

[37] Nanotech Report 2003, *supra* note 21.

[38] According to Merrill Lynch, 23 of the top global pharmaceutical patents will expire by 2008, accounting for an annual revenue loss of over $46 billion. *See generally* D. RISINGER, J. BORIS, B. LI & J. CALONE, US MAJOR PHARMACEUTICAL MODEL AND PIPELINE BOOK, 4TH QUARTER 2002 ISSUE (2003).

Commercial nanotechnology is at a nascent stage. Large-scale production challenges, high production costs, the public's general reluctance to embrace innovative technology without real safety data or products,[39] and a well-established micron-scale industry are just a few of the bottlenecks facing early-stage nanotechnology commercialization. In fact, to continue fostering innovation in nanoscience and maintain intense commercial interest in the field, some key participants need to come together more effectively to catalyze the nanorevolution:

- universities, national R&D labs and industry providing innovation;
- angels and venture capitalists assisting with capital, business and entrepreneurial assistance; and
- states and the federal government providing incentives and enacting favorable regulations.

Robust intellectual property protection may be added to this list. It is critical that the key participants create incentives to reward not only the usual downstream innovators (the end-product development), but also the upstream innovators (the early-phase innovation).

9. Challenges Facing the PTO: Too Little? Too Late?

Patent offices around the world are struggling to evaluate and prosecute nanotechnology patent applications. As the US patent system expands to accommodate nanotechnology-related inventions, the PTO has yet to implement a plan to handle the soaring number of patent applications being filed. The rise of nanotechnology is presenting new challenges and problems to this overburdened agency as it attempts to handle the enormous growth in applications filed and patents granted in a wide rage of disciplines encompassing "nanoscience" or "nanotechnology." Some shortcomings at the agency regarding examining nanotechnology applications requiring urgent attention are discussed below[40]:

***(a) Lack of a Technology Center*:** The agency lacks a dedicated Technology Center (department) to handle applications on small tech. As a result, US patent examiners lack focused expertise in nanotechnology. Some have criticized this, especially since there is traditionally little collaboration or communication among the various technology centers. However, the PTO has no plans to form a new technology center, primarily due to the interdisciplinary nature of nanotechnology. This author considers the formation of a separate technology center premature, and instead suggests creating a working group/committee within each technology center that identifies small tech patent applications as they are filed, formulates examination guidelines, undertakes training of selected examiners, and periodically meets with its counterparts from other technology centers. A progress report should be periodically presented to PTO customers at nanotechnology partnership meetings (discussed below).

***(b) Lack of a Classification System*:** There is no formal classification scheme for US nanotechnology patents.[41] Additionally, the PTO lacks effective automation tools for nanotechnology "prior art" searching. This could render examination unfocused and inefficient, resulting in the issuance of unduly broad patents. Some patent practitioners argue that a separation of the search from the examination of a patent application, as proposed by the *21st Century Strategic Plan of the PTO*, could further undermine the examination of small tech applications.

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39 There are a handful of products on the market today; in reality, they are more evolutionary than revolutionary.

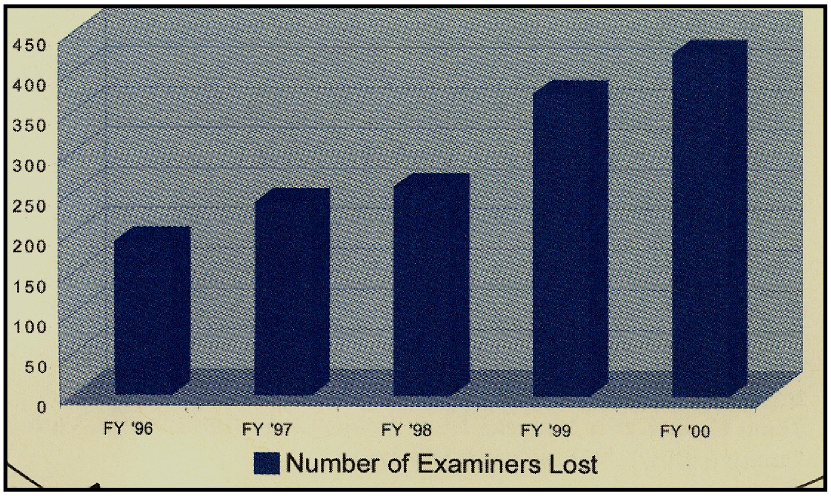
40 *See* Raj Bawa, *Nanotechnology Patents and the US Patent Office*, 4 SMALL TIMES IP-8 (2004).

41 The Japanese Patent Office (http://jpo.gov) has formed a unique nanotechnology patent classification system.

***(c) High Attrition*:** The PTO is under-staffed in numerous examining areas and it is plagued by high attrition rates (*Figure 7*).[42]

Figure 7: Patent Examiner Attrition Trend (Fiscal Years 1996-2000)

(Courtesy of Ronald Stern and Lawrence Oresky, Patent Office Professional Association)



***(d) Funding Problems*:** PTO's funding problems are compounded by Congress's long-standing practice of "diverting" user fees collected from patent applicants to the general budget.[43] Naturally, many of the PTO's problems would be solved by ending this practice of diverting user fees to other agencies. In fact, the pending legislation encompassing the *21st Century Strategic Plan of the PTO* promises to end this diversion.

***(e) High Patent Pendency*:** The backlog in patent applications continues to build. This slows the ability of businesses to bring innovative new products to market. Since there is a backlog of almost half a million patent applications, presently the average time to process an application (i.e., patent pendency) is over two years[44]. However, given the current trend, the agency expects this backlog of unexamined patent applications to skyrocket to more than 1 million by 2008 (it was 70,000 in the mid-1980s). This implies an average pendency of 3-5 years (or longer) for patent approvals.[45] Since small tech patent applications are spread throughout the

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42 The agency's inability to retain a talented pool of patent examiners is highlighted by the cumulative loss of examiners from its biotechnology group (Technology Center 1600) since fiscal year 2001. Couple this to the average growth rate (i.e., new application filings per period) of greater than 10% for the past five years, and the pendency figures become more serious. *See* Kathleen Madden Williams, *Current State of the Art at the U.S. Patent & Trademark Office*, GENETIC ENGINEERING NEWS, June 1, 2003, at 6.

43 Since 1990, the agency has been totally funded by user fees (not taxpayer money) collected from inventors, businesses, universities and corporations. The President's recent proposal to allow the PTO to keep all of the $1.3 billion in patent fees it collects each year is being praised. The proposal will allow the PTO to hire hundreds of new examiners to attack the enormous patent application backlog. It is yet to be seen if Congress will uphold this directive, or if the damaging drain on the agency's resources will continue.

44 Latest patent pendency statistics were released by the PTO in February, 2004. *See* http://www.uspto.gov/web/offices/com/annual/2003/060404_table4.html).

45 The Director of the PTO described his agency as being in a state of "crisis" while discussing this issue. *See* Eriq Gardner, *Patent Pending*, CORPORATE COUNSEL, October 2003, at 104-107.

agency, it may be virtually impossible even to gauge the precise backlog in this case.

***(f) Limited Industry-PTO Interaction*:** Only a handful of experts from industry or academia have lectured on nanotechnology at the PTO. In fact, the first-ever Nanotechnology Customer Partnership Meeting was held at the PTO on September 11, 2003.[46] The meeting was designed and developed to be a forum to share ideas, experiences and insights between individual users and the PTO. However, the agency does not intend to use the meeting to arrive at any consensus.

***(g) No Examiner Training or Guidelines*:** To date, no training modules or examination guidelines have been developed to educate patent examiners in the complexities and subtleties of nanotechnology. No written guidelines for the practitioner have been published in the *Official Gazette of the PTO*.

The results of the shortcomings cited above are all too familiar to the patent community:

- An improper rejection of a nanotechnology patent application due to an examiner's erroneous conclusion that the subject matter is not novel; or
- Issuance of an "overly broad" nanotechnology patent that infringes on previously issued patents and/or gives far too much control over a particular swath of nanotechnology, allowing the patentees to unfairly exclude competition;[47] or
- Issuance of a nanotechnology patent in spite of existing prior art that was overlooked during patent examination.

Either of the above results is unacceptable. Issuance of patents of poor quality[48] (or too many "invalid" patents on early-stage research) is likely to cause enormous damage to the global nanotechnology industry by:

- suppressing market growth and innovation; and/or
- causing a loss of revenues, resources and time; and/or
- discouraging industry from conducting R&D and inducing unnecessary licensing; and/or
- resulting in a flood of appeals and infringement lawsuits.[49]

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[46] The author was invited to attend the meeting, and his recommendations to the Assistant Commissioner were video-recorded. According to the PTO, the meeting highlights and presentations will soon be available on their official website. The next meeting is scheduled for April 20, 2004.

[47] Issuance of overly broad patents may stifle future development of nanotechnology by allowing inventors and corporations control of basic technologies; this violates the primary directive of the patent system to stimulate innovation and commerce.

[48] Many, including the Federal Trade Commission (http://ftc.gov), believe that the PTO is often issuing patents of poor quality. *See* Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, October 2003. In fact, more than ever before, many experts are suggesting removing the presumption of validity associated with issued patents. Some of the factors contributing to poor examination at the PTO are the increasing number of patent applications filed each year and the agency's inability to attract and retain a talented pool of patent examiners. Moreover, even today with all the quality initiatives underway at the agency, examiners are still largely rewarded on the quantity of their work, not quality. Although flawless patent examination is impossible, cooperation between the Patent Office Professional Association (the labor union representing the examiners), the US Department of Commerce and Congress is urgently needed to address this critical issue.

[49] Litigation, generally a last resort for most companies, is an untested area with respect to most sectors of nanotechnology. Few patent infringement cases actually result in trial. Figures from past years have been below 5%. According to the *Harvard Law Review*: "The current patent examination system is in crisis. The PTO grants approximately 97% of patent applications, yet courts invalidate 46% of litigated patent claims." *See Stopping Madness at the PTO*, *supra* note 9. Unlike biotechnology, mechanical and chemical patent practice, patent practitioners in

As industry and trade groups continue to highlight these concerns to the PTO, the agency appears to have finally taken notice. However, critics charge that the PTO has failed to take any concrete steps to address the numerous concerns of the small tech community. They point to the fact that the PTO has not taken any proactive steps to train its patent examiners in nanotechnology or undertaken any classification projects setting out the sub and cross disciplines in the field, generally first steps in organizing new technologies.[50]

Some tips for US patent applicants and experts are as follows:

- Due to the interdisciplinary nature of nanotechnology, patent applicants should become familiar with the patent examination guidelines for computer-related inventions as well as biotechnology-related inventions. For example, they should consult regulations concerning the submission of computer programs, flow charts, nucleotide sequences, etc.
- Nanotechnology experts should educate the PTO on nanoscience developments via lectures, documents, seminars and personal interviews conducted during patent prosecution. They should participate in various customer partnership meetings held at the PTO. On the other hand, PTO officials should be invited to present at major small tech conferences and seminars.
- Extensive and current prior art should be submitted during patent prosecution.
- Nanotechnology experts should assist the PTO in devising a proper classification scheme as well as developing uniform guidelines/definitions for the various nanotechnology sectors.
- Nanotechnology patent applicants should employ language in patent applications whose meaning is well recognized in the technology.

For now, it appears that the PTO will continue to struggle with nanotechnology patent applications. How many invalid or overly broad patents have been issued so far by the agency? At this point, it is anyone's guess. However, if its track record on gene-therapy, genomics and "business method" patents is any indication, the current agency practice presents the frightening prospect of mismanagement of the patent application and prosecution process for nanobusiness. It is hoped that the agency will not take the same lax approach that resulted in the serious backlog of applications that beset these technology areas. If the shortcomings described above are not addressed promptly and effectively, US patents of poor quality could stifle research and impede nanoscience from realizing its true potential, undermining the future of this promising technology. Furthermore, it is likely to have a serious negative impact on business ventures, venture capital and entrepreneurs—all vital contributors to the development, exploitation and promotion of the nanotechnology revolution.

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nanotechnology do not yet have an established body of patent law specific to small tech. Some experts have proposed providing a means to invalidate a patent short of litigation (similar to the current European "patent opposition"). Such a process would be beyond the present limited reexamination procedure. In fact, this simple "postgrant review" of patents would provide an inexpensive option compared to litigation as it would allow for withdrawal of a patent when it fails to fulfill the criteria for patentability, thereby encouraging licensing and commercialization activity. *See also* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 120-141 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

[50] In fact, the PTO is de-emphasizing the role of its classification system as a tool for searching prior art.