Intellectual property issues around nanotechnology

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Intellectual property protection strategies for nanotechnology

Abstract: The field of nanotechnology has been widely recognized as comparable to biotechnology and digital information revolutions. As a general-purpose technology, nanotechnology is expected to have widespread applications across many critical industrial sectors. The growing market and competition require careful attention to intellectual property (IP) rights and strategies. The American patent system is currently going through the biggest reform since the passage of Patent Act of 1952, and many changes apply directly to the field of nanotechnology. This review discusses basic IP definitions, recent IP developments, and advanced protection strategies to better understand the *status quo* of IP specifically in nanotechnology. The potential impact from the patent system reform is also discussed.

Keywords: intellectual property; nanotechnology; patents.

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1 Introduction

Human creativity in nanotechnology dates back to the ancient times, as exemplified by the Lycurgus cup from the fourth century, which has colloidal gold and silver incorporated in the glass [1, 2]. It was not until the invention of scanning tunneling microscope (STM) (1981) and atomic force microscope (AFM) (1986) that seeing and manipulating materials at the nanometer scale became reality and nanotechnology began its era [3]. Today, the potential impact of nanotechnology in the US and worldwide industries elicit billions of dollars of investments for research in order to capture a part of the projected trillion-dollar nanotechnology market. In 2000, it was projected for nanotechnology products and services to reach $3 trillion by 2020 [4]. Since the launch of the National Nanotechnology Initiative (NNI) in 2000 through 2012, Congress has appropriated approximately $15.6 billion for nanotechnology, including approximately $1.7 billion in 2012 funding under the Consolidated and Further Continuing Appropriations Act of 2012 [5]. President Obama has requested $1.8 billion in NNI funding for 2013. More than 60 nations have established similar programs, with an estimated private sector investment of $9.6 billion in 2010 [5]. Although it appears that the USA is the overall global leader in nanotechnology, the governments of Europe, Japan, China, Canada, and Singapore already have invested billions of dollars in advancing their own nanotechnology programs [6].

Vast differences exist between different countries and technology areas in nanotechnology development. A study was conducted to characterize and analyze the importance of specific nanotechnology domains for the East and the West [7]. When comparing regional strengths and weaknesses, USA leads significantly in nanobiotechnology, which indicates a potential support in the relevant research domain by public and private funding or the potential interests of critical mass of expertise to explore the biological application. Although European regions show their strong activity in researching nanomaterial domain, Asian regions have shown their strong research performances in the nanoelectronics domain, but they have lagged greatly behind in nanobiotechnology [7].

In the past decade, the numbers of nanotechnology workers, scientific papers, products, and global investments have all increased by an average annual rate of 25%. In comparison, the number of global patent applications in nanotechnology experienced an even sharper growth, with an average annual increase rate of about 35% (Figure 1). In the USA alone, the annual number of nanotechnology patent applications grew from 405 in 2000 to 3739 in 2008 [4]. The number of issued patents displays a similar growth rate, both in the USA and other industrial leading countries [9, 10]. The market increase is expected to follow that same trend in the coming decade [4]. With

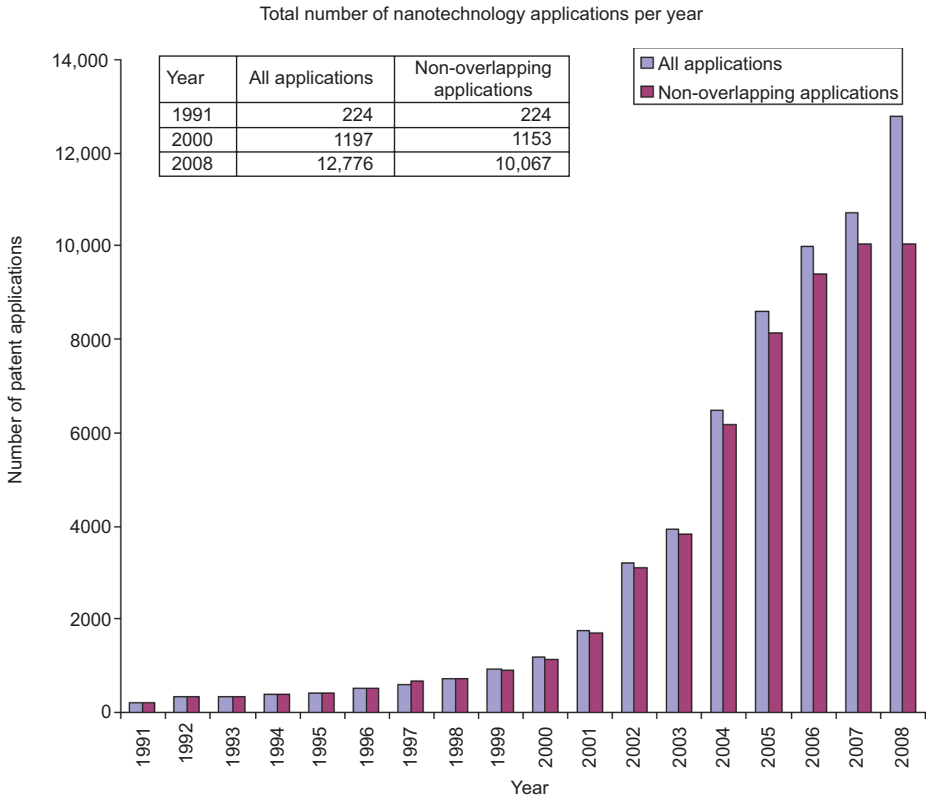

Figure 1 Number of nanotechnology patent applications in the world.
For non-overlapping patent applications, one application is counted per patent family [8]. (Reproduced with kind permission from Springer Science+Business Media: *Journal of Nanoparticle Research: An Interdisciplinary Forum for Nanoscale Science and Technology*, "Trends in Worldwide Nanotechnology Patent Applications: 1991 to 2008", Vol. 12, 2010, pp. 687–706, Dang et al., Figure 1.)

the increasingly competitive market and rapid generation of intellectual properties, as well as the recent reform in the US patent law system, more effort and attention must be paid to intellectual property (IP) protection strategies. This review will introduce nanotechnology, basic intellectual property rights, recent developments, and advanced IP strategies in the nanotechnology field.

2 Basics

2.1 Scope of nanotechnology

The definition of nanotechnology by the NNI is "the understanding and control of matter at the nanoscale, at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications" [11]. A number of other definitions for nanotechnology exist, and there is still debate as to whether a dimension limit should be set for nanotechnology, and if so, what it should be [10, 12]. Despite the debate, those definitions commonly emphasized that nanotechnology must involve new phenomena and properties that arise from the miniaturization of matter in at least one dimension, and such phenomena and properties can enable new applications not achievable by those at greater or smaller scales.

In 2004, the US Patent and Trademark Office (USPTO) created a cross-reference art collection for nanotechnology, Class 977. Class 977 adopted the dimension range set in the NNI definition, and it noted that the mere fact that the size of a subject matter falls within that dimension limit would not place the subject matter in Class 977 unless it possesses a special property or function or produces a special effect "uniquely attributable" to the nanoscale dimension [13]. Such a requirement is consistent with the understanding of nanotechnology in the scientific community [10, 12].

The above definition indicates that nanotechnology encompasses all the fields of natural science and all the applications related to those fields. Table 1 shows some examples of nanotechnology fields that have achieved rapid development in the past decade and have great future outlook.

Table 1 Examples of nanotechnology advancements.

Category	Field	Technology examples
Tools	Computation	– Simulation of nanoparticle self-assembly – Statistical analysis of nanostructures
	Nanocharacterization	– High-spatial-resolution scanning probe-based microscopy measuring a wide range of phenomena – Atomic-scale imaging of nanostructures by electron beam-based microscopy
	Nanomanufacturing	– Scale-up synthesis and patterning of nanostructures – Controlled integration of nanoelements into multiscale ensembles
Applications	Nanobiotechnology	– Nanoparticle as carrier for drug delivery – Nanostructured polymers for tissue repair
	Nanoelectronics	– Transistors with features below 30 nm – Carbon electronics featuring graphene
	Nanomagnetics	– Magnetic random access memory using quantum spin Hall effect – Semiconductor spintronics
	Nanophotonics	– Plasmonics-enabled ultrahigh-resolution imaging and targeted medical therapy – Silicon-based light amplification and emission for transmitting information optically across a chip
	Sustainability	– Nanocomposite membranes for water purification – Nanostructured solar cells for solar energy conversion

Source: Ref. [4].

2.2 IP rights

Detailed descriptions of IP protections in the USA can be found in Ref. [14] and are summarized in Table 2.

For nanotechnology, all the subject matter can be potentially protected under patent rights. The process of obtaining a patent can be expensive and may take several years. The criteria for patentability are complicated and have recently been reformed under the Leahy-Smith America Invents Act (AIA). Despite the associated high cost and complexity, patents provide the most powerful protection for nanotechnology inventions because it allows the patent owner to maintain a monopoly on the inventive concept.

Patent right is only protected by the country where the patent is filed. To obtain protection in one or more countries, separate applications through the patent office of the respective country must be done. The global nanotechnology developments and applications have made foreign patent prosecution an important aspect in business and legal considerations.

The novelty definition in each country can be different, and the grace period in US patent law may not exist in some other countries. Inquiring local patent practitioners in a given country is strongly recommended.

There are several paths for foreign filing, which are usually expensive because of the associated government fees and translation cost. For example, one may first file

Table 2 Summary of IP rights.

	Subject matter	Enforceable period	Cost of acquiring in US (USD, approximate)
Patent	Process, machine, manufacture, composition of matter, or an improvement of an existing idea that is new, useful, and nonobvious [15–17]	20 years from the earliest effective filing date (EFD) [18]	>$10,000 for filing >$20,000 for issue and maintenance
Trade secret	Any information that has been kept in confidence and has business value [19]	Infinite until information is disseminated publicly	No formal filing procedure
Trademark	Distinctive word, phrase, logo, symbol, or other device to distinguish a product or service from competitors	10 years following the date of registration, subject to renewal	$1000–$3000
Copyright	Original and creative work that is fixed in a tangible medium of expression	Effect instantly and for the life of the creator plus 70 years (individual creator) or for 95–120 years (business creator)	<$100
Mask work	Two- or three-dimensional layout or topography of an integrated circuit	10 years from the earlier of registration and the first commercial exploitation	<$2000

a Patent Cooperation Treaty (PCT) application and then apply for patents in individual countries (national stage) within 30 months from the priority date. A PCT application can cost about $4000 [20], and national stage filing cost can vary from $2000 to $8000 [21]. Alternatively, one may file in the USA to secure a filing date and then file in selected foreign countries where significant commercial activities are planned. To claim the priority date of the US filing, the foreign country must be a member of the Paris Convention, and the foreign filing should be done within 1 year. Top places for this path include the European Patent Office (EPO) and Japan. Filing in Japan or EPO costs about $9000 [20, 22]. An EPO patent needs to be validated in member countries to receive protection, which may cost approximately $3000–$5000 each for the five top countries (UK, Germany, France, Italy, and Spain) [22]. Maintenance fee is required in each country, which costs about $20,000 in Japan and $7000–$18,000 in each of the top five EPO member countries [22]. Carefully evaluating those options is essential to maximizing business objectives.

Trade secret, if diligently maintained, is an inexpensive way to protect IP that is not patented but should not be disclosed for various reasons. That is important to any nanotechnology company and is especially valuable for start-ups, who may be at the stage of prioritizing the markets to encompass and are yet to set their corresponding patent strategy.

Trademark, copyright, and mask work can be very useful for nanotechnology companies in certain situations.

A nanotechnology company may want to register trademarks for its name and logo as well as its products. It is possible to apply for trademark protection in foreign countries. One application can be filed for a group of countries under the Madrid Protocol. Alternatively, protection can be sought for each country in which one is interested because the trademark application cost is moderate compared with patents.

Copyright protects the expression of work, not the idea embedded in it. Therefore, it can be used for protecting against piracy. In contrast, the underlying idea can only be protected by patents. Copyrights can be applicable to nanotechnology in software computation tools, software developed in research and engineering, and technical manuals. Reciprocal copyright protections are available to nationals of the participating countries under the Berne Convention or the Universal Copyright Convention (UCC).

Mask work protects original circuit design against copying by means of, for instance, photographing each layer of the integrated circuit. Mask work protection must be sought in individual countries; thus, it is important to register in those countries with large manufacturing activities.

3 Recent IP developments

3.1 Recent court rulings

3.1.1 Subject matter: US Supreme Court "101"

Eligible subject matter under 35 USC Section 101 sets forth the categories for patent protection, stating that "Whoever invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title" [15]. On June 28, 2010, the US Supreme Court held that the claims of Bernard Bilski's and Rand Warsaw's patent application were not directed to patentable subject matter [23]. Bilski and Warsaw applied for a patent on methods for hedging risks for commodities trading. The Patent Office rejected their patent application as covering an abstract idea not eligible for patent protection under (101) of the Patent Act. Bilski appealed to the US Court of Appeals for the Federal Circuit (CAFC). The court ruled that the patent application at issue was not tied to a machine and did not result in transformation and therefore was excluded from patentability under 35 USC 101. Although affirming the outcome of the case, the Supreme Court rejected the Federal Circuit ruling that the "machine or transformation" test is the "sole" test for determining whether a process or method claim is patentable "subject matter" under 101 [23].

Post-Bilski, lower courts continued to analyze claims under Section 101 using the machine-or-transformation test, and if a claimed process satisfied the machine-or-transformation test, then it was a patentable subject matter. If the claim failed the test, then it might still be eligible for patent as long as it did not merely claim a law of nature, physical phenomenon, or abstract idea.

A most recent case and unanimous US Supreme Court decision in *Mayo v. Prometheus* marks the first instance of a court invalidating a patent that passed the machine-or-transformation test [24]. The decision in *Mayo v. Prometheus* clearly shows that even if a claimed process satisfies the transformation test, it does not necessarily claim patentable subject matter. The patent claims covered processes that help doctors who use thiopurine drugs to treat

patients with autoimmune diseases to determine whether a given dosage level was too low or too high. The issue in *Mayo v. Prometheus* was whether the claimed processes have transformed the unpatentable natural laws into patent eligible applications of those laws. The court concluded that the "steps in the claimed processes involved well-understood, routine, conventional activity previously engaged in by researchers in the field". The court further noted, "upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries". Therefore, the court reversed the judgment of the Federal Circuit and found the claimed processes to be not patentable.

3.1.2 Obviousness: KSR rationale applied to nanotechnology

The decision in *KSR v. Teleflex* in 2007 has made a significant impact on patent examination and prosecution process [25]. The US Supreme Court rejected the Federal Circuit's decision of exclusive use of the teaching, suggestion, and motivation test (TSM) that was held in Graham [26] for determining whether the patent is obvious as not to be inventive. The Supreme Court held that the standard provides an invention is not patentable when "the subject matter of the invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art". To determine as to whether an alleged invention is an obvious combination of existing objects and methods [17], the court in KSR went much further than Graham in discussing the standards for proving obviousness in regard to combination inventions. The court stated, "when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result" [17]. The court further provided that "if a technique has been used to improve one device and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill" [17]. KSR described the court's earlier combination patent cases in terms that suggest a rule that shifts the burdens of production and persuasion to the patent holder, an absent proof by the patent holder that the improved function was beyond the skill of the ordinary person, or that the invention possesses a new function [17]. Because issues of obviousness turn on whether an invention is predictable to one of ordinary skill in the art at the time of the invention, it is necessary for courts to establish the proper approach to determining predictability. The differences between the prior art and the claimed invention and the reasonable expectation of success in bridging these gaps provide the basis for proving whether an invention is predictable to one of ordinary skill in the art [17].

3.1.3 A most recent case in nanotechnology

In *re Mouttet* [27], the US CAFC affirmed the USPTO's determination and found the claims obvious, using standards for administrative review that respect the USPTO's factual findings. The examiner rejected claims as unpatentable over a prior publication and four prior art patents (US patent 5,249,144) issued to Falk. Patent 5,249,144 disclosed a device for performing arithmetic and logic operations. Falk disclosed all of the elements of Mouttet's invention, with the exception Falk's crossbar array used intersecting optical channels instead of electronic circuitry. In Falk, the intensity of light at intersection along the crossbar's optical paths represented particular logic states used to perform the arithmetic processes. Because Mouttet's claims required the use of wires in the array, the examiner combined the teachings of Falk with those of an article by Das, which taught a nanoscale crossbar array of electrical wires with molecular switches. Applicant argued that the prior art "teaches away" but failed to support his points by failing to cite references that help his argument. Under US patent law, "teaching away" from the claimed invention can preclude a finding that the reference renders the claimed invention obvious. As the Supreme Court explained in KSR, "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." The USPTO Board of Patent appeal and interference affirmed the examiners' rejection, agreeing that an electrical engineer with several years of experience would have recognized that combining the teachings of the prior art references would yield Mouttet's claimed circuit [27].

The patentee appealed to the Federal Circuit Court and the court affirmed the USPTO Board of Appeals decision, finding that Mouttet's invention was obvious in light of Falk and the other prior art. The court concluded that mere disclosure of alternative designs in a prior art reference does not teach away from a nonpreferred alternative [27]. After this court's decision, the applicant should highlight that the reference discourages

using the nonpreferred embodiment or that the reference teaches that the nonpreferred embodiment would be unlikely to work rather than just stating that multiple alternatives teaches away from the claimed invention.

3.2 US Congress patent rule changes re AIA

On September 16, 2011, President Obama signed into law the most significant reform of the Patent Act since 1952, the AIA. The AIA is bringing significant changes to the patent system, which include the "first-inventor-to-file" system, substantial fee reductions for micro-entities, and various types of postgrant proceedings (see Appendix), all of which will have an impact in the way the members of the nanotechnology community seek patent rights and protection. With the new AIA reform, the USPTO will have the tools and resources to speed up the patent examination process, improve patent quality, and reduce the existing backlog [28].

Effective March 16, 2013, the patent will be awarded to the inventor who filed the application first, regardless of when the inventor actually invented the invention. The new changes in the patent law intend to eliminate the century-old "first-to-invent" system and replace it with the "first-to-file" requirement. This provision will provide harmonization of the American patent process with the rest of the world, in addition to encouraging all applicants to be diligent and file any patent application as soon as possible to avoid losing patent rights. Large organizations and institutions with significant resources may be able to mobilize those resources quickly to obtain patent protection, while smaller organizations, for example, start-up companies and government entities, may be less likely to act promptly and thus risk losing patent protection for their inventions.

One consideration under the new provision is that a public disclosure by the first person to invent may not be used as prior art against that person if he or she gets to file an application within a year, while that same public disclosure can be used against the first person to file to show that the invention was already in the public domain [29].

Under the AIA, although a disclosure of the inventor or derived from the inventor in the 1-year grace period is exempted prior art, more clarity is still needed on the treatment of certain disclosures. For example, does secret "public use" or secret "on sale" constitute a "disclosure" under the scope of the grace period [30]? As to derivation, will a derived disclosure be treated as prior art if it does not appear identical with the disclosure by the inventor [31]? Those questions still need to be decided by USPTO or in court. For now, it is safer to avoid any public disclosure before patent filing.

Proponents to the "first-to-file" system under the new law claim that the system prevents the long extended lawsuits and potential hounding by larger companies with the resources to litigate against a small company for a long time over the smaller company's patent. Although previously there were concerns under the old system because of the cost associated with proving that one was in fact the first inventor, opponents to the new "first-to-file" system believe the law could actually hurt the small business sector particularly in the case of inventors who are slow with paperwork and filing. Therefore, small businesses, start-up companies, and government entities may be less likely to act so promptly to file and thus risk losing patent rights [32]. Furthermore, opponents to the new law believe that the implementation of the new law places legal uncertainty over patent rights and takes away crucial legal provisions that small businesses and start-ups carried for many years, while large organization with significant resources may be able to file quickly and claim for patent rights.

As the grace period provided in Section 102(a) is repealed, and replaced with an insubstantial grace period that creates unacceptable risk of loss of patent rights that no business can rely on, while adding strong protections for large companies that can raise all their financing and resources, every inventor will then be in a race against all other possible disclosures. The grace period has been very important for nanotechnology start-up companies as inventors initiate discussions with third parties such as investors, outside subcontractors, or outside strategic partners for manufacturing or marketing. Unfortunately, currently, inventors will not be able to talk to investors without a patent and will not be able to file an application without an investor's financial venture.

Section 3(i) of the AIA amends 35 USC 135 to provide a new derivation proceeding aimed at ensuring the person obtaining a patent is a true inventor and did not derive the invention from another. Derivations proceedings are a new form of *inter partes* proceeding that replaces the interference proceedings for all applications or patents filed after March 16, 2013 [33]. Derivation proceedings provide a way to establish that a patent applicant or patentee was not an inventor, but rather they derived the invention from someone else. A derivation proceeding may only be requested by an inventor who has filed a patent application claiming the same or substantially the same invention as another applicant without the inventor's authorization. The petition for a derivation proceeding must be filed within 1 year of the first publication of the invention

by the earlier applicant. Similar to interferences, a derivation proceeding can be settled by the parties or the parties can agree to arbitrate the derivation proceeding. The losing party can request a review of the PTO decision by a US District Court or can appeal the decision directly to the CAFC.

Under Section 10 of the new law AIA, an interesting new development is the implementation of reduced fees for micro-entities [34]. Most governmental patent fees are based on whether the applicant is a large entity or a small entity; however, under the new law of AIA, Congress enacted this new category that is intended to aid entrepreneurs and small businesses to receive a 75% reduction in fees [34]. A micro-entity is defined as an entity that has not previously filed more than four patent applications and has an adjusted gross income of less than three times the median income, which is about $150,000 [34]. By default, all applicants for patent are considered to be a large entity unless otherwise claimed as small entity. A business that qualifies under the small entity status is entitled to receive a 50% reduction in many, if not most, patent fees. A small entity is defined as business with 500 or fewer employees. Even if a business has fewer than 500 employees, it could still be considered a large entity if the business is licensing the patent pending technology to a company that has more than 500 employees. Moreover, a university or nonprofit organization qualifies under the definition of small entity status [34]. The applied micro-entity system may help nanotechnology start-ups companies and universities with an affordable cost effective for patent filing if the application is filed promptly under the "first-inventor-to-file" system. However, the governmental patent fees are usually not the largest portion of the total patenting cost, in comparison with the attorney's fees and inventor time. Coupled with those AIA provisions that can pose significant difficulty in seeking investment and obtaining a patent, how small businesses will actually benefit from the micro-entity fee reduction remains a question.

3.3 How the international community regulates nanotechnology?

There is an ongoing globalization of nanotechnology and an increase in international trade in nanomaterials, with the demand for international coordination and harmonization of regulatory procedure being set to increase. The World Trade Organization's (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement) provides the international framework for IP protection of nanotechnology inventions, particularly patent protection [35].

The TRIPS Agreement compels member countries to make patents available for inventions in all fields of technology subject to standard patent criteria. As more nanomaterials and nanotechnology-enabled products enter international trade, a global governance gap is emerging with regard to environmental, health, and safety regulation. One major concern that the TRIPS left unresolved was the exhaustion of patent and other IP rights [36]. International exhaustion means that, as soon as a product is placed on the market of any WTO member country by the holder of a patent with his consent, the patent no longer can block the importation of the product in any other WTO country [37]. Although this system places a restriction on market forces for some period, it produces greater economic welfare gains for society than it would without the grant of such monopoly [38].

Developing nanotechnology industries in a responsible manner will require governments to work together to reduce uncertainties and promote coordination and cooperation at an early stage.

Another ongoing harmonization effort took place in December 2012, when the European Parliament voted positively in proposals for draft EU regulations on a unitary patent for Europe. The unitary patent – or "European patent with unitary effect" – is a European patent granted by the EPO under the rules and procedures of the European Patent Convention, to which, upon the request of the patent proprietor, unitary effect is given for the territory of the 25 member states participating in the unitary patent scheme. The unitary patent will coexist with national patents and with classical European patents. The agreement on the Unified Patent Court (UPC) is devised to resolve some problems that occur during the enforcement of some European patents by creating a specialized patent court (the UPC) with exclusive jurisdiction for litigation relating to European patents and European patents with unitary effect [39].

4 Advanced protection strategies

4.1 Patenting emerging nanotechnology standards

Standards are important to research, product business, consumers, and patent practice. In the broad field of nanotechnology, standards can have several meanings including

1. Standard language, definitions, and units of measurement
2. Means for conducting measurements

3. Instrument/product performance (e.g., quality or safety standards set by regulatory agencies)
4. Standard reference materials (meeting national or international standards to have characteristics in standard physical units) [40]
5. Benchmark product or service that is recognized and adopted as "standard" by industry and consumers

For standards 1–4, there are many nanotechnology standards-setting groups in the world who voluntarily set standards, among which the standards that are the best formulated and with the strongest scientific foundation are most likely to be adopted globally. Some of the leading standards-setting organizations with active nanotechnology standards-setting activities are [40]

- International Standardization Organization (ISO)
- ASTM (formerly known as the American Society for Testing and Materials)
- International Electrotechnical Commission Technical Committee 113 (Nanotechnology Standardization for Electrical and Electronics Products and Systems)
- Institute of Electrical and Electronics Engineers' Nanotechnology Council

To draft a patent for successful issuance and advantage in a lawsuit, the language should be consistent with the standards, such that it can clearly describe the subject matter and the claimed invention. If new terms are unnecessarily defined and used in place of well-established language in the patent specification, they can confuse the examiner, which may cause prosecution delay and claims rejection. It also makes prior art search and analysis much more difficult for others, which have caused many patent disputes [41]. Thus, patent practitioners and inventors need to be versed in current and emerging nanotechnology standard terminology developed by those leading standard bodies to reduce patent language ambiguity.

The applicability of standards 2–4 depends on the technical area of endeavor. They will be discussed as applicable in the following paragraphs, where we will briefly overview some technical areas and their emerging trends or standards.

4.1.1 Modeling and simulation

Modeling and simulation play a significant role in nanotechnology. In the past 20 years, there has been much advancement in fundamental theories in nanoscience and nanotechnology. Those theories are being applied numerically and analytically through modeling and simulation to develop the understanding of structure-properties relationship of nanoscale matters and to explore the applications of nanoscale systems. For example, the usage of nanopores may lead to affordable methods for sequencing DNA, which is of critical importance to enable personalized medicine. In one of those methods, a DNA molecule is threaded into a nanopore within the insulating layer of a silicon-based capacitor. An external electric bias drives the motion of the DNA strand. Molecular dynamics simulation was used for correlating the nucleotide sequence of DNA with the electrostatic potential difference across the capacitor [42].

Computation tools are also essential in addressing the challenge of predictive nanoscale material and device design, which is demanded by the nanotechnology industry to significantly accelerate research and development. Specifically, tools such as "multiscale modeling" will be crucial to link atomic scale physics and chemistry to nanostructured materials to integrated nanoscale systems and scale-up nanomanufacturing of those systems. High-speed computer and advanced computational methods will be needed as well as any other computation infrastructure to establish such links.

The modeling and simulation technologies in nanotechnology, including the algorithm, software codes, software or hardware user interfaces (such as visualization), informatics, integrated simulation-experiment system, data compression methods, simulation services, and databases, can be protected by the IP rights in Table 2. For patent protection, it is important to ensure that the technology is an eligible subject matter. Software or algorithm can be coupled with hardware, e.g., a computer, or computer network, where the inventive concept must be implemented by the hardware, such that the invention is not merely an abstract idea. Patenting those technologies also requires knowledge in current and emerging standards in the sector of communications and computer technology.

4.1.2 Nanocharacterization

Advancements in the nanoscience frontier and quality control in nanomanufacturing demand metrology instruments that can access the composition, structure, and properties of materials and devices at nanoscale. Existing nanocharacterization tools such as scanning probe microscopes and electron beam microscopes have greatly expanded the variety of materials and phenomena that they can measure. Examples include the scanning probe microscope that can image *in situ* thin film structure

and photocurrent generation in an organic solar cell [43] and electron microscopes that dynamically demonstrate atomic motion in graphene [44].

Nanocharacterization will progress toward higher-speed dynamic measurements, *in situ* measurements of specimen at conditions that mimic actual use conditions, three-dimensional architecture at atomic resolution, ease of use, etc. The technical hurdles overcome during the developments in those aspects at nanoscale size regime are fertile grounds for inventions. The methods and instruments as well as software tools and user interface may all be protectable by patents. In addition, ISO has been publishing standard guidelines on the characterization of some nanomaterials. Patenting subject matters compatible with those standards may lead to effective patent protection.

4.1.3 Nanomanufacturing

Among many nanomanufacturing concepts that have been proven in laboratories, some have reached production scale or demonstrated scalability. For example, graphene was originally fabricated by simply exfoliating graphite, but now it can be produced by a large-scale roll-to-roll technique. Because of its high transparency and excellent electrical conductivity, it can be expected to replace indium tin oxide, which is the standard in current transparent electrode applications but faces the issue of limited indium supply [45].

The scale-up manufacturing of nanotechnology products brings a wide variety of new challenges (Figure 2) such as new manufacturing tools, process modeling, meeting safety standards, supply of standard nanomaterials, metrology for quality control compatible with production process. Many technical difficulties will arise and provide excellent opportunities for generating inventions that can be protected by patents.

4.1.4 Applications

For any nanotechnology application, if a technology meets the common element in existing definitions of nanotechnology, i.e., possessing new or unexpected properties and phenomena by nanoscale dimension, it is likely to meet the nonobviousness criteria in patent law in major regions, e.g., US, Europe [47]. The patent should take advantage of that characteristic and proactively set up the disclosure to overcome any potential obviousness rejection during examination.

Because nanomaterials possess new and unique properties, there are uncertainties associated with their impact on the environment and human health. In the past 5 years, research on the safety of nanomaterials has started to flourish and made progress on nanomaterial toxicology assessment. Federal regulating agencies, such as the Environmental Protection Agency (EPA), have been funding research programs to develop standardized screening methods and protocols for nanomaterial risk assessment [48]. For any nanotechnology application, especially those involving engineered or natural nanomaterials, it is important that environmental, health, and safety regulations be considered as an integral part of new product design and manufacturing. Technologies that meet emerging safety regulatory standards are one of the important factors that can ensure the success of a product

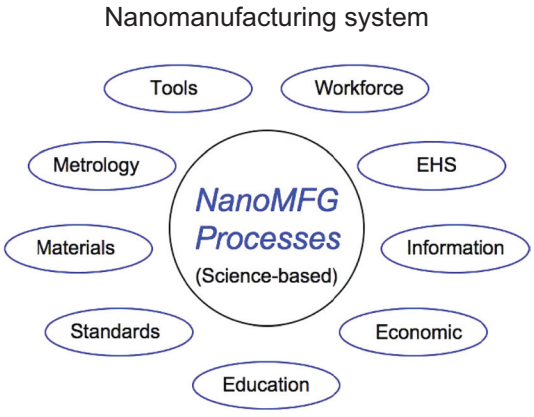

Figure 2 Vital parts of a robust nanomanufacturing system. (Reproduced with kind permission from WTEC [46].)

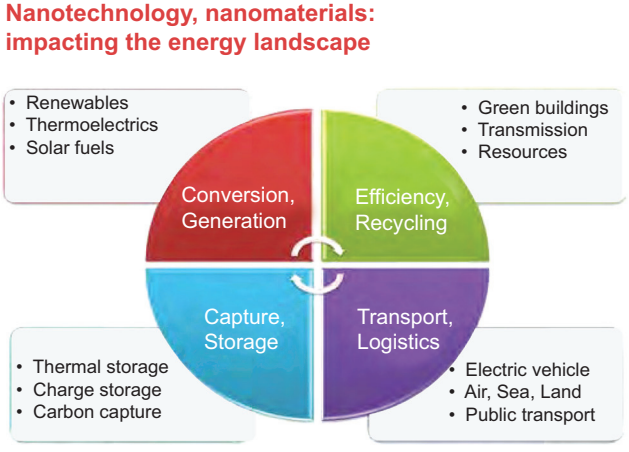

Figure 3 Impact of nanotechnology on sustainability cycle. (Reproduced with kind permission from WTEC [49].)

in future market, and they should be patented with higher priority.

Nanotechnology can be a powerful enabler for many sustainable energy technologies (Figure 3). For example, nanostructured materials can improve internal surface area, electronic/ionic conduction, and phase stability in batteries, which is critical for improved energy storage for electric vehicle and mobile electronic devices. Nanotechnology can also be a crucial player in solar energy generation, electrical storage, and efficient lighting. It may set new benchmarks in solar power conversion efficiency, battery energy and power density, and luminous efficacy in lighting technology. For inventions in those areas, one should project emerging energy efficiency standards for the targeted product market and patent the technology with sufficient disclosure that can cover products meeting those emerging standards.

In health care, nanotechnology has started to radically transform diagnosis and treatment methods. For example, a bio-barcode assay developed in Northwestern University uses gold nanoparticles as probe, bio-barcode carrier, and optical signature provider. Such detection method has significant advantage over the current technologies, which require amplification steps and are time-consuming and expensive [50]. Furthermore, carbon nanotube can be used as electron source in X-ray to enable spatially distributed X-ray source array to increase resolution and speed in imaging; nanoparticles with high surface tunability and multifunctionality can be used as contrast agents for multimodal imaging; and porous nanoparticles for drug delivery can be controlled by mechanisms such as molecular machinery actuated by pH, light, or enzyme action [51]. In nanomedicine applications, the most promising directions include point-of-care diagnosis and treatment, nonintrusive diagnostics with ultrasensitivity and ultraselectivity, and personalized medicine with increased effectiveness and reduced toxic effects (Figure 4). Their common goal is to set a future health-care standard that is low-cost, personalized, and effective. In addition, new manufacturing methods will be developed for those new medical products. As already mentioned, the safety hazards and future regulatory standards by agencies such as EPA and Food and Drug Administration (FDA) should be addressed for those products, if applicable. The patents protecting them should target the technology direction that meets emerging regulations and the envisioned future standard of health-care delivery.

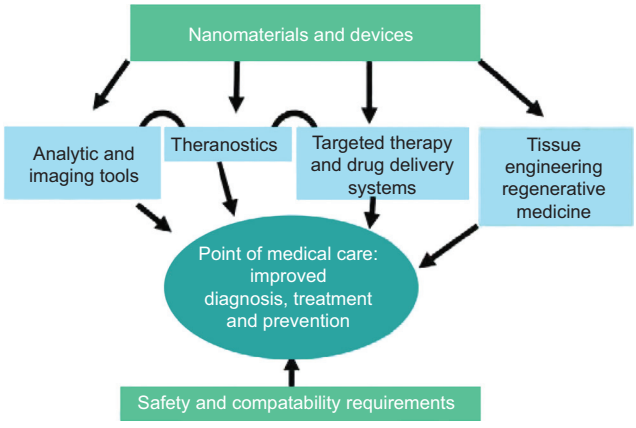

Figure 4 The cornerstones of nanomedicine (Reproduced with kind permission from WTEC: A. Nel [51].)

4.2 Licensing vs. litigation

4.2.1 Licensing

When companies get involved in a patent dispute, they choose to assert their patents using their IP portfolios by entering licensing deals with competitors or, as a last resort, suing for patent infringement. Nanotechnology sectors seeking to protect their ideas and rights face new and unique challenges, especially when it comes to licensing. Many nanotechnology start-ups and companies, while able to develop nanotechnology patent assets, may not have the ability to manufacture and market their inventions and instead choose a business strategy that is based on a licensing model. For example, in the case of semiconductors or pharmaceutical start-ups, whose capital expenses are high, the strength of their business strategy could well be based on the company's ability to enforce their patent rights [52]. Many companies that have overlapping patents related to nanotechnology enter into cross-license agreement. The license agreement between the parties is a covenant not sue one another. This will allow both parties to practice the other party's patent right without infringement. Although opponents of cross-licensing agreements indicated that this type of licensing with a covenant not sue has a negative impact on the economy and does not serve public interest because it limits competition and future competitive growing market, cross-licensing between start-ups and large corporations limits litigation exposure from courts, encourages the parties to use the technology in the marketplace, and minimizes costs associated with legal battles fighting infringement suits.

Within the nanotechnology sector, when a licensor and a licensee enter into a license agreement, they must consider factors that may have an economical impact for

both parties [52]. These factors include governmental controls under the Bayh-Dole Act. As a funding agency, the government may step in when the licensor fails to take effective steps to achieve the invention or fails to satisfy health and safety needs of consumers [52]. This may deter the licensee from taking the risk to pursue a license, and the licensor might find it difficult to license the technology. Therefore, both parties must perform due diligence to satisfy this criterion. In addition, the licensee may not want to enter into the license if there are risk liabilities that are unknown, e.g., nanoparticle toxicity. Here the licensor may broaden the indemnity provision within the license agreement and provide standard procedure and protocols for any information that may be health risks posed by the nanomaterial.

4.2.2 Patent infringement litigation

Although there currently are many issued nanotechnology patents and many more pending patent applications, there has been no significant nanotechnology infringement litigation reaching US district courts that will provide guidelines on the validity of nanotechnology patents.

Considering the expense of patent litigation, a last resort to protect a patent is for a company to decide to engage in patent suit litigation. It is estimated that a patent litigation can cost on average in excess of $1 million per claim [41]. The cost of patent litigation includes IP attorney fees, expert witnesses, and investigation and discovery costs. The determination on whether to enter into a patent infringement litigation suit should be carefully evaluated, and the companies should make a risk management plan and assess whether to market the nanotechnology product. Evaluation should include prior art search, review of prior market and commercial activities, and gathering opinions from IP attorneys to determine whether the patent will infringe on any relevant patent.

Moreover, to prevail in an infringement case, the patentee has the burden not only to establish infringement but must also overcome numerous defenses that the defendant might assert. For example, for patents that are subject to validity challenges, an infringer may counter claim and challenge the validity of the party's issued patent. Although there is a lack of litigation cases of nanotechnology that prevents the determination of the appropriate measurement for the court to use, the Supreme Court is reconsidering to lower the burden of proof to find a patent invalid. The challenge of validity of litigation can be done by filing for a reexamination of the patent before the Patent Office. Once the reexamination is granted by a patent examiner to determine the validity of the patent, the trial can be stayed pending the outcome of the reexamination. Once the examiner reaches a conclusion of the reexamination and holds the patent to be invalid, the claims for patent infringement will terminate. However, if the examiner holds that the patent to be valid, the defendant cannot challenge it at trial. Such estoppel effect is limited to any grounds that were raised or that could have reasonably been raised during the reexamination; thus, the accused infringer may still be able to attack the validity of the patent on other grounds. Seeking a reexamination of a patent is an alternative strategy when considering ways to reduce the cost of litigation.

The AIA recently instituted a postgrant review, which allows a third party to challenge the validity of an issued patent under any statutory patentability provision. If a third party has not initiated first a civil action, he or she will be able to challenge a patent filed after March 16, 2013. For the review to be granted, the petitioner must request a review within 9 months after the patent is granted and demonstrate that it is more likely than not that one of the patent's claims is unpatentable [53].

One of the strategic implications that the new patent proceeding will have for patent litigation is estoppels effect. The petitioner will be estopped from bringing a civil action or proceeding in the Patent Office on any ground that was raised or could reasonably have been raised during the postgrant review or *inter partes* review [53, 54]. In the postgrant review, the likelihood for estoppel is greater than *inter partes* review because the challenge applies to any grounds for patent invalidity. Therefore, a petitioner considering a narrowly focused postgrant review should be aware that it may be estopped from raising other potential challenges to the patent in any later proceeding if it could have been reasonably raised in postgrant review. Although an estoppel could preclude an accused infringer from raising any invalidity defense during litigation, the accused infringer can still challenge the novelty and nonobviousness of the invention based on evidence of public use or sale and based on an insufficient disclosure or patentability ineligibility.

The new postgrant review will provide the Patent Office with one more chance, before litigation, to determine the validity of an issued patent. However, such a procedure needs very careful execution because it could become another path, similar to reexamination, taken by better-capitalized big businesses to delay the enforcement of patents owned by small businesses or just to divert competitors' resources to deal with challenges to the patents.

4.2.3 Patent infringement: a case study

One of the first cases related to nanocrystalline patent taken to a jury trial was in 2008, plaintiff *Elan Pharmaceutical International, Ltd. (Elan), v. Abraxis Bioscience, Inc. (Abraxis)* [55]. Elan filed a complaint in the US District Court for the District of Delaware alleging that the cancer treatment Abraxane, manufactured by Abraxis, directly infringes two of Elan's patents (5,834,025 and 5,399,363) by making and selling Abraxane.

Elan asserted that patent 5,399,363 claims "surface modified nanoparticles" [56] and the claims further define the invention as particles "consisting essentially...crystalline medicament" [55]. Patent 5,834,025 claims a method of reducing adverse physiological reactions associated with administering nanoparticle compositions [57]. The plaintiff's prayer for relief consisted of damages of up to three times, willful infringement interest, and cost of lawsuit. Elan also requested for the issuance of preliminary and permanent injunctions to restrain the acts of infringement [58]. Abraxis denied the charges of infringement and argued that both patents were invalid and void for failure to comply with one or more of the provisions of Title 35 of the US Code, including sections 102, 103, and/or 112 [58].

Elan opposed the assertion made by Abraxis that Abraxane was an amorphous compound rather than crystalline. Elan relied on the FDA-approved label that states that paclitaxel is known to be a crystalline material (paclitaxel protein-bound particles for injectable suspension) and thus infringes patent 5,399,363 [58].

The issue is whether Abraxis has proven by clear and convincing evidence their claims that patents 5,399,363 and 5,834,025 are invalid for lack of enablement or for lack of adequate written description and whether patents 5,399,363 and 5,834,025 are unenforceable due to inequitable conduct.

The court ruled in favor of Elan, and although Elan withdrew its allegation for infringement of patent 5,834,025, the jury ruled that Abraxis has infringed upon Elan's patent 5,399,363, which runs until 2011, and awarded Elan $55 million in damages for sales of Abraxane. The facts and outcome of this case bring an interesting and important factor for clearer understanding of drafting patent claims for nanotechnology and interpreting these claims. Furthermore, this case demonstrates the problems of overlapping claims and complicated scientific technology that overwhelms courts to resolve a complex forum for determination of convoluted patent law issues that arise based on size, scale, and reactions at the nanoscale level.

4.3 IP checklist for start-up venture funding

Substantial investment is required for developing innovations in nanotechnology into marketable product. However, the return on investment will be substantial with regard to jobs created, the US competitive position in the global economy, and improvements in human standard of living that directly result from nanotechnology.

Venture capital funding is a generally recognized financial resource needed by start-ups. Although most nanotechnology patents are filed by large companies, small- and medium-sized enterprises have increased their share of patent filings from 20% in the 1990s to 35% in 2006 [59]. In addition, global venture capital investment in nanotechnology grew steadily during the first decade of this century [4]. Those indicators show that more and more investors have identified nanotechnology as the frontier of new industries.

Many areas of nanotechnology are still in the early stage, and nearly 50% of nanotechnology start-ups are university spinoffs whose innovations directly grew up from fundamental research at the boundary of scientific understanding [59]. Furthermore, transferring those technology into manufacturable products involves many uncertainties and explorations, which could require a very long time and high cost in product development. Venture capital investors need to consider several factors to determine whether a start-up has a protectable IP portfolio.

4.3.1 Assess the value of protecting an invention

Before committing to the high cost of prosecuting a patent, one needs to consider these factors:

- What are the technical merits of the idea? What problem does it solve and how does the idea solve the problem? Investors can discuss with scientific experts regarding the relevant technology area and the feasibility of that technical idea. It will also be beneficial to talk to customers who are the prospective receiver of the product. If the concept has been proven at laboratory scale, what challenges may arise at mass production scale, and are there ongoing research and development projects that are promising solutions to those challenges? Those discussions are crucial for estimating a realistic timeline for the product launch.
- Will the patent be issued? The invention must meet the basic patent law requirements in eligibility, novelty, and nonobviousness. Inventors should watch for patent filings within the field of the company's

core technology, including US and foreign filings, along with available nonpatent literature. Prior art will guide the patent practitioners to craft claims that avoid occupied IP space and extract the broadest claims for inventors.

- Will the issued patent be enforceable? The patent can only be enforced if an infringement of the technology can be detected. To analyze nanotechnology products, high-capability analytical tools may be needed such as microscopy with high resolution and/or high sensitivity in chemical composition analysis. Thus, whether those facilities will be accessible for product infringement analysis should be considered.
- Will the enforcement (i.e., excluding others from practicing) result in competitive advantage? Can competitors easily design around it? Such contemplation is usually difficult because it asks for alternative ways to practice the invention, which are out of the boundary of existing thoughts. Skilled patent practitioners should be able to write the broadest claim, guide the inventor to design around the broadest claim by developing additional embodiments, and draft claims targeting those "design-arounds".

4.3.2 Patent prosecution strategies

Before filing patent applications, a company should analyze its existing patent portfolio. In the analysis, technologies can be categorized based on their degrees of alignment with the business. That will set the company's patent prosecution strategies to serve its long-term goals such as to enhance the protection for current products, expand into new markets, or/and generate income directly by patents.

A nanotechnology invention using a fundamentally new phenomenon may find its application in many other markets that are not core to the company. Those patent filings should be prioritized according to the factors related to potential licensing value such as market size and the emerging competitor technology in those markets.

Patents can be used defensively to deter competitors from reverse engineering and copying the products. Meanwhile, if competitors assert an infringement, a strong patent portfolio can bring the company into a good bargaining position and may settle a case by cross-licensing agreement instead of paying the costly litigation fees or royalties.

Companies also use patents offensively by licensing patents to generate royalties or by suing competitors for infringement damages. A recent example is *Apple Inc. v. Samsung Electronics Co., Ltd*. More than 50 lawsuits were ongoing by July 2012 around the world, among which Apple was awarded more than $1 billion in damages by the US court [38].

Patents can be used in many other ways. For start-ups, patents can significantly build up credibility and ease fund seeking from venture capitalists. Furthermore, nanotechnology start-ups typically do not possess a clustering of capital including equipment and labor that large companies have; thus, patents may constitute the primary assets of the start-up in potential mergers and acquisition. In addition, patents symbolize ingenuity and uniqueness, and a product marked with patent information can establish a positive image before the consumers.

If considerable commercial activities are expected in foreign countries, one must first determine whether the start-up can afford litigation in foreign countries before spending resource on the expensive foreign filing process. In contrast, trademark costs less than patent, and registering one in each country of interest can be done.

4.3.3 Quick filing – provisional patents

Nanotechnology sectors can choose to file provisional patent applications as soon as they initiate new inventions. Provisional applications do not include claims of the invention but disclose a description of the invention; once the provisional application is filed, the applicant has 1 year to file a nonprovisional application [60]. In addition, provisional applications are available to all types of entities and are a fast, low-cost way to obtain patent rights. Although provisional application may benefit nanotechnology start-ups, the costs may still be considered high for a company with limited assets. For a typical start-up invention, the cost of attorney's fees and inventor time for a provisional application can be $10,000 or more [61]. To save cost, inventors can file provisional applications by themselves, but it is still advisable to have the specifications reviewed by a patent practitioner before filing.

A provisional application must meet the written description, enablement, and best mode requirements of patent law [62]. If poorly drafted or incomplete, the provisional application may cause estoppel problems in the prosecution history when the nonprovisional application is later amended and may not provide the benefit of its filing date, which will have an especially damaging effect under the AIA.

4.3.4 IP protections other than patents

Companies should take advantage of the lower-cost IP protections other than patents, including trade secrets, copyright, and mask work. Among them, trade secrets are especially important for nanotechnology start-ups. Trade secret is the only IP protection for invention concepts before the patent application is filed. In addition, trade secret can protect experimental trials and failures that form the foundation of the subsequent successful findings, valuable details of nanofabrication processes that are not patentable or do not justify patent filing cost, as well as all the business information such as investor and customer lists.

Examples of trade secret tools are confidentiality agreements with employees and collaborators, invention assignment agreement, and noncompete agreements with employees. In addition, a start-up company should have employees sign statements confirming they will not carry trade secrets from former employer to prevent issues arising from conflict of interest.

Because of the high initial capital investment needed in nanotechnology research and development (R&D) and also because many nanotechnology start-ups are university spinoffs, they collaborate with universities research groups, use university laboratories, or receive some government sponsorship. In such situations involving joint R&D efforts and resources, IP rights agreements must have sufficient clarity as to the ownership of potential IP generated.

5 Conclusion

Nanotechnology is expected to have far-reaching applications in mass use and has a strong potential of achieving revolutionary new solutions in human standard of living. Being deep-rooted in fundamental scientific discoveries, the commercialization of nanotechnology applications requires clustering of capital, including equipment and technically proficient labor, as well as deep market knowledge. Those requirements typically put large multinational companies at an advantage. Despite the challenges, a great number of new small companies have joined the competition, all of which are transferring state-of-the-art fundamental research achievements into commercial products, which can further create jobs and strengthen the US competitive position in the global economy.

However, whether the trend described above can continue its momentum is questionable under the patent reform. The new reform act that was signed by President Obama in September 16, 2011, offers little benefit to small business in nanotechnology. The new policy has taken away the protection that was especially crucial to start-ups and treated small nanotechnology companies and large companies alike, thus further benefiting large companies, as they have the resources and financing for research, development, and marketing. The new system runs the risk of negatively impacting the US economy by decreasing product efficiency and creating far greater costs for businesses in the long term.

Although nanotechnology inventors need to stay abreast of the law changes and be actively involved from the conception of their invention to the patent filing to ensure proper protection of their IP rights under the new law, policy makers need to contemplate an effective system that can draw a balance between harmonizing with the rest of the world and maintaining essential protection that inventors deserve. The US Constitution Article 1, Section 8 grants Congress the power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries" [63]. The article grants Congress the power to protect inventors' rights in their creations, rather than the first person to file at the Patent Office.

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Appendix

Selected AIA provisions related to nanotechnology.

Provisions	Amended 35 USC	AIA section	Effective date
Defined "micro-entity" – Entitled to a 75% discount of many PTO fees	§ 123	10	September 16, 2011
Prioritized examination – Additional §4800 fee (50% discount for small entities) – Goal is to provide a first substantive PTO response within 12 months of filing		11	September 26, 2011
Priority examination for important technologies – At the request of the patent applicant and for products, processes, or technologies important to national economy or national competitiveness, without extra cost of prioritization		25	September 16, 2012
Third-party submissions of prior art – Any third party may submit printed prior art in a pending patent application. Other timing requirements apply – Submission must include a description of the asserted relevance submitted document	§ 122(e)	8	Took effect on September 16, 2012 Applies to any application filed before, on, or after September 16, 2012
Emphasis on first-to-file and redefined prior art -102(a)(1) prior art: events before effective filing date (EFD): – Patented – Described in a printed publication – Public use – On sale – Otherwise available to the public Exceptions: – Disclosures by or derived from the inventor, made within 1 year – Disclosures made within 1 year by others but after an earlier disclosure by inventor: (A) the disclosure was made by the inventor, joint inventor, or another party who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor or -102(a)(2) prior art: patent/application: – US patent or published application filed before EFD Exceptions: – Subject matter derived from inventor – Subject matter publicly disclosed by inventor (or derivers) prior to EFD of art – Common ownership with the claimed invention	§100(f)–(j) § 102 § 103	2, 3	Any application and any patent issuing thereon with an EFD on or after March 16, 2013
Derivation proceedings and civil actions for derivation – Effectively replaces current interference practice used to determine the first inventor – If an inventor in an earlier application is found to have derived the invention from the true inventor, then claims in the earlier application will be refused or cancelled	§ 135 § 291	3	Any application and any patent issuing thereon with an EFD on or after March 16, 2013
Repeal of the best-mode defense – Eliminates an alleged infringer's ability to argue that the patent owner did not identify the best mode in the patent specification	§ 282	15	Proceedings commenced on or after September 16, 2011

(**Appendix** Continued)

Provisions	Amended 35 USC	AIA section	Effective date
– The PTO retains the ability to reject an application for lack of best mode disclosure			
New supplemental examination – Who – patent owner only – Basis – any grounds – Threshold – substantial new question – When – any time after grant	New § 257	12	Takes effect on September 16, 2012, for any patent issued before, on, or after September 16, 2012
Citation of prior art and written statements – Submission may be patent owner's statements regarding claim scope	§301	6(g)	Takes effect on September 16, 2012, for any patent issued before, on, or after September 16, 2012
New *inter partes* review – Who – third party only – Basis – patents and printed publications – Threshold – reasonable likelihood of prevailing – When – after the later of 9 months after grant or date of termination of a postgrant review and within 1 year from infringement suit (with joinder exception)	Chapter 31	6	Takes effect on September 16, 2012, for any patent issued before, on, or after September 16, 2012
New postgrant review – Who – third party only – Basis – any grounds – Threshold – (1) more likely than not for at least one claim to be unpatentable or (2) novel or unsettled legal question – When – within 9 months from grant	Chapter 32 (new)	6	Takes effect on September 16, 2012, for any patent issued before, on, or after September 16, 2012 (exceptions apply)

Source: Fernandez & Associates, LLP.

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[63] US Constitution, Article 1, § 8.

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