INTELLECTUAL PROPERTY RIGHTS OF NANOTECHNOLOGY (CHALLENGES AND SOLUTIONS) WITH LOOKING AT TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AGREEMENT (TRIPS)

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Abstract:

With the emergence of any new technology, nanotechnology creates opportunities as well as challenges in adapting the patent regime to its particular context. There is some consensus that patenting nanotechnology innovations poses more problems than other technologies, owing to their multi-disciplinary character, cross-sectoral applications, broad claims as well as difficulties in fulfilling the patentability criteria. This is aggravated by the lack of a standardized terminology which impedes easy identification of nanopatents and also the fact that patent offices may not be well-equipped to handle nanotechnology. These problems are likely to be compounded for developing and least developed countries, which irrespective of their state of technological advancement, and capacity of the domestic regime, are obliged to confer IPR in the new technology.

In order to keep a desired level of in depth analysis this work will only contemplate the TRIPS Agreement. The paper finally arrives at certain recommendations, to help reconcile the need to incentivize innovation in the new technology, with the imperative of ensuring that the public interest is served and access to the patented knowledge is not hindered.

Keywords: Nanotechnology, Intellectual Property Law, TRIPS Agreement, patentability Criteria, Challenges of patentability, Solutions.
1. Introduction

The potential impact of nanotechnology on society has been raising debates regarding its ethical, legal and social aspects. Many of the issues debated concerning nanotechnologies are neither new nor exclusive to this field of technology, but rather reflect concerns previously rose concerning other emerging technologies. However, unlike other emerging technologies of the past, nanotechnology has the potential to change profoundly not only our standard of living and world economy but also the very fabric of society and even according to some the concept of humanity. In social and economic terms its impact is expected to be at least similar or even deeper than the impact that information technology has had over individual and collective lives over the past two decades, but the impact on the human body and biological identity can become so deep as to lead to the next evolutionary step: a tailor-made post homo sapiens.

Nanotechnology related research can be applied virtually to every industry and for this reason nanotechnology is being considered by social scientists, governments and international organizations as being of great political and economic strategic importance and naturally patent law is expected to play an important role, since it holds the important function of providing incentive to commercial and industrial innovation. Quick technological progress and its business mode within the area of nanotechnology will challenge the traditional regulatory systems. [1]

This new technology raise more questions than answers. As nanotechnology is an extension of traditional technology within the area of engineering, biology, chemistry and physics, its unique character lies in the meaningful and accurate manipulation and handle of atoms and molecules for exploiting the unique properties of materials that emerge at the nano-scale. Nanotechnology may severely challenge the current regulatory competency to respond quickly and maintain the tough balance between risk and profit. Nanotechnology is closely involved with in a number of separate phases; each of its advancement is depending on of its own legal, regulatory, societal and political issues. The multidimensional uses and convergence of domains of nanotechnology such as in the food sector, medicine field, environmental field, military uses, IT, transformation and energy field etc. make it challengeable to regulate it and also require greater transparency between regulatory agency and government of a state. It should also be checked that each individual sector need nano regulation or ‘one size fit for all’ i.e. one regulation which regulates all provable sectors of nanotechnology. There is also a question whether the regulation assesses each nano product basis or process basis. In this respect, EU took of the position of process basis assessment and regulation. Although there is no specific nanotechnology regulation in the EU and there is a great possibility of risk and dead lock in the trade relationship between state to state if there is separate regulation for nanotechnology in each national level. To regulate the nanotechnology and adopt a sound regulation system for nanotechnology priority must be given to human safety, environmental risk, privacy, intellectual property and lastly international law. In a low regulatory system, the advancement of nanotechnology is a great threat and also a danger in respect of global economy. Moreover the transitional NGOs (Non-Government Organization) can play an important role in future
nano regulatory policy and debate relating with societal, democratic and jurisdictional legitimacy in the coming nano age. [1]

The large influx of investment in nanotechnology research should accelerate the availability of commercial nanotechnology applications. Therefore, it is critical to develop intellectual property strategies that allow for fluid transfer of government-funded science to the private sector for commercialization of nanotechnology.

As with the emergence of any pioneering technology, nanotechnology creates issues and opportunities in perfecting intellectual property rights. Patenting technology in a scientific field relatively new and characterized by its interdisciplinarity and ability to simultaneously produce or enable application in several very diverse fields of technology such as nanotechnology, necessarily leads to new challenges and rediscovering known issues under a new light. The challenges in the nanotechnology intellectual property arena are numerous. This article contains a brief overview of the most preeminent general trends in nanotechnology patents related with patentable subject-matter issues and with possible implications in the debate surrounding the functioning and characteristics of the (future) patent system.

Concerns have been raised over the lack of the South’s (developing nations) participation in nanotechnology development due to the high barriers set up by patenting. Universities and companies holding breakthrough, foundational patents in the North (developed nations) are likely to shut out their poorer counterparts. Though the rhetoric of the benefit to the south has been vociferous, the reality of the high royalties and licensing fees may bury the hopes of any technology transfer altogether.

Today, nanotechnology intellectual property issues focus primarily on patents, with additional issues relating to trade secrets. There is some consensus that IPRs in nanotechnology could be more problematic than other technologies and give rise to a number of complex situations. Some of the current issues and challenges encountered in nanotechnology intellectual property are briefly described below.

Laws covering products and technology since the Industrial Revolution may not apply to nanotechnology. Can you patent an atomic or molecular structure? How do you protect an atom or molecule-sized device from being illegally copied? How will patent policies evolve and affect the scope of nanotechnology patents? Will nanotechnology patenting live up to its promise or become a litigation minefield? Will the ranks of academic researchers maintain their integrity in the face of ever increasing commercial pressures for patenting? Will patent offices across the world be able to stand up to the challenge of ensuring that invalid, too broad or overlapping patents are not issued? Will society be able to bridge the nano-divide, sharing the benefits of envisaged wealth creation? These and other intellectual property questions require resolution in order to make effective and efficient use of nanotechnology innovation. The resolution of these challenges and their implementation remains to be witnessed.

It is generally accepted that the properties of matter and other fundamental scientific discoveries are not patentable. An initial challenge for patent strategists is to determine how to obtain patent coverage that is based on the discovery of inherent properties of
materials. Simply submitting a smaller version of a known structure would not be considered patentable without additional utility or novelty. In order to secure a patent, the invention must be "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[2]

Nanotechnology is a new field and most of its patents are for basic inventions, not for fully developed final products, creating problems because patents on basic inventions are inclined to cover larger areas than final products [3-4].

Since nanotechnology is a broad discipline encompassing several others, the granting of very broad patents spanning multiple industry sectors could be problematic. Broad patents granted to inventors can lock up or impede crucial improvements needed to take a new field from interesting lab results to commercial viability. As nanotech research is too expensive and complex for small players, nanotech will accelerate the trend towards corporate concentration of power and monopoly formation. These apart, it is difficult for nanotechnology patents to fulfill the patentability criteria for novelty, non-obviousness and industrial application.

The traditional bases for patentability criteria can be secured by focusing on previously unattainable size, structure, compositions, organization, methods of measurement and methods of changing the property of materials, as well as applications of the new properties.[3]

This could be aggravated by the lack of capacity of patent examiners to determine ‘prior art’ owing to the fact it spans across a wide range of scientific areas and disciplines.

IPRs in nanotechnology are likely to prove even more challenging for developing and least developed countries, which irrespective of their state of technological advancement, are obliged to confer IPRs in the new technology. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement obligates all WTO (World Trade Organization) member countries to adopt and enforce minimum standards of intellectual property, with WTO members having to allow patents in all fields of technology. As international patent trends indicate, multinational corporations, universities and nanotech start-ups have already secured numerous patents on essential nanotech tools, materials and processes. Participation in this proprietary nanotech revolution for developing countries is, thus, likely to be highly restricted by patent tollbooths, obliging payment of royalties and heavy licensing fees to gain access. For many developing countries, the rationale for accepting stronger IP regimes has been the argument that their economies would prosper from increased technology transfers and foreign direct investment.

However, the reality is that stronger levels of IP obligate developing countries to make a massive transfer of resources to the developed countries, in order to acquire licenses for proprietary technologies.

For developing countries, the challenge will be to tailor an IP regime for nanotechnology, which while offering the mandated protection under TRIPS, is able to explore the flexibilities within TRIPS to serve developing country interests. Capacity
building and training of patent examiners and suitable modifications/amendments in the patent regime would be required in order to enhance its ability to deal with this new technology. While developed countries like U.S.A, European Union and Japan have realized the need to have separate classifications for nanotechnology and impart training to patent examiners, India is yet to take any such steps in this direction.

Another important issue which comes up in the context of nanotechnology patenting is how to ensure the equitable sharing of IP rights arising out of research collaborations, which is inevitable given its multi-disciplinary nature and cross-sectoral application.

With nanotechnology patenting activity by the government and academic institutions being considerably high, the relevance of the newly drafted legislation to protect IP arising out of publicly funded research is also worth looking into.

In the context of the above background, some of the key questions which IPRs in nanotechnology give rise to, particularly for India are:

(a) What are the broad issues and challenges in adapting the intellectual property rights regime to nanotechnology?

(b) Are these challenges compounded for developing countries, which are obliged under TRIPS to provide IPRs in nanotechnology, irrespective of their level of development and the capacity of the domestic IPR regime to handle nanotechnology? Do developing countries face certain unique challenges?

(c) What are the major trends and characteristics of the nanotechnology patent landscape? Who are the main holders of nanotechnology patents (and publications) in India and what broad inferences can be drawn from this?

(d) Do IPRs in public funded nanotechnology research lead to ‘privatisation’ of ‘public’ goods? What could be the possible implications of the draft Indian legislation on Protection of Public Funded Intellectual Property on nanotechnology developments in India? Would it provide a boost to more public research in the field or end up blocking public access to the fruits of research from public funds?

(e) What could be the possible role of ‘beyond IP’ approaches in addressing some of the problems which IPRs in nanotechnology give rise to? Could patent pools, open source approach be a solution to the problem of access?

The objective of this article is to explore these key questions, which emerge in the context of intellectual property rights (IPRs) in the emergent field of nanotechnology. The article hopes to provide a platform for diverse stakeholders to deliberate on these questions and arrive at recommendations for IPR regime, which helps reconciles the dual objectives of incentivizing invention and ensuring the public good, which is ideally the goal of the IP system.
2. Searching for a definition of nanotechnology

The definition of what fall into the concept of nanotechnology is not universal, and has been the subject of controversial among scientific community. Such intense debate may help explain why at the present moment there is not a unique legal definition of nanotechnology.

A precise and uniform definition of the terms nanotechnology and nano-scale has long eluded scientists and patent offices. Lack of a standardized definition has implications for patent search and classification, and for tracking patenting trends. It magnifies the risk that relevant prior art remains undetected and creates uncertainty about how an ordinary person skilled in the art – one of the yardsticks against which patentability is established - might interpret “nanoscale”. It heightens the risk of a nanotechnology patent being invalidated and of overlapping or conflicting patents being granted.

Also, descriptive terminology is essential to providing effective patent protection for nanotechnology inventions, particularly from the perspective of future licensing and litigation activities. One of the key difficulties in patenting nanotech inventions, however, arises from the absence of established terminology. Failure to clearly define one’s invention can lead to a number of unfortunate consequences, ranging from an overly narrow patent covering a limited scope of subject matter to a vague or overly broad patent susceptible to invalidation.

The patent offices must have a dedicated examination group for nanotechnology, patent applications that may be covering the same or overlapping subject matter may get routed to different examination groups because of the different terminology used, and ultimately be issued. This could lead to barriers in communications between scientists, complicated litigation when construing claims where terminology is not uniform, as well as act as a barrier to successful commercialization of nanotechnology because of the inability —to consistently characterize the properties and benefits of the basic building blocks that underpin much of the theoretical work.

Another difficulty is that at the present moment there are not many pieces of legislation directly and specifically aimed at regulating nanotechnology. Nonetheless a few documents with legal relevance may help shed some light into the subject. According to a recent comprehensive literature review on The Social and Economic Impacts of Nanotechnologies, prepared by scholars at Monash University (Australia), researchers have identified eighteen substantially different definitions in relevant sources. [6]

The United States National Science Foundation defined nanotechnology and the nanoscale as follows: [7]

‘Research and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1-100 nanometer range, to provide a fundamental understanding of phenomena and materials at the nanoscale and to create and use structures, devices and systems that have novel properties and functions because of their
small and/or intermediate size. The novel and differentiating properties and functions are
developed at a critical length scale of matter typically under 100 nm.’

In contrast, in the UK the Royal Society and the Royal Academy of Engineering have agreed
on the following definitions:[8]

‘Nanoscience is the study of phenomena and manipulation of materials at atomic, molecular
and macromolecular scales, where properties differ significantly from those at a larger
scale.’
‘Nanotechnologies are the design, characterization, production and application of
structures, devices and systems by controlling shape and size at nanometer scale.’

In the same document the nanoscale is defined as covering realities between 0.2 nm and
100 nm, which contrasts with the American counterpart that sets a lower limit at 1 nm. The
importance of these definitions originates from their influence and impact in social sciences
researchers and law makers. The RS/RAE report was one of the first comprehensive works
regarding the subject and was the consolidation of an open consultation to the scientific
community and other stakeholders such as technologic based companies and advocacy
groups. Its conclusions had great influence in later working papers and official European
Union documents.

2.1. Nanotechnology definition(s) in European Union documents

The European Commission defined Nanosciences and Nanotechnologies at more than one
occasion adopting definitions that are similar and complementary to each other, sometimes
using the singular other times using the plural form:
‘Conceptually, nanotechnology refers to science and technology at the nano-scale of atoms
and molecules, and to the scientific principles and new properties that can be understood
and mastered when operating in this domain.’[9]

‘Nanosciences and Nanotechnologies (N&N) are new approaches to research and
development that concern the study of phenomena and manipulation of materials at
atomic, molecular and macromolecular scales, where properties differ significantly from
those at a larger scale.’[10]
‘(...)In the broadest sense understood here, N&N research encompasses all research
activities dealing with matter at the nanometric scale (1 to 100 nm). It includes all man-
made nano-objects be they engineered or involuntarily generated. Naturally occurring
nano-objects are excluded from the scope of the Code of Conduct (...’)[11]
The EU Commission has realized the essential importance of the harmonization of
terminology and concepts. The 2004 Commission strategy for nanotechnology [12] included
the development of metrology and standards at one hand and harmonization of the legal
definitions of nanotechnology inventions at patent offices as primary goals. Such priorities
are conceived not only at European Union level, but preferably at international level.

2.2 Nanotechnology at the International Organization for Standardization
The rapid growth of nanotechnology and nanotechnology based products in the market has caught the attention of the International Organization for Standardization (ISO). Its member states and the international scientific community have long stressed the need for harmonization of scientific and technological terminology in this field. Addressing such concerns the International Organization for Standardization has developed a standard concerning nanotechnology (ISO/TS 27687:2008), announced as the first part of a projected series on terminology and definitions covering the different aspects of nanotechnologies and intended to be a valuable tool to facilitate communications between research, industry, consumers and society in general.

This standard is concerned with the terminology and definitions for objects at the nano-scale, in its different shapes (this document refers to three basic shapes: nanoparticle, nanofibre and nanoplate), it was adopted in late 2008 and is currently under revision meaning that it can either be confirmed, modified or revoked.

2.3 Nanotechnology and the Patent System

Despite the divergences in the scientific community and the corresponding legal implications, the patent system at its various levels was compelled to establish a working definition(s) of nanotechnology.

2.3.1 Patent Cooperation Treaty - International Patent Classification

According to Arts 1 and 2 of the Strasbourg Agreement all contracting parties, which includes all EPO member states, are bound to follow the international classification of patents which was established pursuant to the provisions of the European Convention on the International Classification of Patents. Nanotechnology inventions fall into the B82B subclass that is entitled ‘Nano-Structures; Manufacture or Treatment thereof’, under this provision nano-structure is defined as follows: (i) is formed solely from an atom, a molecule or an extremely limited collection of atoms or molecules, which collection in its entirety is undetectable by an optical microscope; and (ii) has been formed by having its atoms or molecules individually manipulated as discrete units during its manufacture.

As stated in the notes that explain this subclass, B82B does not cover chemical or biological structures per se, as these are dealt with elsewhere. In addition, such nano-structures that have special features directly related to their size, are classified in this subclass regardless of the method of manufacture, being also subject to classification in other classes and subclasses provided for their structural or functional features, if such features are of interest.

This classification structured around the concept of nano-structures has been subject to critics as being too narrow and leaving outside of its scope many nanotechnology inventions, resulting in a dispersion of these inventions though several different classes and subclasses. Although all member states follow the International Patent Classification many patent offices have internal classifications or tagging codes.
2.3.2 Nanotechnology tagging at the USA Patent and Trademark Office

The US Patent and Trademark Office (USPTO), has chosen an approach also based on the notion of nano-structure and imposing a bottom limit of 1nm, as follows:

‘CLASS 977, NANOTECHNOLOGY
This Nanotechnology art collection provides for disclosures related to:

i. Nanostructure and chemical compositions of nanostructure;

ii. Device that include at least one nanostructure;

iii. Mathematical algorithms, e.g., computer software, etc., specifically adapted for modeling configurations or properties of nanostructure;

iv. Methods or apparatus for making, detecting, analyzing, or treating nanostructure; and

v. Specified particular uses of nanostructure.

As used above, the term “nanostructure” is defined to mean an atomic, molecular, or macromolecular structure that:

(a) Has at least one physical dimension of approximately 1-100 nanometers; and

(b) Possesses a special property, provides a special function, or produces a special effect that is uniquely attributable to the structure s nanoscale physical size.’[18]

2.3.3 Nanotechnology tagging at the European Patent Office

The EPO on its turn has created the Y01N code in order to accommodate Nanotechnology inventions. According to the EPO, such code is not meant to be static, but rather is under constant revision and regularly improved following emerging aspects of this new technology. The Y01N code is divided into six main groups from Y01N2 to Y01N12, with each group collecting nanotechnology patents of similar technological backgrounds (table 1). The EPO defines nanotechnology as follows:[19]

“The term nanotechnology covers entities with a controlled geometrical size of at least one functional component below 100 nanometers in one or more dimensions susceptible of making physical, chemical or biological effects available which are intrinsic to that size. It covers equipment and methods for controlled analysis, manipulation, processing, fabrication or measurement with a precision below 100 nanometres.”

From the above mentioned it can be inferred that in order to be considered as falling into the category of nanotechnology an invention has to either fulfil the following requirements:

- To have at least one dimension bellow 100nm;
- The nano-dimension must produce a functional scale effect (an effect that derives merely from size);
- The scale effect can either be physical, chemical or biological;

An invention that does not contains the previous requirements can still fall under the nanotechnology category if it concerns equipments and methods for controlled analysis, manipulation, processing, fabrication or measurement as long as having a precision below 100 nanometres.

It is interesting to notice that the EPO does not include a bottom limit as it was suggested by the RS/RAE Report, and contrary to the approach chosen by its American counterpart the US Patent and Trademark Office that has chosen a bottom limit of 1nm.
2.3.4. EPO Classification of nanotechnology inventions:

<table>
<thead>
<tr>
<th>Code</th>
<th>Nanotechnology field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y01N2</td>
<td>Nanobiotechnology</td>
</tr>
<tr>
<td>Y01N4</td>
<td>Nanotechnology for information processing, storage and transmission</td>
</tr>
<tr>
<td>Y01N6</td>
<td>Nanotechnology for materials and surface science</td>
</tr>
<tr>
<td>Y01N8</td>
<td>Nanotechnology for interacting, sensing or actuating</td>
</tr>
<tr>
<td>Y01N10</td>
<td>Nano optics</td>
</tr>
<tr>
<td>Y01N12</td>
<td>Nanomagnetics</td>
</tr>
</tbody>
</table>

Table 1 : Source: EPO[19]

3. Patentability Criteria for Nanotechnology Inventions

3.1. When is a nanotechnology novel?

As a general rule, size is not a sufficient condition to establish the novelty of an invention. Some nanotechnology inventions, however, involve nanoscale formulations of previously disclosed chemical compounds, structures and materials. Does this mean that these inventions are not patentable?

When nanoscale inventions exhibit properties that are, in some measure, unanticipated or different from those found in larger scale prior art, exceptions have been made. For example, in BASF v Orica Australia,[20] the EPO’s Technical Board of Appeals (TBA) held that a prior patent which disclosed polymer nanoparticles larger than 111 nms did not destroy the novelty of a subsequent application by Orica for nanoparticles smaller than 100 nms. Orica’s smaller particles exhibited remarkably improved technical properties resulting in a glossier coat compared to the larger particles protected under the prior patent. The difference in properties was held to be sufficient to impart novelty. But does an invention lack novelty if it claims to use particles in a range of sizes that overlap with those disclosed in the prior art? Generally, even the slightest overlap is sufficient to destroy novelty but exceptions have been liberally applied to nanoscale inventions.
Under the EPO’s approach to assessing novelty of these so-called “selection inventions”, the overlap must be narrow relative to the larger prior art range, sufficiently far removed from the larger range and indicative of an invention, for example, by exhibiting a new or unexpected effect that occurs only within the selected sub-range. The new effect does not, of itself, render the sub-range novel; rather, it permits the inference that the sub-range has been specifically selected to provide a technical advantage or resolve a technical issue in the prior art and that it is, therefore, novel. Additionally, the EPO assesses the relevance of the sub-range to prior art documents by asking whether a person skilled in the art would seriously contemplate applying the technical teachings of the prior art in the range of overlap.

The EPO’s TBA applied this measure in a recent case involving Smithkline Beecham Biologicals v Wyeth Holdings Corporation [21]. The question was whether Smithkline’s patent application on a Hepatitis B vaccine adjuvant lipid measuring 60-120 nms lacked novelty in light of a prior patent on a similar adjuvant with particles measuring 80-500 nms. The TBA found that Smithkline’s patent was novel because the overlap was:

- narrow - only 10% of the larger range in the earlier patent;
- at the extreme lower end of the prior art range; and
- exhibited significantly improved adjuvancy – the smaller particles resulted in an unexpected and favorable shift in immune response.

Moreover, the prior art gave little guidance on how to prepare the smaller particles. A skilled person who followed the vaccine supplier’s protocol would have produced particles of between 115 and 951 nms. The technical teachings in the prior art were, therefore, not considered relevant to Smithkline’s patent application.

Granting patents for inventions falling within such overlapping ranges has become more common in nanotechnology than in any other field. Arguably, this creates a fragmented patent proprietorship landscape with multiple “blocking” patents on the same invention. The existence of “a dense web of overlapping rights” creates uncertainty and inhibits inventors in “designing around” existing patents. Such a dead weight of patents for inventions falling within overlapping ranges already overshadows research on nanotubes, nanowires, nanocrystals and nanoemulsions and threatens to severely arrest innovation and the further development of the nanotechnology sector [22].

### 3.2. When is a nanotechnology non-obvious/inventive?

In addition to proving novelty, a nanotechnology patent application must pass the test of non-obviousness. Both terms (non-obvious/inventive) are equivalent. A novel invention can be non-obvious if it represents a sufficient advance in relation to the state of the art to be considered worth patenting. If an invention would be obvious to a person of ordinary skill in the field concerned, it would not denote progress to the stage qualifying for patent protection.

Generally, an invention is considered obvious if it miniaturizes known elements, performing the same function, and yields no more than might be expected from the diminished size. Technology is considered non-obvious if it produces new and unexpected results or serves
previously unrecognized functions that overcome a technical problem relating to the prior art. As practically all nanoscale technologies display these characteristics, only those results which are not likely to emerge from extrapolations by a skilled person working with smaller structures are deemed patentable.

In the Smithkline Beecham Biologicals v. Wyeth Holdings Corporation case, the vaccine adjuvant was held to be inventive because of its unexpectedly improved effect and the fact that nothing in the prior art had suggested that a skilled person might consider reducing the particle size to achieve that advantage.

Nanotechnology applications can pass the non-obvious test if the invention affords a significant technological advantage over prior art, for example, by enabling a skilled person to practice the previously disclosed invention at the nanoscale for the first time. In BASF v Orica Australia [18], Orica’s claimed invention involved manufacturing polymer particles at 100 nms or less by initiating polymerization at temperatures below 40°C. BASF argued that the invention was obvious because a prior patent had disclosed the same manufacturing process using temperatures below 50°C to yield particles averaging 111 nms or more. They argued that a skilled person exercising no inventive effort and repeating reactions on a trial-and-error basis for all temperatures between 0°C and 50°C would have derived sub-100 nm particles at temperatures below 40°C.

The EPO rejected this argument and reasoned that the prior patent suggested using temperatures not exceeding 50°C. While this “did not rule out the use of temperatures below 40°C, it was far from suggesting their use.” Moreover, the patent was aimed at manufacturing particles larger than 111 nms only. A skilled person following the teachings of the prior patent would not have used temperatures below 40°C or foreseen that lower temperatures would result in particles smaller than 100 nms. The TBA held that Orica’s invention provided, for the first time, a method of creating smaller variants of polymer nanoparticles and was, therefore, inventive [22].

3.3. Industrial Application

For an invention to be patentable, it must be capable of use in any kind of industry. Since nanotechnology is still in its infancy and many applications have not progressed beyond the laboratory stage, one couldn’t possibly fathom the extent of plausible industrial application. The nature of nanotechnology inventions often points the way to their industrial applicability: nanotubes for making light and strong constructions, nano drug delivery systems, or nanotechnology used to create high electric conductivity are self-evidently industrially applicable.

3.4. Enablement Issues

The patents act requires an inventor to disclose the best way of manufacturing his invention, to enable a person skilled in the art to do the same, post expiry of the patent. A major problem posed by nanotechnology to the present patent regime, is that the scope of the invention and the field of knowledge itself is far too wide. Expressing and explaining the
The quintessence of the criterion of ‘sufficiency of disclosure’ is thus encapsulated:

1. That the invention is disclosed in a way that allows it to be practiced, and
2. That the (teaching of the) invention must be reproducible.

The first requirement implies that the person skilled in the art on the basis of the disclosure can rework the invention without an undue burden. Reproducibility indicates that the result of the invention can be reached over and again and not just on the basis of chance or only with a smaller or larger degree of predictability. If the examining or opposition division has no way of knowing or inferring the practicability of a nanotechnology invention, let alone its practicability across an entire range, it may very well require the patent applicant or patentee to beef up its disclosure and provide more detailed instructions for the reworking of the invention. Additionally, the fact that the invention produces the claimed results in a repeatable way may pose problems for nanotech inventors. In nanotechnology, analytical methods, tools and metrologies are often not available to the person skilled in the art. Without these the reproducibility of an invention may be difficult to ascertain. An inventor would thus be obliged to disclose these in the patent in order to make his claims verifiable[23].

4. Trends in Nanotechnology IP

4.1. Foundational Patenting

This is nearly the first new field in almost a century in which the basic ideas were patented at the outset[3]. In what can be called —enabling ‘technologies’[,] such as —computer hardware, software, the Internet, and even biotechnology[,] the —building blocks[,] of these patents were either unpatented by mistake or because patents obtained by university and government researchers were either licensed freely by the government ,invalidated, or the inventors had no interest in patents.[3]

For example, patent protection for software was not even available until 1981[24-26] while much early software development had been progressing without such protection.[27]

And at the beginning of biotechnology, partly because the Bayh-Dole Act had not yet passed to provide an investment path to commercial exploitation, and partly because policy at the time dictated that matters of public health should be dedicated to the public, universities were not patenting their research[28].

Even in some industries, when foundational patents did issue, they had no effect on the initial industry growth because the patents were locked up in interference proceedings while the industry was growing [3].

Antitrust policies also helped to ensure that some foundational patents were licensed freely rather than dominated by a single entity.[3,29] For example, AT&T, which held early patents on the transistor, was forced to license its patents under an antitrust consent decree. IBM also granted nonexclusive licenses under an antitrust consent decree. [3]
In sum, a review of emergent technologies over the last eighty years or so shows that— invention after invention was put into the public domain, freely licensed because of government or university policy, subjected to inventorship disputes for decades, or otherwise avoided patenting during the formative years of the industry. [3]

By contrast, in today’s age, given the importance of patents to securing licensing revenues and venture capital, coupled with a patent policy in the government and universities which favors patent exploitation, as indicated above, nanotechnology patents have been sought early and often. Indeed, some commentators believe that the early foundational patenting is being done so that royalties can be extracted from licenses that will be required to practice these early patents without being sued for infringement. [30]

There have been a few industries in the past that also had their foundational inventions patented, which arguably led to some problems [30].

Some of these instances are discussed in the later sections of this Note. [3] Multi-Industry Nature Nanotechnology has its roots in materials science, but to be put to its broad applications, expertise is necessary in numerous fields such as semiconductor design, biotechnology, telecommunications, and textiles. [2, 31]

The key is that the exploitation of materials’ properties at the nanoscale can be adapted to these various industries. [3]

This means that some inventions will have applications in more than one industry. While some nanotechnology inventions exist within a single industry, the multi-industry nature of many of the inventions will lead to a situation in which patent holders are not participants in every industry to which their invention could be applied. [3] This situation can have an effect on a patent holder’s incentives to license their patent [3].

— Certainly, the experience of the semiconductor, Internet, and information technology industries has been that patentees who do not participate in the market are more likely to sue to enforce their patents than those who are in the market. [3]

While past experience is not dispositive of how patent holders will treat their nanotechnology patents, it does indicate that people looking to secure rights will have to look outside their own industry [3].

4.2. Issuance of Too Many Patents

Another rising challenge is the ability of patent offices to cope with the increasing number of patents being applied for. In the US the number of patent applications granted stalled at 4% in 2005, compared with 25% the previous year, while the number of applications grew by 52% to 2,714. The largest challenge to developers of downstream nanotechnology products is the large number of patents issued by the PTO. The bottleneck that has developed, due to the increasing complexity of patents, is a considerable limiting factor for innovators in acquiring intellectual property rights. The fragmentation of intellectual property creates minefields that firms must cross in bringing products to market. The costs of licensing numerous patents are exorbitant, and alternative arrangements such as cross-licensing and patent pools are unlikely to emerge. As a result, the large number of patents could limit the commercial potential of nanotechnology.
As a result, patent and trademark offices around the world will need to respond to the rising demands of cross-disciplinary patent examination [32].

4.3. Distinction between discoveries and inventions
Discoveries are one non-patentable subject matters or activities mentioned in article 52 (2) EPC that may assume particular relevance for nanotechnology inventions since in some case it may be difficult to make the distinction between inventions and mere discoveries, particularly in the field of nanobiothecnology.
Nanotechnology designates a group of techniques that enable the manipulation of matter at nanoscale, which means building structures and new materials at an atomic, molecular and macromolecular scale. At nano scale classical laws of physics do not apply, instead the properties and behaviour of matter is govern by quantum physics. Since the fundamental properties of materials such as electrical conductivity, magnetism, optical characteristics, hardness or fluid qualities, chemical reactivity, and melting point are all subject to change at nano scale, while manipulating matter at this scale scientists often encounter new and surprising properties of materials and thus many nanotechnology inventions relate to finding new properties of known materials or naturally occurring elements.
Pursuant to article 52 (2) EPC discoveries are not patentable, and the mere finding of a ‘product of nature’ (a substance or element) or of a new property of a ‘product of nature’ cannot be regarded as an invention by itself or in the article 52 (2) formulation the patent application can not relate to these subject-matter as such [33].

4.4. Cross-Industry Patents
Another factor driving the importance of patents in nanotechnology is its unique cross-industry structure. Nanotech is not confined to a single field of endeavor, but exploits the peculiar properties of matter at the nanoscale across many different fields of modern engineering. Thus, a basic nanotechnology patent may have implications for semiconductor design, biotechnology, materials science, telecommunications and textiles; even though it is held by a firm that only works in one of these industries. To be sure, many nanotechnology inventions exist comfortably within a single industry – this is notably true of semiconductors – and don’t seem to have significant cross-industry applications. But many others take advantage of the unique physical properties of nanoscale materials to put things to radically different uses. Companies may use organic self-assembly to create electronic components that traditionally required mechanical deposition, for example.[34]

Unlike other new industries, in which the patentees are largely actual or at least potential participants in the market, a significant number of corporate nanotechnology patentees will own rights not just in the industry in which they participate, but in other industries as well. This may significantly affect their incentives to license the patents. Certainly, the experience of the semiconductor and information technology industries has been that patentees who do not participate in the market are more likely to sue to enforce their patents than those who are in the market.[35]

Whether it does or not, at a minimum it means that companies looking to clear patent rights in nanotechnology must look not only to inventors in their field but must search in widely disparate fields as well.

4.5. Rejection of Claims That Should Issue
The failure of the patent offices to prepare for nanotechnology is resulting in the rejection of some valid claims. The complexity of the field may cause some examiners to mistakenly conclude that inventions are obvious or not novel. The denial of valid claims is a wasted expense and reduces the incentive to innovate. Although an applicant can petition for reconsideration, the process is costly, and the delay can be devastating for smaller companies.[34]

4.6. Broad Patent claims
The issue of broad patent claims has been considered not only by advocacy groups but also by academics. The global scientific community has noted and express concerns that a broad interpretation of article 27 of the TRIPS agreement within national or regional frameworks could result in blurring the distinction between invention and discovery, and monopolization over basic blocks of technology [36].

Some have questioned the ability of the patent offices, to understand these new technologies. In their view the patent offices lack scientifically qualified staff and such results in excessively broad and often overlapping patents being granted [37].

The EPO has addressed such criticism by setting up in 2003 a Nanotechnology Working Group with the mission to organize internal know-how and call on external experts (when needed) in order to develop a strategy for facing the challenges brought by nanotechnologies. At their website the EPO declares that: ‘To avoid an inflation of low-quality patent applications that could clog up the EPO and create a backlog, the EPO has introduced a quality policy to bring certainty to the market, for both the applicant and the public. The EPO’s approach is one of “quality rather than quantity.”’[38]

Without making assumptions, it should be mentioned that such criticism is not accompanied by substantiated data other than the fact that apparently broad patents have been granted. Pointing the finger at the technical qualifications of the patent examiners seems to be a rather simplistic explanation for a question that is neither new, neither exclusive to nanotechnologies and may have several optional explanations and/or different contributory factors deeply rooted in characteristics of the patent system in itself. The issue of broad and overlapping patents appears to be more a consequence of the overall less restrictive approach that the EPO has been taken in connection with biotechnology inventions and assumes considerable relevance in nanotechnology, since on one side there is an observed tendency for patent to be filed (and granted) covering early stages of technological development and on the other side the nature of nanotechnology tends to further blur the already difficult distinction between inventions and discoveries

4.7. Overlapping and classification:

Some experts fear that nanotechnology will create complicated broad patent thickets where it will be difficult to clarify the patent ownership.[3] According to Lux Research ‘there may be multiple nano-thickets, covering different platform of technologies such as dendrimers, quantum dots and carbon nano-tubes.’[39] Most companies are interested in fundamental building blocks inventions of nanotechnology. When any other company of the market wants to use the protected nanotechnology the production may take a lot of license negotiations because nanotechnology covers a multidisciplinary field of science with a wide
area of application. Different companies may own different patents in nanotech and there is a huge possibility for patent infringement litigation. This may hamper the further development of nano-related inventions.[3]

According to NanoBusiness Alliance ‘several early nanotech patents are given such broad coverage; the industry is potentially in real danger of experiencing unnecessary legal slowdowns.’[3, 40]

From the view of economists, the requirements of acquire rights from different players will also create ‘double marginalization’ or ‘hold-up' problems.[3]

Some of the experts think that by imposing a strict utility requirement like in chemistry and biotechnology may stop the overlapping of nanotechnology patents.[3]

On the other side, while a large portion of nanotechnology patent rights is owned by universities, to stop patenting basic building blocks by imposing exclusive licenses, may encourage downstream innovation of nanotechnology. [3]

Another possible way to stop overlapping litigations is to create patent pool agreements in the like software and biotechnology fields.[41]

A patent pool is a jointly arrangement among several patent holders, which is necessary to produce product or in process and here all patents are licensed jointly as a similar price [42].

The LuxReport suggested that nanotech firms could pool their patents and start licensing schemes. [43]

But many patent experts criticised the patent pool idea as being against the main spirit of IPR and a free market economy. Basically IPR encourage competition and innovation in the market but the patent pool system is anti-competitive manner and it encourages collusions and price fixing.[3]

4.8. Patent Trinkets
Patent trinkets can be described as unintentionally formation of dense interconnected and often overlapping intellectual property rights with different owners. The possible formation of Patent trinkets has been mentioned in the literature with particular incidence in nanoelectronics, were some annalists have identified the existence of patent trinkets in the area of dendrimers, quantum dots, and carbon nanotubes.[44]

Patent Trinkets are often a consequence of the above mentioned broad and overlapping patents being filed and granted, and in general terms give rise to problems such as unintentional infringement of patents and the subsequent liability created as a consequence of the said infringement; the problem of anti-commons; the creation of barriers to entry; and the need for licensing.[45] Some authors considerer that the costs of cross-license schemes may be so disproportionally high that the industry will either simply ignore the problem by unofficially ‘agreeing’ in avoiding the enforcement of their patent rights,[46] resolve to the creation of patent pools or even join/create open source movements.[41]

The increasing rate of patent applications by universities and private research organizations highlights another potential challenge for the nanotechnology industry: striking a balance between maintaining freedom of operation for a large number of innovators, while rewarding innovations with patent rights.[47]

A large number of patent owners exercising the right to exclude others from practicing various aspects of nanotechnology can seriously restrict future research and development. Before commercializing nanotechnology products, companies may have to obtain licenses from a large number of patent owners. In order to attain the proper balance between innovation and exclusion, patent strategists will need to consider ethical questions about the division and aggregation of legal rights and reassess the scope of licensing practices.[48]

4.10. Trade Secret Challenges

Trade secret protection offers the advantage of avoiding the effort and expense of patent applications and has a potentially indefinite duration, subject, of course, to reverse engineering. With lengthy commercialization timelines for some nanotechnologies and the 20-year limit on the patent term, it may be advisable to opt for trade secret protection as long as the product is not easy to reverse engineer in the near future.[49]

However, trade secret protection requires continuous diligence, and once a trade secret is revealed, it has no further protective value.[50]

Pressure to publish in academic circles makes trade secrets difficult to maintain. It also is very difficult to obtain government funding and maintain trade secrets given the governmental funding reporting requirements. The increase in funding and companies pursuing nanotechnology applications further will increase employee mobility and necessitate stringent safeguards against the theft of trade secrets by departed employees. Finally, as a general matter, investors tend to avoid technologies that lack patent protection making trade secret protection a non-viable option for many innovative technology companies.[49]

4.11. Intellectual Property Litigation

Nanotechnology intellectual property litigation has already emerged around trade secret issues. For example, in July 2000, Caliper Technologies Corporation ("Caliper") sued Aclara BioSciences ("Aclara") for misappropriation and conversion of Caliper's proprietary technical, strategic and intellectual property information relating to microfluidics.[49] In response, Aclara sued Caliper for patent infringement. After Caliper obtained a jury verdict against Aclara in its trade secret suit the parties settled.[49] Later in October 2002, Nanogen announced the settlement of a lawsuit with former employee Donald Montgomery for taking its trade secrets to Acacia Research Corporation's ("Acacia") CombiMatrix unit and filing patent applications related to the disputed technology under his name. [51]
Under terms of the settlement, Acacia agreed to pay Nanogen $1 million to cover litigation costs and issue 4 million shares, or 17.5 percent, of its unit's stock. Acacia also will pay Nanogen royalty payments on sales of products developed by either CombiMatrix or affiliates that use the disputed technology. [52]

Finally, Zyvex Corporation, a company developing NanoElectroMechanical Systems (“NEMS”) for prototype nanoscale assemblers, obtained a permanent injunction against a former employee for misappropriation of trade secrets.[49]

Given the breadth of the field and opportunity for broad patent coverage, intellectual property litigation over patents is likely to emerge in the near future. Long lead times for the commercialization of some nanotechnologies will delay challenges to patents, creating business uncertainty and concerns over patents which may become invalidated years in the future. Considering the expense of litigation, innovators lacking the resources to litigate patent validity may be forced to license these patents rather than contest them.[49] Given the novelty of the technologies involved, the patentability of some nanotechnology inventions may ultimately be addressed by the courts rather than by the USPTO.[53]

To date, litigation over nanotechnology scale patent infringement has been primarily focused on biotechnology products such as nanogold particle labels used in diagnostics, microfluidic devices and microarrays. [49]

For example, Affymetrix and Oxford Gene Technology have each brought a series of patent infringement lawsuits against competitors in the field of DNA microarrays. [49]

A recent decision in the Federal Circuit highlights two particular defenses to general patent infringement that merit attention based on their applicability to nanotechnology. In Madey v. Duke University.[54] the Federal Circuit narrowed the application of the “experimental use defense” while leaving a newer “government license defense” open to further exploration.[50]

In remanding on this issue, the Federal Circuit held that the experimental use cannot further the alleged infringer's legitimate business and must focus on whether the use was "solely for amusement, to satisfy idle curiosity, or for strict philosophical inquiry."[50]

The Federal Circuit left this issue open in view of the lack of a record on appeal respecting this issue, noting that the parties could develop the issue on remand.

Under this standard, virtually all professional labs are excluded from this defense, thereby limiting the experimental use defense as a practical matter. On the other hand, the government license defense may allow potential infringers to assert third-party beneficiary rights to practice the patents at issue on the government's behalf because of the government's rights in the patents and the use of the allegedly infringing devices in the performance of government sponsored research.[50]
The government license defense is double-edged -- any intellectual property rights secured under government sponsorship would be subject to the same "government license" defense to infringement by others.

The government license defense may be particularly helpful to nanotechnology researchers due to the substantial amount of government sponsorship of nanotechnology.

4.12. Universities and the patent ‘land grab’ race

Universities traditionally did not seek patent protection for their inventions but surprisingly are the top patent owners in nanotechnology-related inventions,[3] a fact that has been noted as a worldwide trend of change in the publicly-funded research organizations’ (PROs) paradigm.[55] In the USA prior to the Bayle-Dole Act (1980)[56] universities were not allowed to patent the results of federal funded research, intellectual property rights belonged to the US government which had the policy to grant only non-exclusive licenses. The Bayle-Dole Act encouraged PROs to assume and establish a technology transfer function changing the university research paradigm from an open science model (in which no intellectual property rights are retained by PROs) to a licensing model.[55] In Europe although the traditional ‘publish or perish’ approach is still very present, it is no longer the exclusive basis of assessing the validity of science and scientists. Some countries are successfully implementing policies and tools destined to encourage knowledge transfer from PROs to industry following the licensing model; such includes subsidies, tax incentives, seed capital funds, incubator facilities, etc.[57] While others, notably the UK, Scandinavian countries, Netherlands and Belgium, have been developing with good results the Innovation Model, characterized not only for seeking patent protection and licensing and/or contract research but by feedback and frequent interactions at different levels between research and industry.

4.13. Academic Publication as Premature Disclosure

The nature of academic research tends to make securing intellectual property rights more challenging. Publication and early disclosure is the traditional measure of academic performance. The ultimate reward for a researcher relies on the rapid and wide distribution of research results so that research can be cited by others. Premature disclosure can defeat trade secrets and weaken the ability to secure patents.

In order to strike a compromise between sharing information and securing U.S. patent rights, researchers can use provisional patent applications, which delay the impact of publicly available information from being used against patentees as prior art for one year prior to the patent application in the U.S. only.[50]

However, taking shortcuts in drafting a provisional application increases the likelihood of falling short of minimum disclosure requirements, resulting in limiting the scope of claims that can be supported by the final specification.[49]

4.14. Procedures for Technology Transfer
With the increasing importance of securing nanotechnology patent rights in early stages of research, universities and laboratories need to refine mechanisms to ensure that researchers are aware of the diligence required to establish and transfer intellectual property rights. Organizations need to reassess intellectual property procedures governing invention disclosures, notebook keeping, publication approval, patent filing approval and confidentiality agreements, as well as implement reasonable precautions against the theft of trade secrets. In the interest of avoiding ownership disputes and litigation over the huge market potential for nanotechnology products, special attention should be focused on securing intellectual property rights at each relevant step in the research process.

For example, the California NanoSystems Institute at UCLA and UC Santa Barbara coordinates all its intellectual property administration with the already established campus Office of Intellectual Property Administration (“OIPA”).

The OIPA has attorneys specializing in assessing innovative research and securing intellectual property rights on behalf of the Office of Technology Transfer (“OTT”) for the University of California Regents. [58]

The OIPA works with researchers and performs all the necessary steps in filing provisional, utility and international patents for all nanotechnology research for each campus. The OIPA also coordinates licensing contracts with entities outside the university for technology transfer. As of February 2004, the OIPA offered 12 UCLA nanotechnology license listings,[59] and the University of California Regents offered 113 nanotechnology related licenses.[60]

4.15. Government IP Rights in Funded Research

Funding derived from the Nanotechnology Act will impact the nature of the patent rights derived from the funded research. Under the Bayh-Dole amendments to the Patent Act, universities and small business entities retain intellectual property ownership rights in federal government sponsored research.[61]

The government retains a royalty-free license to any patented technology funded by the government. Transfer and acquisition of these rights require compliance with certain formalities, such as when a licensing deal is made with a corporation or when a company is spun out by a professor. The university also must consider the potential for premature disclosure in government reporting requirements associated with the funding of sponsored research.

4.16. Business IP Rights in Funded Research

Global companies including IBM, Hewlett-Packard (“HP”), 3M, General Electric, Lockheed Martin, ChevronTexaco, Samsung, Mitsubishi and DaimlerChrysler are making significant investments in nanotechnology research efforts. [62].IBM, HP and 3M are allocating approximately one-third of their respective research budgets to nanotechnology. [63]

Venture capital investment is growing rapidly, with more than $1 billion in funding over the last three years and as much as $700 million in investments for 2004.[64] A vast amount of
funding from corporate and private sources has made its way into sponsorships of university research. For example, companies have made alliances with the California NanoSystems Institute at UCLA and UC Santa Barbara by investing millions of dollars in sponsorship of nanotechnology research. In exchange for funding, companies generally share intellectual property rights for specifically sponsored research projects. For example, contractual agreements between the CNSI and corporate alliance members provide that if a sponsor funds up to 50% of a nanotechnology project with CNSI, that sponsor gets up to 50% of intellectual property rights on that project.[58]

4.17. U.S. Patent and Trademark Office Challenges

In February 2004, the number of issued U.S. patents incorporating the term “nano” reached 1,348 patent titles and 82,740 patent descriptions.[64] At the same time, the term “nano” has been incorporated into an additional 911 published patent application titles and 28,779 published patent application descriptions.[64] Considering the fact that the U.S. Patent and Trademark Office (“USPTO”) receives roughly 300,000 patent applications a year, nanotechnology now impacts almost 10% of applications under consideration.[65] It is unclear if the USPTO can handle the anticipated exponential increases in nanotechnology patent applications, especially in national and regional patent offices where examiners are generally assigned to examine a single class or related classes of technology.

While the U.S. Patent Classification System organizes issued patents, published applications and prior art references based upon their common subject matter, there is no specific classification for nanotechnology-related inventions.[53] Today the USPTO designates ten classes as potentially containing prior art for nanoproducts.[53] A potential problem with the lack of a unique classification for nanotechnology-specific prior art is that the examiner may have a difficult time locating the best available prior art to a nanotechnology patent application. Given the multidisciplinary nature of nanotechnology developments, specialized examiners may not be familiar with advances in other areas necessary for the complete examination of a new technology. [49] The convergence of several fields with different terminologies for the same phenomena increases the chance that patents will be issued without proper narrowing of the scope of claims in view of prior work and publications, or in view of the practical difficulties in applying the technology. [49]

Although it has undertaken a nanotechnology customer partnership which attempts to address issues related to patent prosecution for interdisciplinary inventions in nanotechnology, the USPTO has no plans to create a nanotechnology classification or to form any new group to evaluate nanotechnology applications.[66] The lack of cross-functional nanotechnology expertise at the USPTO and delays in establishing nanotechnology-specific guidelines may lead to the issuance of overly broad patents by examiners despite relevant prior publications, which is likely to lead to litigation.[67]

4.18. Foreign Patents

Patent protection is typically only effective within the issuing country. In light of the considerable worldwide efforts in nanotechnology research, early foreign patent protection
will be essential. Securing international patents will increase the administrative effort and expense of nanotechnology patent protection.

Many foreign patent offices follow the USPTO’s lead in dealing with novel subject matter. Although they may lag behind the USPTO in granting novel nanotechnology patents, certain foreign patent offices have taken steps beyond the USPTO in establishing unique classifications for inventions in nanotechnology. The World Intellectual Property Organization’s International Patent Classification system includes a specific nanotechnology classification (IPC Class B82B) and the Japanese Patent Office has likewise created an internal patent classification (“Micro-Structural Technology; Nanotechnology”).[53]

4.19. Enforcement

The massive economic possibilities connected with nanotechnology will not only result in a huge number of patents applications to the patent office but the courts will also face enormous challenges regarding nanotech patent infringement actions.[68]

Nanotechnology patents may be very difficult to enforce because it will be tough to detect infringement of nanotech products. [3]

If the court applies the doctrine of equivalent then for infringement action the plaintiff must prove that the accused product or process elements are identical or technically equivalent to the patented invention and hence enters within the scope of the claim.[68]

The court needs to interpret the language of the claims of the patent and other real evidence. This other real evidence also includes the specification and the prosecution history.[68]

But in nanotechnology the confined bordered written description is too difficult, thus in many cases the court finds difficulties to take on any infringement actions. For example, the accused infringer of macro scale carbon fibers can avoid the court action by claiming that a patent characterizing traditional materials would not meet the disclosure requirement for a nanotechnology invention. [68]

At the nano-scale level, the behavior of the materials is unpredictable; for this unique problem of nanotechnology, the law enforcing authority will face some problems to take infringement actions.

4.20. Detecting Abuses

The cross-industry application of nanotechnology, as well as the tendency to grant patents on “selected inventions” (those using particles in a range of sizes that overlap) makes policing and enforcement of nanotechnology patents prohibitively expensive and practically impossible. There is no easy way for a patentee to know whether a competitor or a firm operating in another sector is using a protected technology without authorization. The only way to determine whether a marketed end product infringes a nanotechnology patent is to use sophisticated and expensive microscopy techniques and equipment. Analysis of every suspect product is beyond the purse of most outfits. Moreover, as much of the current
nanotechnology research is guarded behind closed doors in corporate research facilities and university laboratories, it is often difficult to establish a legal basis for an infringement action even if abuse is detected. These factors risk undermining the primary incentive for patent disclosure, namely, to obtain an exclusive monopoly to use and commercialize an invention.

**4.21. Future challenges towards Nanotechnology patents**

Nanotechnology is passing its early stages compared to other fields of science. It is too early to predict how nanotech inventions will face patenting problems and how IPRs deals with nanotech inventions accurately. [3]

But it can be said that more of basic building blocks of nanotechnology will be patented than in any other branches of science and technology.[3] Some experts believe that nanotechnology IP avoid ‘self destructed IP war'. Because huge numbers of cross-licensing agreements by starts-up and large numbers of IP for specific application licensed by group of large companies. [69]

Actually high cost of nanotech IP and too restricted licensing system are creating new legal challenges in the field of nanotechnology. [ibid] The experts will face different types of legal problem for patenting nanotechnology inventions. [69]

**4.22. Ethical issues:**

The ethical issues are mainly concerns about the question of fairness, equity, justice, non-discriminatory license practice and social relationships. [70] It also includes the possible clash of interest arising from dealings among government, industry and universities and IP ownership. [71]

The advancement of nanotechnology is progressing on a daily basis and its outstanding inventions attract great public interest but critical voices are also rising at the same time. [72]

These voices assume that the products of nanotechnology will be harmful for public health and environment and that the risk assessment in nanotechnology research is insufficient. Some of the environmental experts express concern that the nano-manufacturing process will cause bad effects on the environment. [70]

Although no researchers yet are able to show the specific impact on the environment, it is true that human safety issues are one of the burning ethical issues towards nanotechnology development. Some nano-particles can easily enter into the human body but the human health implications have not found yet. [71]

Another important issue is privacy issues related to nanotechnology. Nanotechnology leads are highly efficient and consist of smaller electronics and IT chips, by which one can easily monitor a person, retrieve one's personal or confidential data and information, medical records, etc. Without consent and a lawful authority, it's a threat for civil rights and privacy rights. [70]
4.23. Possible Dangers from Current Nanotechnology Patent Landscape

With an ever increasingly dense landscape with broad and overlapping claims, nanotechnology could face three potentially serious implications: (1) Decreased rate of innovation, (2) Widespread nanotechnology IP disputes, and (3) Reduced rate of consumer acceptance.

1) Decreased Rate of Innovation

Patents were originally designed to help spur innovation by granting exclusivity to the creator. However, the potentially large number of poor quality patents may actually slow down this field’s pace of advancement.[73]

With so many patents being accepted, those who consider conducting research and hopefully one day patenting their discoveries may hesitate to start for fear that their idea may already be patented. After all the money, time, and energy invested into their work, they may unweltingly find a patent that already covers their desired topic. They see no economic reward for their efforts in the end as a result. That apprehension of not gaining anything worthwhile, besides increasing the general body of knowledge, may weigh heavily on researchers’ minds and their corporate sponsors’ alike. If such feelings become common among the nanotechnology research sector, retardation in the rate of innovation and progress is a possibility.

2) Outbreak of Widespread Nanotechnology IP Disputes

Another potentially negative consequence of having too many overlapping and conflicting nanotechnology patents is an “intellectual property war. The length and cost of litigation will be another reason for the decreased rate of advancement. Investors may be unwilling to invest or keep money in a company that is being charged with infringement for fear that, if they lose a patent dispute, they will not only lose an important market but also will be forced to pay a licensing fee, will be penalized with a patent infringement fine, or will have to buy the patent outright [74].

Companies may, as a precaution, be forced to keep a sort of security deposit in case of an infringement battle. Mr. Wieland anecdotally jokes that companies should “budget $3-$4 million for lawsuits when creating a new product.”

The adverse effect of such a measure is the money in the security deposit is essentially frozen, and not being used for such things as research and development (R&D). There is also the chance that no infringement case will be brought up, thereby freezing that money indefinitely.

3) Reduced Rate of Consumer Acceptance
The final societal implication of poor nanotechnology patent quality stems once again from the possibility and handling of patent disputes. Increased costs for legal action could reduce the enthusiasm with which companies market their products for fear that they may, unknowingly and unintentionally, be infringing on other company’s patent. Consumers will then be less likely to buy said products because they do not know about it; lack of public consumption will hurt a company’s bottom line and see no need to further promote and manufacture said goods. So it is a cycle: lack of company support affects consumer buying patterns which in turn affect company support.[75]

5. Suggestions - The measures to allow the patent regime to rise to the challenges

By its very nature, nanotechnology is a multidisciplinary area of science. As such, its inventions are based on a wide spectrum of technologies including materials science, electronics, physics, chemistry, and biology. While this diversity may foster creative new approaches to the technical hurdles posed at the nanoscale, it also creates some significant difficulties in patent examination, classification, and analysis.

For example, the broad definition of ‘nanotechnology’ leads to challenges in classifying new inventions for Patent Office purposes. On one hand, an application may use other terms, such as 'microscale' or 'quantum dot,' to describe a nanotechnology invention. On the other hand, an applicant may incorrectly describe his invention as ‘nanotechnology,’ perhaps seeking to capitalize on the positive press associated with this term, or use terms like 'nano-second' that arise in other contexts. Inventors and examiners must, therefore, be particularly cautious when searching for prior art in this area—‘nano' alone is not a good search term[76].

A second problem relates to where nanotechnology patents will be examined within the Patent Office. In the 1980s and 1990s, judicial decisions in the US cleared the way for inventors to patent inventions in the expanding areas of biotechnology and Internet business methods. Inventors sprinted to the Patent Office, overwhelming it with new applications. The Patent Office recognized the importance of these new technologies and eventually responded to the surge in applications by establishing two new groups solely devoted to examining Internet business methods and biotechnology inventions. To date, however, the Patent Office has declined to do the same for nanotechnology. According to the Patent Office, this is because nanotechnology broadly cuts across all technologies, so that having one group dedicated to it would present difficulties in examination and classification. However, the Patent Office remains open on this issue and has indicated that it will revisit this decision if a sufficient 'critical mass' of nanotechnology applications is received. A recent survey, using one definition of nanotechnology, found that the number of nanotechnology patents issued by the Patent Office rose from 538 in 1976 to 6425 in 2002.[77]

The multidisciplinary nature of nanotechnology places an increased burden on patent examiners, who understandably do not have a wealth of experience in this new area. Indeed, the small pool of nanotechnology engineers and scientists who become patent examiners limits the ability of the Patent Office to recruit examiners with appropriate technical backgrounds. However, a group dedicated to examining nanotechnology
inventions might result in better trained examiners, even if they were not initially schooled in the field, and a better product from the Patent Office.

If examiners are unfamiliar with or untrained in nanotechnology, applications are more likely either to be rejected improperly because the examiner mistakenly concludes that the application is not novel, or else they may issue overly broad claims. In either case, the nanotechnology industry and public will suffer. For example, if an application is improperly denied, the applicants might have to file costly petitions to the Patent Office and, possibly, even the courts to have the decision reviewed. Overly broad patents may be of poor ‘quality’ in that they are more vulnerable to successful challenges based on prior art not considered by the Patent Office. Conversely, the issue of an overly broad patent may serve to improperly exclude competitors from entering the market, thus giving a single company far too much control over a particular part of a technological field. Obviously, this will discourage innovation, and thus frustrate the purpose of the patent system.[78]

Even if the Patent Office establishes a dedicated nanotechnology examining group, giving greater consistency in the standards that must be met to obtain a patent, inventors need to actively assist their patent counsel in prosecuting their application claims. For example, because the Patent Office does not currently classify nanotechnology patents in a single area, US examiners may not be aware of potentially relevant prior art from other areas. [79] As it would be both more efficient and less costly to distinguish such art in the Patent Office (rather than in a court), inventors will benefit by quickly bringing such literature to the attention of the attorney handling their applications. In addition, US law requires inventors to disclose all information that might be relevant to the Patent Office in determining patentability. This 'duty of disclosure' is taken very seriously by the Patent Office and the courts. Failure to disclose such information is another ground on which US patents can be lost. Recently, proposals have been made by the Patent Office and the Federal Trade Commission to introduce an 'opposition' system in the US Patent Office, similar to that already used in the European and Japanese Patent Offices. This would allow interested third parties to bring prior art to the attention of the Patent Office and permit an inter partes proceeding in the Patent Office to determine validity. [80]

Some recommendations for Dealing with challenges of patentability of nanotechnology inventions are proposed below.

5.1. Patent offices Reform

As nanotechnology begins to flourish, the patent offices will be confronted with an increasing number of patent applications. The patent offices should take action to prevent the rejection of valid claims, force patentees to narrow overly broad claims, and reduce the total number of patents issuing by ensuring that claimed inventions are not obvious in light of the prior art. The patent offices has faced challenges similar to those presented by nanotechnology with other emerging technologies. the patent system must ready and able to meet the challenge of this new technology”[81] and cannot remain passive or it risks contributing to an IP crisis in nanotechnology.

By 2000, the PTO had instituted special review procedures, including subjecting applications to a second review by a second patent examiner before issuance as discussed below.
The patent offices should institute a system that directs nanotechnology patents to specific people tutored in nanotechnology within the different technology centers. “Having a set of nanotechnology specialists within the patent offices and in communication with each other could unify prior art searches and ensure more accurate consideration of nanotechnology patents and increased quality of granted patents.”[82]

steps must take to educate patent offices examiners about nanotechnology toward improving quality and efficiency of review.

5.2. Patent Reexamination

If a device firm doubts the validity of a blocking patent, PTO's patent reexamination procedure can be used as a lower-cost alternative to litigation for challenging the patent's validity. Some recent high-profile reexamination cases (such as the ones involving RIM's Blackberry, eBay's “Buy It Now” feature, and the University of Wisconsin's stem cells) have put this once little-known procedure into the public spotlight and demonstrated the role it can play in a defensive patent strategy.

PTO offers two types of reexaminations: ex parte and inter partes. In ex parte reexaminations, which are used far more frequently, the patent challenger is allowed to remain anonymous. Therefore, the challenger can request a reexamination to test the validity of a blocking patent early in the product development stages before investing substantial time and money. The challenger must submit in its request a “substantial new question of patentability” based on another patent or a printed publication. Statistical data published by PTO indicate that more than 90% of reexamination requests are granted.

Once PTO grants a reexamination, the patent owner is given the option of filing a response. The challenger then has two months to reply to the patent owner's response if one is filed. (But to avoid giving the challenger this opportunity, the patent owner will often decline to file a response.) This is the extent of the challenger's participation in the reexamination process; the remainder of the reexamination takes place between the examiner and patent owner only. The challenger's limited participation is one of the major disadvantages of the ex parte reexamination method.

After these opening exchanges, much of the reexamination procedure follows the general rules governing the examination of patent applications. However, there are two major differences that subject the patent to a higher level of scrutiny than that applied in an ordinary examination. First, a three-member PTO panel reviews the decisions at key points in the reexamination process. Second, reexaminations are assigned to a special corps of highly skilled patent examiners who work solely on reexaminations.

At the conclusion of a reexamination, PTO issues a decision that cancels any claims that are found unpatentable, confirms patentable claims, and makes any necessary changes to the claims. According to one study, almost 75% of ex parte reexaminations result in the cancellation or modification of at least some of the claims.[83]

The inter partes process works similarly to the ex parte process, and like ex parte reexaminations, more than 90% of requests are granted by PTO. The main difference in a
inter partes reexamination is that the challenger is allowed to actively participate in the process by submitting rebuttals to statements made by the patent owner. Also, unlike ex parte reexaminations, the challenger’s identity is revealed to the patent owner.

The challenger’s active participation may explain the higher success rate in inter partes reexaminations—86% as of September 2006. If an inter partes reexamination is successful, all claims in the patent are canceled, effectively extinguishing the patent.

One of the potential disadvantages of inter partes reexamination, however, is that the challenger is not allowed to use the same arguments, or even arguments that could have been made, to challenge the patent in any subsequent court litigation (an estoppel). But this problem is largely mitigated by the fact that the challenger can appeal any unfavorable inter partes reexamination decisions to the PTO board and subsequently to the Federal Circuit court [84].

5.3. Risk-Assessment Strategies

Having a comprehensive view of the patent landscape is vital to operating in the nanotechnology space because multiple patents from different sources may need to be licensed to bring medical devices using nanotechnology to market.

A nanotechnology-based medical device will probably implement multiple layers of nanotech platforms. Take, for example, a hip implant with a nanocomposite coating designed to improve tissue regeneration around the implant. In addition to licensing the nanocomposite coating from the supplier, the raw nanomaterial component of the coating may need to be licensed from another patent holder, and the technique for applying the coating to the medical device may need to be licensed from yet another patent holder.

The obstacles presented by this patent thicket should be addressed early in the product development cycle before a firm spends a significant amount of money on developing a nanotechnology-based medical device. A well-planned licensing strategy can help manufacturers avoid a situation in which a company licenses one set of patents to develop a product only to learn later on that more patents need to be licensed[84].

5.4. Survey the Patent Landscape

In a field that is dominated by patents, due diligence and a proper survey of the patent landscape are critical to a successful nanotechnology licensing strategy. When licensing a nanotech platform to incorporate into a medical device, device firms must always consider whether any other patents owned by third parties might restrict the proposed use of nanotechnology in the product. This type of question is typically answered through a product clearance investigation (also called a right to use or freedom to operate), which involves a search of patent databases and an analysis of relevant patents.

Although a comprehensive clearance search incorporates multiple search strategies, manufacturers can conduct a preliminary patent search on the database available at the PTO Web site (www.uspto.gov) using potential keywords. A search within the PTO nanotechnology classification (Class 977) may also be helpful, but the results may be limited
because this classification was only recently created. Device firms can further analyze potentially relevant patents identified by the search to determine whether there are indeed blocking patents, and if so, whether the patents are valid. Sometimes a patent is invalid because of a prior publication, such as a scientific article disclosing the claimed invention, that was not considered by the PTO during the examination process. If a blocking patent is believed to be invalid, manufacturers can challenge its validity through a patent reexamination request.

5.5. Anti–Royalty Stacking

If licensing a nanotechnology patent, consider having the patent owner share some of the risk posed by an uncertain patent landscape. One way to do this is to insist on an antistacking provision in the licensing agreement to prevent royalty stacking. This stacking arises when several parties who own overlapping patent rights demand royalty payments for use of their technologies in the product that you wish to bring to market (i.e., the royalties stack up on each other).

An antistacking provision requires the licensing patent holder to share some of the financial burden. A typical provision states that the royalty rate payable to the patent owner will be reduced if other third-party licenses are required for a given product. One method used to reduce the total royalty burden is to include a clause that the royalty rate will be reduced by a percentage (one half, for example) of the second royalty rate. For example, if a first-obtained license has a royalty rate of 7% and a subsequent license has a royalty rate of 4%, the adjusted royalty rate for the first license would be: 7% – (4% × 0.5) = 5%.

5.6. Indemnification

Another way to have the licensing patent owner share the risk of an uncertain patent landscape is to include an indemnification clause in the licensing agreement. In such an agreement, the licensing patent owner agrees to defend the license user from patent infringement claims by third parties. From a risk-allocation perspective, this arrangement makes sense because the patent owner is likely to be more aware of the activities of competing third parties that are developing similar technologies, and thus, the patent owner is in a better position to know of potentially overlapping patent rights.

However, obtaining indemnification from the licensing patent owner is usually difficult. The best way to prepare for indemnification negotiations is to properly assess the level of risk posed by the patent landscape. The more the license user knows about the potential threat of third-party patents, the more leverage the license user will have in negotiations[84].

5.7. Licensing schemes

Licensing of —building block nanotechnology patents is another plausible solution to the patent thicket problem because licenses can be very diverse in their implementation. Licenses can be either exclusive or non-exclusive. An exclusive license agreement allows only one entity to license the patent or invention. [85]
A company looking to exclusively license —building block patented technology will tend to —generate more lucrative business opportunities and higher revenues, since the exclusivity of the license allows it to directly benefit from any future commercialization of products derived from the exclusive license. On the other hand, a non-exclusive license allows for multiple companies to use the licensed technology, thus increasing competition. [85] of a non-exclusive license is that it has lower licensing and royalty fees, which results in the final cost of the product to the consumer being lower.[85]

In addition, licenses can be restrictive in terms of geographic location, or —field-of-use,[86] meaning the licensee can only practice the licensed IP in certain applications (i.e., therapeutic applications, veterinary applications, etc.).[85]

Once a licensee has been granted a license, it may freely practice the patent without the repercussions of infringement.[86]

Cross-licensing occurs between two or more parties with symmetrical interests: a firm needs its competitor’s patent just as badly as its competitor needs its patent.[3]

Cross-licensing has been used with limited success. For example, the semiconductor industry has experienced success with cross-licensing because it consists primarily of a limited number of firms that produce similar products and hold similar IP portfolios.[69]

Critics contend that competing firms tend to use cross-licensing to limit competition and avoid litigation, which directly harms public interest by reducing the amount of competition in the marketplace.[87]

Some of the anticompetitive effects from cross-licensing include artificially inflated prices, reduction in output to simulate characteristics of a monopoly market or a collusive duopoly market, and a reduction in innovation of that particular technology.[88]

However, each of these anticompetitive effects can be managed to mitigate antitrust proclivities. Furthermore, the potential for larger firms to collude in efforts to muscle out smaller firms is ever present: larger firms could create economic barriers to entry in nanotechnology. One barrier to entry would involve larger firms initiating hold-ups of smaller firms.[89-90]

Larger firms could also practice double marginalization,[91] where two firms (or two divisions of the same firm) both mark up their license price above their own costs—passing those costs on to the small firm licensees. Another barrier is the prohibitively high transaction costs that arise once more than two parties are involved in the cross-licensing.[45]

The overall problem with cross-licensing in thenanotechnology patent thicket is that—the inefficiencies stifle the ability of innovators to use necessary scientific techniques and tools in order to continue researching and developing nanoproducts[92].

Collaboration by nanotechnology patent owners through patent pools or cross-licensing may be the most effective way to cut through the nanotechnology patent thicket. Cross-licensing is the mutual sharing of patents between patent holders that grant each the right to practice the other’s patents, which may range from as few as two patents (one from each of the parties) to an entire portfolio of patents. Cross-licensing is the preferred means by which competing companies clear blocking patent positions among themselves, and often, these cross-licenses involve no running royalties. But again, due to the multidisciplinary nature of nanotechnology, the relevant patent holders may not be competitors in the medical device industry and, therefore, may have little interest in exchanging patents with a device company. As such, cross-licensing may not be the best strategy for device firms to resolve patent disputes in nanotechnology.

Patent pools are another form of cooperation among different patent owners. Pools are particularly useful when there are many different players. In a patent pool, two or more patent owners combine their patents into a pool to establish a clearinghouse for related patents, which can then be licensed as a package. A patent pool can potentially have all the patents required to practice a particular technology. Therefore, an effective patent pool can provide the convenience of one-stop shopping for potential license users and prevent manufacturers from licensing a subset of patent rights that are useless without other complementary rights.

For medical device companies, patent pools may be the most attractive option for avoiding the high cost of the fragmented and confusing nanotechnology patent landscape. However, creating a successful pool takes considerable effort and cooperation among multiple parties. Parties must agree on the many aspects of how the patent pool will work, such as the relative value of each patent contributed, the identification of essential patents, and the formula for distributing the royalty dividends. They must also agree on the overall royalty rate, along with the other terms under which the pool will be licensed to interested parties.

It remains to be seen whether licensing managers at the universities and companies that hold key nanotechnology patents would be willing to forgo unilateral licensing efforts and engage in patent pools instead[84].

5.9. Commons

A proper solution to the nanotechnology —building block‖ patent thicket problem should dissolve the barriers preventing further research, development, and potential commercialization of nanotechnology. One method for untangling the patent thicket involves implementing a commons. Scientific and technological commons are socially driven efforts to achieve cooperation among various parties, where no individual party exercises exclusive IP rights on the science or technologies in question.[93]

One scholar advocates that scientific and technological commons are the ideal mechanism for untangling the nanotechnology —building block‖ patent thicket, because a commons-based strategy protects foundational research tools and manufacturing processes from individual ownership and grants broad access to technologies that are incorporated in the commons.[94]
Commons are designed to be pools of —building block‖ technology or science that are free for anyone to use; that is, no one directly receives monetary compensation when a —building block‖ technology is used by another.[93]

While commons-based strategies have worked in developing other areas of modern science, such as open source code for the development of free software,[93] in the case of nanotechnology, implementation of a commons would be problematic for several reasons. First, a plethora of —building block‖ nanotechnology patents already exists. [32]

Second, a large portion of nanotechnology —building block‖ patents have issued to research labs, such as universities, which work exclusively in research and development of scientific foundations.[32] Universities hold a disproportionate share of nanotechnology-related patents: universities hold almost 12% of all nanotechnology patents, where normally universities only hold 1% of all patents in general.[3]

Implementation of a commons-based solution to the patent thicket problem would cause universities and research entities to suffer an economic disadvantage compared to corporations because other than exercising the IP licensing of their work, these entities lack a means to capitalize on their discoveries. Corporate entities, on the other hand, are in the business of commercializing their products to generate capital [3].

and need not rely on income resulting from the licensing of IP. Mackey contends that implementing a commons will not cause universities too much financial hardship because they have many other ways to market themselves.[94]

While the income generated from IP held by universities only amounts to approximately 3–5% of a university's total budget at best,[85] implementing a nanotechnology —building block‖ commons now would have a larger impact on universities than just causing a hiccup in their finances. Imposing a commons would unfairly strip universities of their nanotechnology IP and would dislodge the competitive nature of scholastic achievement and vision. It also seems that universities that develop foundational research techniques in nanotechnology and obtain patents on such techniques have a propensity to continue that research in efforts to obtain new IP rights for the innovations that result from furthering their research. [95]

If the monetary incentive ascribed to patenting technology is removed from the equation, universities would lose motivation to continue innovating. 2. Infringement litigation
 Naturally, patent litigation is another approach for steering through the nanotechnology patent thicket. In patent infringement litigation, a patent owner seeks monetary damages, injunctive relief, or both against further infringement. [96]

Once nanotechnology evolves into a financially lucrative endeavor, patent litigation will be a useful tool for assessing who actually owns what intellectual property. Presently, however, the costliness of patent litigation is a deterrent from this course of action.[97]

Fear of litigation discourages competition. Lawsuits can either make or break competitors, particularly in cases of broadly claimed or fundamental IP.[88] The outcome of a suit could
determine whether a firm will be able to continue in the business, because its competitor will be out of business.[88]

5.10. VERTICAL INTEGRATION

One way downstream product manufacturing companies can avoid the need to negotiate licenses with upstream manufacturers is to simply buy the upstream research company that controls the patents the downstream company needs.[3]

Not only does this alleviate the possibility of infringement, but it may also put the downstream company in a more symmetrical position with firms both upstream and downstream from it if it acquires patents that may be valuable.[3]

But it is unlikely that start-ups attempting to develop a product have the resources necessary to purchase upstream research houses. If, however, vertical integration became something of a trend in nanotechnology, it would have the benefit of consolidating patent rights to fewer rights holders, thus helping to clear the patent thicket and —reduce[] the risk of holdup.||[3]

But this may not always be possible, since it is often universities that hold the upstream patents, and they are not capable of vertically integrating with market participants.[3]

But often times the inventors of a patent arising from university research will found a company and will negotiate for the patent to be licensed to the inventors to further develop the technology for commercialization.[34]

In a similar vein, it seems that the National Science Foundation promotes the approach of creating partnerships at the upstream level between universities and the private sector.[98] Furthermore, at the rate that universities seem to be offering exclusive licenses, partnerships may have an effect similar to vertical integration if these start-ups are able to truly develop the technology for commercialization.

Vertical integration can also implicate antitrust, as consolidating companies that are in the same field of endeavor can lead to decreased competition by promoting a monopoly. This is precisely the thought behind the Department of Justice’s innovation market theory. Under the theory, —a merger of two companies whose sole aspect of competition was in the same field of scientific research could be blocked in order to prevent the advancements produced by such research to be owned by one entity.[||[29] More recently, however, the Department of Justice has demonstrated that it will not necessarily block a merger of companies that are still in the early stage of research.[29] Though, if the Department of Justice were to allow vertical integration as described above, consolidating upstream and downstream companies, it would not just include companies engaged in early stage research. Indeed, given that the NNI seeks to ensure that nanotechnology is spread across many companies, this goal would not be served if large corporations were able to simply buy up the foundational intellectual property.[29]

Thus, vertical integration may not be able to escape antitrust scrutiny if the desire is to consolidate intellectual property both up and downstream.
5.11. REEXAMINATION AND PATENT VALIDITY

As mentioned above, one way to help cure the holdup problem is to allow possible infringers the ability to challenge the validity of a patent. [86]

The USPTO and the patent laws allow for a limited challenge through the reexamination administrative hearing.[98] The reexamination proceeding allows anyone to challenge the validity of a patent by offering a prior art reference of either a previous patent or printed publication.

[99] The inter partes reexamination provides a number of features that make it an attractive tool for patent infringement defendants, including the following:

beginning a reexamination proceeding will stay a patent litigation until conclusion of the reexamination; the USPTO will apply the broadest possible claim construction during reexamination; the patent owner is under a duty to disclose any information material to the patentability of any claim; the lack of discovery, usually an expensive ordeal in litigation;

review of the patent claims by an expert in the field that was not the original patent examiner; and a claim cancelled as the result of a reexamination may not be enforced in any subsequent patent litigation.[99]

Reexamination may be a viable solution for many of the early nanotechnology patents. Carbon nanotubes are the materials typically discussed when it comes to their not being patentable over prior art that was in existence when the first nanotube patents were filed. There seem to be numerous articles and some patents that seem directed at carbon nanotubes.[100]

One such article was even part of the examination of one of the early carbon nanotube patents, but the examiner accepted a nonfactual argument from the patent prosecutor to overcome his anticipation rejection.[101]

To some degree, the doctrine of inherency should help an argument of anticipation in a reexamination.[100]

These arguments of anticipation should be raised again with the USPTO now that the office has had more experience with nanotechnology patents. As much of the literature focuses on carbon nanotubes, however, it may be that such a reexamination to invalidate nanotechnology patents is in fact limited to the nanotube sector. But while reexamination may not lead to the invalidation of many nanotechnology patents, its usefulness as litigation tool should not go overlooked. While the reexamination proceeding is limited to a reexamination based on prior art, a patent may still be found invalid through full litigation. There are numerous ways in which nanotechnology patents could be found invalid. [100]

Indeed, at least one commentator has suggested that the industry could expend some resources to show that carbon nanotubes are inherent in the prior art processes.

Such a discussion of nanotechnology patent validity is beyond the scope of this Note, but it should be recognized as a way, albeit an expensive one, in which nanotechnology patents can be reviewed for validity.
5.12. Judicial Action

The validity of overly broad claims may ultimately be litigated. When these claims are wielded as monopolistic tools to prevent downstream development, courts should utilize legal tools to narrow their scope. For example, when reviewing claims to carbon nanotubes or semiconductor nanocrystals, courts could limit claims to cover the nanomaterials produced using the methods described in the patents. The enablement doctrine can be used to narrow the scope of claims.

Government Intervention to Facilitate Licensing. Preparing for effective review of future nanotechnology applications might alleviate some future mistakes and confusion. Litigation may even result in the narrowing of the overly broad patents on nanostructures. However, the large number of patents on the tools needed to produce downstream products will continue to plague the burgeoning industry. Mechanisms to combat the tragedy of the anticommons should be explored.

5.13. PATENT EXPIRATION

Because early nanotechnology was so heavily patented, it is possible that many of the upstream foundational patents will expire before commercial products based on them become viable. Indeed, because universities do early stage research, they patent inventions that are far from commercialization; they may therefore actually speed the entry of some inventions into the public domain by obtaining patents that expire earlier.[3]

For example, of the three most commonly cited carbon nanotube patents, the earliest will expire in the year 2013 and the latest in 2019.[100-101]

Because each of these are composition of matter claims, any downstream product or process incorporating carbon nanotubes falling under their claims will be infringing, absent a license.[100-101]

But once these patents expire, anyone may use carbon nanotubes without fearing infringement litigation. But near term products that can be developed now, such as field emitting devices, incorporate carbon nanotubes.

Thus, firms will still have to negotiate licenses to continue developing these products now to ensure they will not be sued for infringement. And depending on their business model, if they are synthesizing their own carbon nanotubes, they will still need to secure licenses for nanotube process patents. Furthermore, carbon nanotubes are but one sector in the broad nanotechnology landscape, and have arguably been known to the scientific community since the 1970s.[100]

Newer developing nanotechnologies will likely not be able to rely on patent expiration as the carbon nanotube sector may be able to do.

5.14. Government Intervention

Preparing for effective review of future nanotechnology applications might alleviate some future mistakes and confusion. Litigation may even result in the narrowing of the overly broad patents on nanostructures. However, the large number of patents on the tools...
needed to produce downstream products will continue to plague the burgeoning industry. Mechanisms to combat the tragedy of the anticommons should be explored.

5.15. Compulsory Licensing

Some commentators have proposed compulsory licensing as a solution to the problems of “blocking patents” in gene patents and business method patents.[102] Despite academic support, the courts and legislature have generally resisted compulsory licensing.[103] The absolute right of the patent owner to refuse to license an invention is statutorily protected: “no patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having... refused to license or use any rights to the patent....”[104] The only two statutory compulsory licensing provisions are for inventions related to atomic energy[103] and air pollution control.[105]

Courts have held patents unenforceable when the patent was obtained fraud-ulently, the litigation was a sham, or there was an illegal tying arrangement.[106]

The resistance to compulsory licensing is well grounded and should be continued in the context of nanotechnology patents. A compulsory licensing scheme would stifle innovation and investment in nanotechnology.[107]

Because of the high risks and development costs associated with developing downstream products, companies need patent protection. Venture capitalists would be much more hesitant to invest in start-ups if they perceived that government could shatter the patent barriers that protect their investments. Further, compulsory licensing could decrease public disclosure of technological progress. Companies would be more likely to rely on trade secrets to protect their inventions instead of patents. Since trade secrets are hidden, it is arguable that they slow technology development.

5.16. Government Encouragement of Patent Pools

Patent pools on the building blocks of nanotechnology could facilitate timely development of downstream products. Such pools would be limited to complementary technologies and would remain open to future licensees. An example of a useful pool would be a pool on the patents covering the chemical vapor deposition process for producing carbon nanotubes. Pools would eliminate the need for future firms to conclude separate licensing agreements with a number of different entities.[108]

Moreover, the constant threat of litigating access to royalties after a downstream product has been developed would be eliminated.[108] Patent pools can reduce or eliminate the need for litigation over patent rights because such disputes can be easily settled, or avoided, through the creation of a patent pool. A reduction in patent litigation would save business time and money, and also avoid the uncertainty of patent rights caused by litigation. Start-up companies could devote substantially fewer resources to licensing transactions and would be more likely to receive financing. The increased commercial development would also generate increased royalties for patent holders. Additionally, reducing transaction costs of licensing would increase the amounts that license seekers are willing to pay for patents. “[P]atent pools can eliminate the problems associated with blocking patents or stacking
licenses in the field of biotechnology, while at the same time encouraging the cooperative efforts needed to realize the true economic and social benefits of genomic inventions.”[108]

but, such pools are unlikely to arise on their own. The patents on upstream processes and tools are held by universities, start-ups, and large corporations. The divergent goals, size disparities, and business models between the relevant patent holders doom private efforts to establish pooling arrangements. Nevertheless, government might consider encouraging formation of such pools in nanotechnology. Public intervention has been responsible for the formation of successful pools in the automobile, aircraft, and synthetic rubber industries.

Government-sponsored patent pools might be more acceptable to industry than privately sponsored pools for three reasons. First, government-sponsored patent pools would reduce the legal uncertainties associated with pooling arrangements. Patent pools often raise antitrust concerns.[108]

Patent pools have been criticized as being anticompetitive for several reasons. First, the pooling of such patents creates a barrier to competitive alternatives to the technology. This argument is based on the assumption that while certain patents may be considered to be legally blocking, such patents actually cover competitive alternatives to a certain technology, and that the pooling of these patents will expand monopoly pricing. [109]

Second, because pools shield invalid patents, they force the public to pay royalties on technology that would become part of the public domain if there was litigation. [109] Third, pools encourage collusion and price fixing. [109] Due to these concerns, patent pools must pass administrative and judicial antitrust scrutiny.

As said above, indeed, one of the primary obstacles to the formation of patent pools is the risk that such pools will be struck down by antitrust authorities. Pools designed by the committee of technology officers could be reviewed and approved by the Department of Justice in advance to resolve any antitrust concerns. As one scholar maintains, government-encouraged patent pools “give the government a chance to prevent the most egregious misuses of pooling arrangements.”[110]

Second, government involvement could provide the catalyst necessary to form the pools. A free-rider problem plagues the establishment of a pool involving numerous patent holders. No single party has an incentive to expend resources in jump-starting the effort when the group as a whole

benefits. Public assistance in designing, coordinating, and implementing the pools might serve as a “visible hand [to help] overcome the collective action problem inherent in group bargaining.”[110]

Third, government might be able to leverage its funding commitments to entice participation. The federal government directly funds most of the basic research at universities. Grants are also available for start-up companies, and large corporations even benefit from government aid. Further, there will be an array of lucrative government contracts to develop products. The government could potentially utilize these financial carrots to encourage parties to participate in pooling arrangements.[110]
We are not, however, optimistic that government can facilitate the emergence of comprehensive pools on the building blocks of nanotechnology. First, government pressure is unlikely to overcome the strong disincentive for participation by companies that wish to use their patents as competitive weapons. As explained earlier, the fragmented intellectual property landscape can be advantageous for large firms vis-à-vis smaller competitors. Second, even if all of the players would be willing to participate, there are complicated problems associated with establishing such pools. For example, it is extremely difficult to establish a fair pricing mechanism for the pool of intellectual property. Different licensees may need to license different bundles of intellectual property from the pool. Thus, the entity administering the pool may have to continually determine values of different patents in different packages. Patent holders are certain to disagree on the relative importance of their intellectual property in different packages. Patent holders tend to overvalue their patents and may ultimately conclude that they can extract greater royalties from refraining from participation in the pool. Further, there are complications associated with attempting to include overlapping patents in the packages. Determining which patents are valid and how patents that may be invalid should be priced could give rise to intractable conflicts between patent holders. Finally, government intervention has only succeeded in the past as a result of threatened compulsory licensing.[110]

Stopping short of compulsory licensing, government efforts to establish pooling arrangements may be thwarted by the same coordination and collective action difficulties that preclude the emergence of pools through the market. As such, innovative solutions to the fragmentation of the intellectual property landscape are needed.[34]

5.17. Advanced Market Commitments

Advanced market commitments are a pull incentive that increase innovation and reduce costs for end users. Advanced market commitments (AMCs) have a variety of names including advanced purchase commitments, global purchase funds, and advance price or purchase commitments (APPCs). They work to ensure that a market will be available in the future so that companies perform research for innovation. To achieve this, donors such as the government or private foundations commit to purchasing a specific quantity of a product such as medicine when it is developed. Costs are lower for end users because since there is a specified large enough market, manufacturing will cost less. In addition, after development AMC funders “could then make the product available to developing countries at no cost, or in exchange for modest co-payments” [111].

There have been few real world examples of AMCs at the time of this paper. One of the first AMCs was created by the United Kingdom to solicit a vaccine for meningitis C. in the 1990s. The United Kingdom ended up buying products from three pharmaceutical companies who each won part of the fund offered [112]. Currently, the most well-known ongoing AMC is the GAVI AMC. The goal of this AMC was to develop a pneumococcal vaccine, and the AMC was launched in 2007 when seven donors (the governments of Italy, the United Kingdom, Canada, the Russian Federation, Norway and the Bill & Melinda Gates Foundation) pledged $1.5 billion to the fund. The GAVI AMC began distributing the first vaccines created and commercialized through the program in December 2010. Since then, more donors have committed money to the fund and more developing countries have applied to receive financial assistance for the vaccination products [113]. Potential AMCs are
also being considered by the UK government for promoting low carbon technologies in developing countries. In 2010, more than 100 delegates from prominent NGOs, developing country governments, private sector investors, and others met to develop more concrete goals for AMCs relating to low carbon development. Like the successful AMC for vaccines, David Wheeler from the Center for Global Development (CGD) states that low carbon technology is comparable to vaccines in the following three ways: proven technology, potential scalability, and investor uncertainty (market failure) [113].

5.18. Cost Reducing Measures

Tiered (Differential) Pricing

One proposed solution for lowering costs to users is tiered, or differential, pricing. Tiered pricing is also called price discrimination and price segmentation. Tiered pricing works by companies “charging low prices in low income markets and high prices in high income markets” as opposed to a uniform price worldwide (Commission on Intellectual Property Rights). Theoretically, this should actually add to companies’ revenues because they reach more customers at appropriate price points. There are several examples of tiered pricing already in use.

One such example is the Aravind Eye Care System in India. Aravind is the “largest provider of ophthalmological services in the world,” as they perform nearly 350,000 eye operations every year, “60% of them delivered at low or no cost.” Differential pricing allows users who are able to pay full price for the operation to subsidize the operation for three or four others (McKinsey, Eye Care). While this is a service, Aravind also manufactures its own intraocular lenses for the cataract surgeries [114]. Aravind is a self-sustaining charitable business because of differential pricing. Many examples of differential pricing currently or previously in use are tiered pricing schemes for pharmaceuticals. ARVs, anti-retroviral drugs, are one of the most differentially priced pharmaceuticals. Since 2000, there has been either a two tier or three tier pricing scheme for ARVs by some pharmaceutical corporations. Some of the considerations for eligibility for discounted pharmaceuticals are a “country’s income level, geographic location ([e.g.] Sub-Saharan Africa) and the prevalence of HIV infection” [115]. While there are many factors, ARV usage is up according to a UNAIDS report from July 18, 2012. In Sub-Saharan Africa specifically, “where 69 percent of people with HIV live, the number on therapy jumped to 6.2 million from 100,000 in 2003”[116]. A final example is that of David Green’s Aurolab. In addition to a variety of other medical products, Aurolab will manufacture and sell low-cost, high-quality hearing aids. Aurolab will sell these hearing aids at different prices in different countries based on typical incomes. Revenue generated from the higher income countries will subsidize hearing aids that will be priced lower in the least developed countries [117].

While this is primarily a solution for the private sector, there are policy issues that must be addressed. One problem caused by differential pricing is parallel importing. According to the World Health Organization, parallel imports are “imports of a patented or trademarked product from a country where it is already marketed” (World Health Organization).
Companies who price products on a tiered scheme are at risk of lower-priced product making its way from developing countries to developed countries with no additional revenue for the company. There are some private sectors solutions that can address this problem. For example, Aurolab’s hearing aid “will be factory-programmed to be configured and controlled by proprietary software that is unique to each country” “to prevent third parties from buying the subsidized hearing aids in one country and re-selling them in another country at a profit” [117]. Still, governmental policy must address concerns with import/exports for this model to be effective, as one of the main reasons differential pricing is not utilized more widely is industry’s worry of profit erosion in higher income country markets [115]. Regarding medicine, the Commission on Intellectual Property Rights from London in 2002 advocates, “Developed countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries.” Some countries already have strict mechanisms to prevent parallel imports, but others such as Japan do not (Commission on Intellectual Property Rights).

Another possible detriment to a tiered pricing scheme is that it may reduce incentive to innovate for developing countries. Barton and Emanuel specifically state this for the pharmaceutical industry, although it could apply to multiple industries. This would occur if companies were unable to break even by selling a full priced product to cover any losses from lower prices in developing countries. Indeed, while differential pricing is theoretically appealing, many companies are worried about differential pricing cutting into their profit margins. This can be remedied by a company’s economic analysis of supply and demand to ensure that enough revenue is made from higher income countries to support lower income countries. Finally, differential pricing may cause tension between higher and lower income countries as consumers learn the real cost of production for some products [118]. It is important for governments not to participate in external referencing “(where countries compare the prices for new products against those prices paid by other countries within the geographical region or income class)” [115]. This is especially necessary relating to pharmaceuticals where governments help set prices for these products. As such, governments need to be transparent about the need for higher income countries to support necessary products for lower income countries.

5.19. Humanitarian Licensing

A method for lowering costs to end users in developing countries that is gaining strength is licensing products for humanitarian use. Many colleges are at the forefront of this movement as they try to increase technical transfer to developing countries. According to AAAS, “A humanitarian license reservation is a provision in a license whereby inventors and technology suppliers protect in advance the possibility of sharing their proprietary technology with third parties for the benefit of people in need.” Primarily, humanitarian licensing has been done by private corporations and universities. However, US policy could impact the lives of developed countries greatly by expanding humanitarian licensing. Some advocate a humanitarian use exemption (HUE) to be built into many licenses of patented products. AAAS has written about an HUE which “would provide an exemption for use of a particular IP product in developing countries while protecting that IP in wealthier countries.” Specifically, some can argue it makes sense to apply a mandatory HUE to products that have
received federal funding which are already able to receive intellectual property protection under Bayh-Dole. There are a number of considerations to be made when constructing a humanitarian use exemption. Examples of considerations that need to be made are geographical (where will the license be in effect), market-based (with specific guidelines for customers with different incomes), and timing (instead of allowing the license to exist forever, it could only exist for limited times and with the greatest need) (AAAS).

Technological solutions are part of an important portfolio for improving the daily lives of those living in developing countries. While the majority of the world does not enjoy a developed country standard of living, the private sector currently lacks incentive to innovate essential technologies. A lack of essential technologies and products with too high of a price point lead to a market failure that the US government can help address. Currently underused pull mechanisms such as prizes and advanced market commitments can increase innovation when used properly. In addition, developing country citizens can gain access to essential technologies with cost lowering mechanisms such as differential pricing and voluntary humanitarian licensing. US policy should expand and aid these four initiatives, closely monitor their efficiency, and possibly increase their use in the future[119].

6. TRIPS Agreement: Origin, Scope, and Patent-Related Clauses

The link between IPRs and trade did not start, as contrary to the opinion of many scholars, at the time of Uruguay Round. In fact, as a compilation of previous multilateral conventions on the matter, The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has not appeared out of a vacuum, it is the culmination of a long maturation of which the root goes a long way back, notably to the General Agreement on Tariffs and Trade (GATT) of 1947, the Berne Convention for the Protection of Literary and Artistic Works of 1886 and the Paris Convention for the Protection of Industrial Property of 1883.

Before the creation of the WTO, multilateral rule-making in the IPRs area was dominated by the WIPO, which administers or co-administers practically all the important conventions in the field. Two factors help to explain why U.S. and European officials chose the multilateral trade negotiations as the forum rather than WIPO.[120] First, WIPO, being a United Nations agency, gives developing countries a strong voice. This is problematic since many of these countries were opposing stronger patent disciplines. By contrast, the General Agreement on Tariffs and Trade (GATT) was a much smaller organization largely dominated at the time by United States and the European Economic Community. Another reason that trade institutions were used to strengthen IPRs is that the powerful dispute settlement mechanism equipped by the WTO will guarantee the effective implementation of TRIPS through, if necessary, cross-sectoral trade sanctions, which is regarded as the biggest advantage enjoyed by TRIPS Agreement over WIPO-administered Conventions.

At the outset of the Uruguay Round, fundamental divergences existed between industrialized counties, which wished to achieve a comprehensive coverage of all IPRs, and DCs and LDCs, which wanted to limit the scope to a code against trade in counterfeit goods.[121] The consequence was that practically all existing IPRs were included in TRIPS.
The TRIPS Agreement consist of the Preamble and Parts I to VII containing seventy-three Articles. In the Preamble, Members recognize that intellectual property rights are private right. Part I of the TRIPS Agreement (Article 1 to 8) contains general provisions and basic principles. Article 1(1) states that the provisions of the TRIPS Agreement set minimum standards for the protection of intellectual property rights, and Article 3 and 4 extend the principles of national treatment and most favored-nation treatment, respectively, to the protection of intellectual property rights.

Part II of the TRIPS Agreement (Article 9 to 40) sets standards regarding the availability, scope, and use, of intellectual property rights. It requires Members to implement in their national laws provisions regarding copyrights and related rights (Article 9 to 14), trademarks (Article 15 to 21), geographical indications (Articles 22 to 24), industrial designs (Articles 25 to 26), patent (Article 27 to 34), layout designs (topographies) of Integrated Circuits (Articles 35 to 38), undisclosed information (Article 39), and the control of anti-competitive practices in contractual licenses (Article 40). Part III of the TRIPS Agreement (Articles 41 to 61) specifies the enforcement of intellectual property rights. Part VI (Articles 65 to 67) contains transitional arrangements, and Part VII (Article 68 to 73) institutional arrangements and final provisions.

The patent section of the TRIPS Agreement was one of the most difficult to negotiate. It involved a number of key North-North as well as North-South issues. [122] The result is impressive, in that the scope and coverage of the Section are comprehensive. The Agreement has nine major provisions regarding patents. First, it requires parties to comply with the Paris Convention. Second, it requires parties to provide national treatment with respect to patent protection. Third, it requires that parties make patents available “in all fields of technology”. Fourth, it requires that patent rights be “enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced”. Fifth, it establishes disciplines for governments that engage in compulsory licensing. Sixth, it requires that the term of patent protection shall not end before a period of twenty years from the filing date. Seventh, it mandates national enforcement of private patent rights. Eighth, it provides a robust dispute settlement process. Ninth, it allows developing countries to delay implementation of certain provisions. With respect to provisions three to seven above, it should be emphasized that these requirements do not exist in the Paris Convention.

6.1. Nanotechnological Inventions and IPRs: Appraisal on TRIPS Agreement Art.27

The patent system provides technology-neutral protection for all kinds of technologies in all possible fields of technology. Article 27(1) of the TRIPS Agreement defines the patentable subject matter under the Agreement.

It States that:“( _) patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (_, _) patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.” [33]
Accordingly, should the patent application satisfy the criteria of novelty, inventive step (or non-obviousness within the US), utility and public disclosure (Article 29), members of the WTO are prohibited from discrimination against bionanotechnology from patent protection under their domestic law. Where bionanotechnology inventions fulfill the requirements of Article 27, protection must be provided by all WTO members for a minimum period of twenty years from the filing date (Article 33), thereby providing the patentee with a bundle of exclusive rights within that country.[123]

Importantly however, not all bionanotechnology applications may be protected by patent grants. As provided for by Article 27(1), patents shall be available for any invention and not mere discoveries. When considering the range of bionanotechnology products that may be patentable under the current international framework, distinctions will need to be drawn between inventions and discoveries, products and processes. While the TRIPS Agreement fails to provide a definition of ‘invention’, it would appear that Article 27(1) is an attempt to discriminate between rapidly blurring distinctions of ‘inventions’ and ‘discoveries.’ As compounds are naturally occurring, Article 27(1) technically prohibits the patenting of the compounds themselves. Article 27(1) does enable however that a requisite inventive step be deemed to belong to the process of creation, rather than the creation itself. [124]

The development of cutting edge technologies including nanotechnology has resulted in a blurring of the interface that previously existed between discoveries and inventions. [82] The blurring of this distinction can be best illustrated by examining the patentability debate of ‘patents on life’ within the bionanotechnology industry. In a critique of nanotechnology patents under the framework of the TRIPS Agreement and the EC Biotechnology Directive (1998), it has been argued that the indeterminate wording of the Agreements provides scientists and potential patentees with too much flexibility in what they can and cannot patent.[125]

Classes of patents based on mere discovery have become ‘patentable’ despite failing to fulfill the ‘invention’ criteria. [125]

These include the discovery of human cells such as umbilical cord cells, plant genes including rice genome sequencing and therapeutic cloning and stem cell isolation procedures. This argument lends itself to the interpretation that the processes leading to such ‘discoveries’ fall outside the spirit of the TRIPS Agreement, and should not be patentable. In contrast, reflecting on developments within the bionanotechnology industry, it is possible to conclude that technological changes have resulted in a broadening of the scope of international patent law and a blurring of the invention/discovery interface. The Etc Group contend that ‘breathtakingly broad nanotech patents are being granted that span multiple industry sectors and include sweeping claims on entire classes of the Periodic Table.[126]

With the advent of second and third generation nanotechnology (bionanotechnology), the Etc Group suggests that the ability to patent basic nanoscale materials ‘could mean monopolizing the basic elements that make life possible.[127] This paper contends that a wide interpretation of Article 27(1) may result in the monopolization of fundamental molecules and compounds.

**6.2. PATENTABILITY EXCLUSIONS IN NANOTECHNOLOGY**
Patent law excludes from patentability any object that cannot be considered an invention. The protection of the public interest, i.e., general values and interests of the community, is one of the traditional functions of the state.\[128\] Thus States have the sovereign right to protect the public interest, such underlines all legislative activity and patent law is not an exception to this general principle. The TRIPS agreement has excluded certain inventions from Agreement provides that “members may exclude from patentability any invention, which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.” These exceptions are in nature different from subject matters excluded from patentability that they don’t fulfill patentability criteria. Exceptions to patentability concern inventions who may fulfill all patentability criteria (novelty, inventive step, industrial application) and still cannot be granted patent protection since those inventions should not be subject to commercial exploitation, while the former relates to subject matter that due to its nature (or lack of technical nature) cannot be the object of a patent right. The notions of order public (public order), and morality are not defined in the agreement. However, it is clear that those inventions that cause injury to human, animal and plant life as well as the environment are excluded. Member countries are given flexibility to adjudicate such matters. Some countries may still provide patent protection for inventions that cause damage to the environment. [127] Patenting of genetically engineered organisms and life forms is generally possible under these provisions. Further, it is also possible for a state to provide patent protection to a gene or a whole organism. [129] Some decisions by the European Patent Office (EPO) show that the effects of an invention on the environment may constitute a valid ground for denying patentability. However, the EPO refused to assume a regulatory role on the introduction of genetic engineering inventions. In dealing with this issue, one of the opposition decisions argued that: “A patent does not give a positive right to its proprietor to use the invention but rather only confers the right to exclude others from using the invention for a limited period of time. If the legislator is of the opinion that certain technical knowledge should be used under limited conditions only it is up to him to enact appropriate legislation.”[130] As noted by Moufang, patent examiners “are not specifically trained in ethics or in risk assessment.” Since patents do not give a positive right to use the protected inventions, other bodies have to shoulder the responsibility for the decisions of society whether certain technology can and should be put into practice.”[131]

The last sentence of Article 27.2 establishes that the sole fact that the exploitation is prohibited by law is not sufficient reason to exclude patentability. This is in line with Article 4 quater of the Paris Convention, which contains a rule equivalent, though not identical, to the provision contained in the last part of Article 27.2: it stipulates that the grant of a patent shall not be refused (or the registration of a patent not be invalidated) for the sole reason that the sale of the patented product is restricted or limited under domestic law. Thus, mere marketing restrictions as such cannot justify exclusions from patentability. There has to be a specific link between the commercial exploitation of the patent and the respective
Member’s order public or morality: Article 27.2 requires that this commercial exploitation would represent a particular danger to either order public or morality. The approach expressed in Article 27.2 was retained in post-TRIPS developments in Europe, and can be found in many other national laws. For example, The 1998 European Directive on Biotechnological Inventions contains a provision (Article 9) similar to Article 53 of the European Patent Convention. The European Directive on Biological Inventions, similarly, provides that the human body and its elements in their natural state shall not be considered patentable inventions.

However, patents over human genes or cell lines have been granted as a matter of routine by the EPO, whose Opposition Division has not found any reasons why the patenting of human genes should be intrinsically unethical. [131]

One important point to be considered is the extent to which the role of a patent office in judging and eventually denying a patent on the basis of moral or public order grounds may be sufficient to prevent the harmful effects from taking place. Given the limited competence of a patent office, non-patentability would only ensure that an invention is not the subject of property rights, but by no means would this be sufficient to prevent the use of the invention by any interested person, since it would remain in the public domain. Paragraph 3 of article 27 of TRIPS Agreement, establishes the possibility for Members to exclude from patentability:

“Members may also exclude from patentability (a) diagnostic, therapeutic and surgical methods for the treatment of human or animals, (b) plants and animal other than microorganism, and essentially biological processes for the production of plants and animals other than non-biological and micro-biological processes.”

These provisions are similar to the provisions provided under the European Patent Convention (EPC). [123]

Article27 (3) clearly establishes the obligation for Members to protect plant varieties; however, each Member can establish on its own national legislation the way to grant such protection, in accordance with the possibilities established on the Agreement (protection for patents, an efficient sui generis system or a combinations of that and this). The UPOV system of plant variety protection is one form of efficient sui generis protection.

Although certain kinds of inventions have been excluded from the patentability but patenting of microorganisms (nanomicroorganisms) and non-biological processes is allowed in TRIPS. Therefore, in other words, microorganisms (nanomicroorganisms) per se, process of their production and process of their use are made patentable,TRIPS agreement however, neither defines the term “microorganism” nor does it specify any parameters concerning the scope of protection to microorganism such as microorganism per se, whether found in nature or created artificially such as genetically modified organism (GMO) etc. However, the EC directives on microorganisms define it as “any micro biological entity, cellular or noncellular, capable of replication or transferring genetic material. [127]

7. Conclusion

In knowledge based society IPRs plays the role as the engine to develop the socio-economical condition of a country. Nanotechnology could be the beginning of an economic
and technological revolution. The ability to manipulate materials at the nanoscale and exploit their nanoscale properties will allow various industries to make advances that were not possible before. Nanotechnology is a newly growing technology sector that consists of several different branches of science and having an enormous amount of potentiality to be used in products covering from biologics, automobiles, IT, polymers, healthcare and electronics to energy etc. The diversity of Nanotechnology is one of the great strengths that there is a huge possibility of application in the many different areas, for example nano-biotechnology to nano-materials and also increases the possibility to produce more commercially benefitted products. It is sure that in the foreseeable future nanotechnology will be the largest sector of economic growth in the knowledge based society because of its application in the variety of field, from military projects to clothing sector. To get the proper benefit of research in the any field of technology including nanotechnology, patent claim is one of the vital means to secure inventors' rights.

In case of patent, although as other field of technology same patent rules, regulation and procedures are followed in the nanotechnology related inventions but it's true that new technology creates new patentability problems. Nanotechnology covers a multiple field of technology. It is quite normal that no one can expert in multiple field of technology at the same time, thus at time of patentability examination, it is very difficult for the examiner to examine the different criteria and step of patentability so accurately. Especially to examine the novelty and inventive steps are crucial for examiner. Segmented patent rights and broad claims have created a patent thicket that will be difficult and costly for industry players to navigate. Another problems will face patent office are the overlapping and classification problem. While start-up companies grant broad coverage patent claims, demand high price and adopt too restricted licensing policy which will create deadlock of patent litigations in the patent office and potential danger for innovation for a nascent technology like nanotechnology. Some patent experts say that strict utility requirement may stop the overlapping of nanotechnology patent claim like chemistry and biotechnology field. Some other experts suggested for patent pools to avoid patent infringement litigation but there is a much possibility of price monopoly which is contrary to open market system. Enforcement issue is also vital factor in case of nanotechnology. Week patent rights create more possibility of patent litigation which very much danger for new innovation because ventures will not invest in the area where there is possibility of confrontation of patent infringement liability and also danger for a country because it will cause to stop wealth creations.

These same characteristics open an opportunity for companies seeking to maximize revenues to holdup commercialization by requiring royalties not proportionate to the value of the patents they hold.

While patents are necessary to stimulate innovation throughout nanotechnology and to secure financing for many start-ups, it is not necessary that those patents are afforded strong stature. The characteristics of nanotechnology suggest that innovation will continue in the absence of strong patent rights. Historically, foundational patents of broad scope have been shown to stifle innovation. Thus, affording such patents less strength to help remedy the patent thicket and holdup problems created by the patent landscape and ensure that nanotechnology can continue marching towards commercialization is
desirable because innovation will continue despite the weaker patent rights. The traditional remedies of cross licensing and patent pooling do not seem as though they will be effective in nanotechnology due to the asymmetry of the industry participants and the highly segmented field of patent rights. A few other tools were discussed but also seem to be of limited value. Outside of questioning patent validity in nanotechnology, government sponsored patent pools, as have been used in the past, seem to offer a very good solution assuming that the government is willing to fund analysis of proper pooling techniques for various nanotechnology industries, as well as to determine how to entice all necessary members to participate. Also, the government is in a position to use its rights under the Bayh-Dole Act to threaten compulsory licensing against those members who are unwilling to participate in the patent pools, and in some limited situations, it should exercise those rights to clear the patent thicket and alleviate holdup. Alternatively, the Bayh-Dole Act may simply allow the government to license publicly funded nanotechnology inventions without going through the tedious procedures of march-in rights. These licenses may lead to the exhaustion of patent rights against downstream product manufacturers commercializing the subject invention. The government should expend the resources necessary to study these options, as they may very well be the best way to ensure that nanotechnology can be commercialized efficiently and with competition in the industry, while still providing enough incentive for continued innovation.

In essence, Nanotechnology is still in its infancy. To enable industry to transform nanoscience into downstream commercial products, government must eliminate obstacles on the intellectual property front. Three courses of action could pave a smoother path on the road to the Nano Age. First, the Patent offices should adequately equip itself with the knowledge and resources to effectively review applications in nanotechnology. Second, courts should be willing to narrow the scope of overly broad patents when they are wielded as monopolistic weapons. Third, government should consider encouraging the formation of patent pools on the building blocks of nanotechnology.

Technological solutions are part of an important portfolio for improving the daily lives of those living in developing countries. While the majority of the world does not enjoy a developed country standard of living, the private sector currently lacks incentive to innovate essential technologies. A lack of essential technologies and products with too high of a price point lead to a market failure. Currently underused pull mechanisms such as prizes and advanced market commitments can increase innovation when used properly. In addition, developing country citizens can gain access to essential technologies with cost lowering mechanisms such as differential pricing and voluntary humanitarian licensing. Government policy should expand and aid these four initiatives, closely monitor their efficiency, and possibly increase their use in the future.

Finally it can be said that although there is many obstacles and challenges are facing for patenting nanotechnology related inventions but it is good news that many giant research companies are interested to invest in the field of nanotechnology and we can take lesson from previous other technologies, for example biotechnology and business method. The lesson learned from biotechnology and business method could also apply in the field of nanotechnology as well.
References:


[5] Vicki Norton, What nanotechnology means for IP, Managing Intellectual Property, June 1, 2003, at 38. According to a study by Toronto's Joint Centre for Bioethics, combined spending on nanotechnology by Western Europe, Japan, and the US increased from $678 million in 1997 to more than $2 billion in 2002. Increased spending projections indicate that this trend will continue. In late 2002, the European Commission announced plans to invest another 1.3 billion [euro] ($1.5 billion) in nanotechnology in its next research program. In 2003 Korea announced its plans to invest $ 2 billion in nanotechnology, while Japan’s estimated investment exceeded $1 billion.


‘Dr. Peter Hatto, Chair of ISO technical committee ISO/TC 229, Nanotechnologies, comments: “International standardization will play a critical role in ensuring that the full potential of nanotechnology is realized and that nanotechnology is safely integrated into society. Standards will help create a smooth transition from the laboratory to the marketplace, promote progress along the nanotechnology value chain and facilitate global trade. ISO/TS 27687:2008 helps to provide clarity in the description and naming of these fundamental building blocks for this important area of technology”. In ‘New ISO/TS 27687 will help defining nanotechnologies’, ISO press release 2008-09-25 available at: http://www.iso.org/iso/pressrelease.htm?refid=Ref1161.


For a comprehensive list see www.epo.org

European Convention on the International Classification of Patents for Invention of December 19, 1954, which came into force and was published by the Secretary General of the Council of Europe on September 1, 1968.

IPC version 2009.01 available at www.wipo.int

Available at: http://www.uspto.gov/go/classification/uspc977/defs977.htm (last viewed in October 2009)

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BASF v Orica Australia Boards of Appeal of the EPO, T-0547/99 (8 January 2002).

Smithkline Beecham Biologicals v Wyeth Holdings Corporation Boards of Appeal of the EPO, T-0552/00 (30 October 2003).

Patenting Nanotechnology: Exploring the Challenges, WIPO MAGAZINE, April 2011.

Kirthi Jayakumar Patenting Nanotechnology- the Challenges posed to the Indian patent regime, Indian Law Journal

Until the 1981 decision Diamond v. Diehr, 450 U.S. 175 (1981),

See Parker v. Flook, 437 U.S. 584, 594–95 (1978);


[38] www.epo.org .


‘Nanotechnology patents may be problematical to enforce because it is hard to discover infringement. Hence, nanotechnology industry will avoid a patent thicket at the research stage in much the way biotechnology seems to have done: not by limiting the scope or issuance of patents, but by merely ignoring them.’ Zekos, Dr. Georgios I. Nanotechnology and biotechnology patents, International Journal of Law and Information Technology, Autumn 2006.


Vicki Norton, What nanotechnology means for IP, Managing Intellectual Property, June 1, 2003, at 38. According to a study by Toronto’s Joint Centre for Bioethics, combined spending on nanotechnology by Western Europe, Japan, and the US increased from $678 million in 1997 to more than $2 billion in 2002. Increased spending projections indicate that this trend will continue. In late 2002, the European Commission announced plans to invest another 1.3 billion [euro] ($1.5 billion) in nanotechnology in its next research program. In 2003 Korea announced its plans to invest $ 2 billion in nanotechnology, while Japan’s estimated investment exceeded $1 billion.


Nanogen Reports Favorable Ruling in Its Litigation Against CombiMatrix Corp. and Dr. Donald Montgomery, PR Newswire Association, Inc. (Aug. 7, 2003). Nanogen’s complaint sought a correction of inventorship on U.S. Patents No. 6,093,302, 6,280,595 and related patents or applications, assignment of rights in those patents or applications to Nanogen, and an injunction preventing disclosure of trade secrets and damages for trade secret misappropriation.

Lance D. Reich, Protecting Tiny Gizmos: The Patent and Trademark Office is preparing for nanotech applications, The National Law Journal, at http://www.law.com/jsp/newswire_article.jsp?id=1075219818243 (Jan. 29, 2004). The classification of an incoming patent application initially determines which technical group and art unit will examine the application, and also determines the technical area(s) of search to locate potential prior art to the patent application. Generally, the existence of prior art that either discloses or makes obvious the invention claimed in the new patent application will block issuance of a patent.

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


[57] Such include the abolishing of the so called Professor’s Privilege that grants ownership over Intellectual property right to researchers. In 2000, Denmark was the first of several other countries to abolish the Professor’s Privilege and grant IP over research results to universities. Sweden and Italy (who against the trend introduced it in 2001) are currently the only EU countries to maintain the ‘professor’s privilege’. See: European Commission, Directorate-General for Research ‘Metrics for Knowledge Transfer from Public Research Organisations in Europe’ Report from the European Commission’s Expert Group on Knowledge Transfer Metrics, Brussels, 2009.


Through the partnership, the USPTO actively seeks speakers who can give technical training to patent examiners in nanotech, and also requests suggestions for information sources for the searching of nanotechnology-specific prior art. The major concerns being initially addressed in the partnership are the classification and examination of patent applications for nanotech inventions.


[79] Salotto, J., Nanotechnology and Classification, USPTO Customer Conference on Nanotechnology (Sept. 11, 2003)


[84] Steven Yu, Navigating the Nanotechnology Patent Thicket. As manufacturers harness nanotechnology for their medical devices, they should be aware of the need for a patent-licensing strategy. (November 1, 2007)


[89] A hold-up is where one party (party A) engages in opportunistic behavior by taking advantage of the other party (party B) particularly after party B has already made a specific investment that is a sunk cost in its nature. See Joseph Farrell et al., Standard Setting, Patents, and Hold-Up, 74 ANTITRUST L.J. 603, 603–04 (2007).

[90] For an example of a hold-up, see MICHAEL R. BAYE, MANAGERIAL ECONOMICS AND BUSINESS STRATEGY 209–10 (7th ed. 2010).

[91] Firms will typically price an output at a price that makes up for any cost of the output to the firm. For an example of double marginalization, see BAYE, supra note 114, at 418–19.


[99] Reed L. Christiansen et al., IP Disputes and Nanotechnology Company Bankruptcies, 6 NANOTECHNOLOGY L. & BUS. 374, 374–75 (2009).

[100] See John C. Miller & Drew L. Harris, The Carbon Nanotube Patent Landscape, 3


