P: ISSN No. 0976-8602 RNI No.UPENG/2012/42622 VOL.-8, ISSUE-2, April 2019

E: ISSN No. 2349-9443 Asian Resonance

Nanotechnology as an Intellectual Property: Issues and Challenges in India

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Abstract

Nanotechnology is one of the most exciting emerging technologies of the world today. Contribution of nanotechnology in the areas of computer storage, semiconductors, biotechnology manufacturing and energy is rapidly growing. This paper provides and insight in to the intellectual property issues arising due to the application and usage of nanotechnology. One of the most emerging issue is patentability of nanotechnology. This work mainly contains issues regarding patentability of nanotechnology, its inventions and the solutions for them. In the last few years, nanotechnology has strongly emerged as an academic and commercial force. Nanotechnological inventions are such that they are also not fitting in the window of Patents therefore, study on those matters has been presented here. Moreover there are certain inventions which are not able to fulfil the criteria of patentability and thus are of confusing nature. Apart from that, issues and challenges related to Nanotechnological inventions are also on high level and some of them do not have proper answers as to its applicability, therefore, the effort has been made to include all such issues in this research work. At last, some suggestions for inventors to prepare patent applications and need for amending current legislations are given. An ideal Intellectual Property regime should be one which creates incentives for innovation without unduly limiting access for consumers and innovators. With the changing regime of intellectual property, the lawmakers globally, are facing and acute lack of workable mechanism to allow for patenting of nanoscience. As with the emergence of any pioneer technology, nanotechnology has created its own issues which hinder the perfecting of existing intellectual property laws. Thus, as an emerging area of intellectual property laws, the researcher has searched various sources and tried to throw light on this subject**.**

Keywords: Nanotechnology.

Introduction

Nanotechnology is a unique and new generation technology which is going to revolutionize the way of life. Now-a-days, the nanotechnology is not confined only to the laboratories, but is making its way to our households also. Nanotechnology is hotter in India than in any other country, indicates the data from Google Trades[1]. The menswear market today is flooded with shirts and trousers those are wrinkle free, stain resistant and have cooling properties. All of these essentially use what is called nanotechnology.

In the field of consumer goods, nanotechnology is being used for manufacturing products with novel functions ranging from self-cleaning to starch-resistant. Nanotechnology based consumer products can easily be found as they have started creeping in our households. Many of us are purchasing refrigerators and water purifiers with nano-silver technology.

Silver Nanoparticles are widely being used in food packaging, clothing, disinfectants and domestic appliances and electronic goods. Nanotechnology is being used for ultra-small long lasting batteries for laptops, cell phones and may other gadgets. Titanium-dioxide nanoparticles can be found in sunscreen cosmetic to protect your skin from harmful ultra violate (UV) sun-rays. Similarly Zinc-oxide nanoparticles are used in cosmetics, paints, and surface coating. Floor-tiles and windows are being manufactured using nanotechnology.

Nanotechnology has a vast potential of application in various sectors, Medicines, Diagnostic, Drug delivery, Tissue engineering, Chemical and Catalysts, Filtration, Information and Communication, Energy, Textile, Cosmetics, Consumer goods, and Food. Everything can be improved with help of nanotechnology, from healthcare to cleaner water

and energy generation. Leading Indian companies in the field of nanotechnology are Innovations Unified, Fore vision Instruments, QtechNanosystems, Velbio Nanotech, Yash Nanotech, Cranes Software International and Icon Analytical Equipment, Auto Fibre Craft, Bilcare, Dabur Pharma, Eris Technologies, Mp3s Nanotechnology, Nano Bio Chemicals, Quantum Corporation, Redex Nano Labs, United Nanotechnologies. Apart from that, the important industry associations are also constituted which includes 'The Nanotechnology Research and Education Foundation' (India Nano), the Nano Science and Technology Consortium (NSTC) etc. Many government and non-government organizations and educational institutions are involved in the scientific research in the field of Nanotechnology.[2]

Most of nanotechnology related researches can be seen in biotechnology and medicine segment in India. Gene Repair Therapy (GRT) has also been patented which is used for treatment of diseases like AIDS and cancer. The commercialization of nanoxel, an injectable vial for dispensing the cancer drug Paclitaxel by Daburcan is seen as a landmark in India's innovations using nanotechnology. Moreover diagnostic tools for tuberculosis and typhoid have been developed by the Defence Research and Development Organisation. (DRDO). Thus, besides the various commercial uses, nanotechnology has a variety of applications in the defence sector. Its military uses include making tools of surveillance and deadly weapons.[3]

As an emerging technology it seeks various kinds of protection and such protection would fall under Intellectual Property Regime only. In last few years, nanotechnology has strongly emerged as an academic and commercial force. Nano technological inventions are such as that they are also fitting in the window of Patents. So, study on those matters has been presented here. Moreover there are certain inventions which are not able to fulfil the criteria of patentability and they have much confusing nature. For that reason also the researcher has made study on it. Apart from that, issues and challenges related to nano technological inventions are also on high level and some of them does not have proper answer as to its applicability, therefore the effort has been made to include all such issues in this research work along with suggestions for inventors to prepare patent applications and need for amending current legislations.[4]

Aim of the research

Nanotechnology is an emerging technology where the new development in almost every field is expected and there is bound to be an overlap and conflict between the existing and settled principles and technical developments. This research study will compare and analyse in brief the parallels in the development of nanotechnology inventions and will attempt to find and/or suggest the possible avenues wherein the legal conflicts can be avoided while appreciating the usage of the novel technology.

Review of Literature

Many journals, books and articles have been reviewed to have a good understanding of the subject. Following are the prime sources of this doctrinal study:

Thewebsiteof Techtarget Network

https://whatis.techtarget.com/definition/nanotechnology-molecular-manufacturing

This website provided the researcher the technical details for nanotechnology and explained the reason why nanotechnology is also called molecular manufacturing.

Jayakumar Kirthi, 'Patenting Nanotechnology: The Challenges posed to the Indian Patent Regime'

http://www.indialawjournal.com/volume3/issue2/article_by_kirhti.html

This article on nanotechnology helped the researcher to understand the intellectual property aspects of nanotechnology. Many challenges faced by the inventors in the field of nanotechnology has been precisely explained by the author in this article.

VenkataramaniSneha, 'Patent Protection in the field of Nanotechnology: The Position with respect of the European Patent Office'

http://www.legalserviceindia.com/articles/ptaav.htm

This article helped the researcher to study the situation of European Union in the field of nanotechnology patents. The author has included some landmark cases in the same subject matter which can help for understanding legal situation in the European Union.

BastaniBehfar& Fernandez Dennis, 'Intellectual Property Rights in Nanotechnology' Information Technology Journal 4 (1) 69-74, 2005. ISSN 1812-5638

This research paper helped the author to understand the technical legal aspects of nanotechnology and how the patentability tests, as required by the law, are satisfied in the nanotechnological inventions.

Forrest David, 'Regulating Nanotechnology Development'

https://foresight.org/nano/Forrest1989.php

This research paper helped the author to understand the legal aspects of nanotechnology regime. It covers the overview of nanotechnology regime and also includes the general implications including various issues pertaining to the use of nanotechnology.

Sattler Klaus D., Handbook of Nanophysics: Nanomedicine and Nanorobotics

This book contains the aspects pertaining to the medicinal aspects of nanotechnology. It helped the researcher to understand the impacts of nanoparticles on the human health. It also helped the researcher to understand the legal implications of such issues.

Nanotechnology & Intellectual property issues NCL Alliance for nanotechnology in cancer (Monthly Treasure October 2006)

This research article was helpful to understand the legal aspects of nanotechnology enabled medicines and also discussed the possibilities about obtaining patents for the same.

Challenges for Nanotechnology in IPR Regime- MIPR 2008 Vol.1. A 59 (j)

This article helped the researcher to understand the challenges of protecting nanotechnology enabled inventions through the existing intellectual property regime. The research could understood many issues which requires prompt attention by the law makers to protect the interest of inventors.

Meaning of Nanotechnology

Nanotechnology is a multidisciplinary field. It can be defined as the understanding and control of matter on the molecular level in scales of the range 1 to 100 nanometre. It enables the scientists to engineer new attributes in a material and the fabrication of devices within this size range. 1 nanometre is a billionth or 10^{-9} of a meter.[5]

Basic definition is '*Nanotechnology is the engineering of functional system at the molecular scale'.* This covers both current work and concepts that are more advanced.

In its original sense, nanotechnology refers to the projected ability to construct items from the bottom-up using techniques & tools being developed today to make complete, high performance products.[6]Nanotechnology refers to a field of applied science, whose theme is the control of matters on an atomic & molecular scale.

According to Professor, Nario Taniguchi**,** Tokyo Science University, *'Nanotechnology' mainly consists of the processing of separation, consolidation and deformation of materials by one atom or one molecule.*[7] Since that time, the definition of Nanotechnology has generally been extended upward in size to include features as large as 100 manometer. Thus here, there are two main ingredients which distinguishes Nanotechnology, those are (1) Size dimension must be limited to 100 nanometre and (2) Any machinery or other devices at the molecular level, must be processed in any manner.

Why Nanotechnology is unique?

Traditional manufacturing methods includes a 'top-down' approach, taking a chunk of material and removing chunks of it, for example, by grinding or by dissolving with acids until the final products part is achieved. The goal of nanotechnology is to include a 'bottom up'approach which starts with individual molecules and bringing them together to form product part in which every atom is in a precise, designed location. In comparison with the 'top-down' approach, this method could potentially have much less material left over, greatly reducing pollution.

Over the last few years, huge research efforts including substantial investments have been seen in the field of Nanotechnology. Nature has proved that control of nanometre structure leads to amazing devices and for this, an example of DNA is most suitable which encodes all the information required to build an organisms into the few molecules. Not only that, but DNA includes within it many ingenious error correcting mechanisms and 'information' which serve more to control the behaviour. This level of information compression, where a single bit of data is encoded in a molecular sized unit, would be considered an amazing engineering achievement, if it had been created by human. Many other examples of the complexity and efficiency of biological system are in existence including comparing a brain to a silicon chip, comparing a tree to solar panel etc. However, for the moment, it suffices to say that the nanoscale world has great promise indeed.[8] It is well said that "*If even half of the expectations of nanotechnology are realized, it will lead to changes in every aspect of human life and perhaps, human nature itself."*[9]

Nanotechnology is a new manufacturing method which is capable to open the new dimensions of the technology and its development. Nanotechnology includes developing fields of nano-science and nano-engineering which is defined by the American Heritage College Dictionary as, *"The science and technology of building electronic circuits and devices from single atoms and molecules. The capability to manipulate molecule and atoms to create computers and machines that in turn can create other computers, machines and useful objects present fresh and complex legal implications for the worlds societies."*[10]

Such capacity to manipulate some elements at molecule level itself becomes an 'Intellectual Property' and therefore it is subject to protection under the current Intellectual Property Regime.

By now, due to a cascade of media coverage about nanotechnology, not only the scientific community but the public at large, has heard about the huge impact that nanoparticles and their capabilities may have on our lives in 21st century. But at the same time nanotechnology applications are expanding the limits of science and medicine, they are stretching the boundaries of intellectual property law. As with other waves of innovation nanotechnology will catalyse change in social, scientific and legal arenas.[11]

Invention - Meaning & Scope

Invention is to find out something, to discover something not found or discovered by anyone before.[12] It is used for the protection of new forms to real objects, or for the creation of unreal objects such as have no existence but in the mind. It is an act or operation of finding out something new. An invention is the finding out, the contriving, the creating of something which did not exist and was not known before and which can be made useful and advantageous in pursuance of business or can add to the enjoyment of mankind[13]. It is a contrivance or production of a new method of an art, kind of instrument etc. which is previously unknown.[14] According to section 2(j) of the Patents act, 1970, *Invention means, a new product or process involving an inventive step and capable of industrial application.*

The term invention is, therefore, the production or introduction of a new thing for the first time by exercising one's own mind, skill and labour, it must not be known to the public prior to the claim made by inventor.

Nanotechnological Inventions

The issue which needs to be understood is relating to the inventiveness in nanotechnology.

Nanotechnology is a method of manufacturing any particular device or machine from the atom by atom or molecule.

Prima Facie, it is not so spectacular an achievement that it is possible to put atoms and molecules exactly where you want them. It is possible through micron scale precision therefore, the question is why should an extra three decimal places make that much of a difference? In answer, it may be said that with the help of this fantastic technology, one can actually manipulate any kind of atom or molecule and not merely the highly specialized materials of microelectronics or biology. With the help of this capability to make structures at such level, assembler systems which can be programmed to make copies of themselves is possible and due to that, making and reproducing other things on rapid and cheap way will be possible.[15] The following are the examples showing new inventive steps contained in nanotechnology.

Materials

Nanotechnological inventions are capable to create various things and articles joining atoms and by this any kind of physical machines, structure may be created. It is also forecasted that with the help of nanotechnology, various materials can be produced which will be stronger and flexible or ductile. Even various materials made from diamond could be stronger than that, and three times lighter and such kind of super materials will possibly allow drastic improvements in the performance of machines and the same may be used in all the fields including energy production, automobile, telecommunications, aviation, space and many more. Thus new, useful and innovative materials would be invented.[16]

Computers and Artificial Intelligence

With the help of nanotechnology, existence of molecular computers, which will be trillion times smaller and faster than today's machinesand devices will be possible. Memory storage will be possible for one gigabyte per cubic micron. To understand this powerful memory storage capacity, it can be said that all the details and information which is currently stored in any huge library can be stored in a small cube with a thickness of a sheet of a paper! In this way, more efficient and human brain similar computer devices may be manufactured which is itself a revolution in technology.[17]

Medicine

It will be possible to manufacture a computer with the size of a human cell and with the help of such computers, various commands may be passed at extremely small level for repairing of DNA and other deficiencies of human body including replacement of damaged cell or destroying dangerous cell. This technology can also help to eliminate death due to various unknown diseases. Most surprising function can be to stop or slow down aging process![18]

Environment Friendly Products

Nanotechnology can also help to deal with environment problems. Various self-functioning devices may be manufactured for replacement of hazardous waste sites. At the domestic level only, recycling of material will be possible. Instead of disposal of waste at dumping cites, it may be disposed at household level only. Harmful components will be transformed into harmless substances by help of such technology.[19]

Military System

Nanotechnology can also help in military operations. All the offensive and defensive systems can be made more effective with the help of nanotechnology. Various devices may be developed for identity of culprits and to eliminate anti-social elements by recognition of their genetic codes which are unique and can be traced at nano-level only. As these are the inventions which would be made by exploring nanotechnology and they would help in many ways to human beings.[20]

Economical Products

Economic aspects of nanotechnology will also be of great significance. As all the materials are possible to be used in a different way, economic value of all such elements like sand, diamond, water, chemical will increase [21]

Protectable Intellectual Property in Nanotechnology

Mostly, Nanotechnology consists three kinds of intellectual property that needs to be protected.

Manufacturing Methods

One approach to building a wide range of nano-scale structures is positional assembly,[22] involving the use of tiny robot arms or similar manipulating devices to precisely position similar manipulating devices to precisely position molecular building blocks for bonding. Initial progress toward positional assembly has been made, for example with the use of scanning tunneling microscopes (STM), it has become possible to push atoms around with their tips in near zero temperatures.[23] Novel methods in overcoming the difficulties of manipulating tiny molecules with instruments that are bigger and bulkier, as well as methods that deal with the tendency of molecules to adhere to the manipulating apparatus will present fundamental steps towards visible manufacture of nanostructures and are IP protectable.[24]

Another approach to build nano-scale structures is self-assembly, involving the design of molecules which aggregate into desired structures. Although self-assembly take place all around us and produces structures ranging from cry stab to like forms, we do not yet understand it in sufficient detail needed for nanotechnology[25]. Aside from techniques of molecular assembly, feasible and useful nanotechnology demands that manufacturing costs remain close to the cost of required raw-material and energy and intellectual property right protect novel manufacturing methods and processes that increase yield and decrease cost. For the low cost manufacturing methods, proposal is made for preparation of a unique self-replacing system containing nano robots[26]

Nanotechnological Inventions

Inventions that have been made by using the nanotechnology for example carbon nanotubes, nano robots, other machines & devices which are working

at nanoscales are also subject to protection by issuing patents. Nanotechnology based memory chips which are more useful in computers & nanotechnology based sensors are another examples of new inventions. Such other inventions are those which possess all the qualities of property and therefore they are subject to be patented. Because of patent protection such inventions would be recognized legally and their commercial applications and usage would be available in applications and usage would be available in country.[27]

Trade secrets and confidential information

Unlike patent, trademark and copyright law, trade secret law is primarily governed by the state law. Trade secrets are of potentially infinite duration since they last as long as secrecy can be maintained[28]. Nanotechnological inventions are also very secret inventions which contains very confidential information. So it is also included in a kind of intellectual property. While patent law requiring a company to disclose its inventions to the public, trade secret law provides protection for concepts those are to be kept secret within the company Nanotech companies rely on patents instead of trade secrets to protect their important inventions. In addition to being critical to attract investors, patents provide a more sturdy form of protection. Nevertheless in certain circumstances in trade secrets may be preferable to patents. Nanotech companies can also use other doctrines such as the duty of loyalty and unfair competition to protect ideas and concepts that are not trade concepts.[29]

Nanotech companies can use trade secret law to protect concepts and ideas that cannot be patented or to protect inventions that do not justify the expense of filing Patents. For example at this stage of development, some of the most valuable information generated at start-ups invoice failed experiments. This "negative information" can be protected by trade secret. Information such as customer and investor lists also ripe for trade secret protection. Finally many nanotech companies prefer to maintain the details of their manufacturing methods as trade secrets.[30]

Patentability of Nano-technological Inventions

Patents are the strongest form of intellectual property protection and are essential to the growth of nanotechnology industry. Patent offers protection for functional concepts, methods, apparatus or processes that are novel, useful and non-obvious.

In contrast discoveries, diagnostic or therapeutic methods or inventions are not compatible with public order or general principles of morality are not patentable. Purpose of the patent is to advance innovation through disclosure and teaching of the details of the invention to the public and in exchange the inventor or owner is rewarded the legal rights of ownership. The legal rights refer to in particular the right to exclude others from making using selling or importing in to the use or offering of the invention, giving the owner the exclusive rights to capitalize on the invention. The ownership rights are granted for a period of 20 years, depending on the date of filing of the patent.31 Here, the meaning of inventive step should be known for deciding whether nanotechnological invention are patentable or not.

Section 2(ja) of the Indian Patents Act, 1970

It provides that *"Inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."*

The law has limited the choice by putting a condition that for satisfying this requirement, an invention must be new, useful and non-obvious. nanotechnological inventions must possess the inventive step so as to get patents protection. The criteria of economic significance or advantage may be used as a test for arriving at a decision on the inventiveness but it is not an exclusive criteria whether an invention would lead to economic advantage when converted into a product or a process could only be determined truly when the invention is actually put in to industrial use till that time one is playing only with conjectures guesses and speculation because there are many more factors which would determine the cost or the economic advantage of the product process. Today, Nanotechnology is one of the very important emerging technologies and it has created tremendous inventions, therefore, if those inventions are fitting in the criteria of patentability, they can be granted patent protection.[32]

Issue Related to Nanotechnology

Major issues in case of nanotechnology patents can be described as:

1. How do we legally classify the new technologies in form of Nanotechnology?
2. Whether new version in form of Nanoversion of prior invention is patentable?
3. How to recognize the novelty and inventiveness of so little nanomachines?
4. Whether strong or weak patent protection of Nanotechnology is best policy to promote growth of Nanotechnology?

Patentability issue

To be patentable, a nanotechnological invention must overcome two preliminary hurdles. It must be novel and non-obvious. Ones, an invention is found to be novel and non-obvious, the description of the invention must also enable a person skilled in the art to build and use the invention without an unreasonable amount of experimentation. There is no single field of Nanotechnology. The term broadly refers to such field as biology, physics, or chemistry, any scientific field or a combination thereof that deals with the deliberate and controlled manufacturing of nanostructure so let us examine the fulfilment of such aspects by nanotechnology.

Novelty

An invention is considered novel if prior to the filing date of the patent, it has not been made available to the public by any means either by oral/written description or prior use. The size of nanoscale component should be sufficient to distinguish that component from that of the prior art.

Any slight difference between the new invention and the prior art will make the invention novel.

The issue of novelty for nanotechnology may not be simple. For example, where a macro sized carbon tube has already been developed and then one produces a carbon nanotube, an examiner would argue on the point of inherency and novelty that the invention is an outcome of the macro sized tube however, the concept of inherency is seen narrowly, thus patents should be granted for nanoversion device because nanotechnology is outcome of bottom up approach, therefore, novelty is there as size becomes too small. So nanoversion must be granted patents as the whole concept is being changed.[33]

Case study[34]

[Decision of European Patent Office (EPO) – Enlarge board of Appeal]

In T 0006/02 [Photodegradable cellulose estertow] case

The increased photo degradability of cellulose ester by adding of nano particle size titanium dioxide is novel as a generic disclosure like plastics materials as laid down in the prior art does not normally take away the novelty of any specific example (cellulosesters) falling within that disclosure.

In T 0915/00 [NanocrystallineMeatals] case

The nano crystal material, obtained by electrode position and having crystalline size of less than 11 nanometer is novel over a substantially identical material disclosed in the literature. Comprising macro crystalline nickel obtained by electrode position.

In T 0509/92 (deceptive crystals) case

The board is of the opinion that there was nondisclosure in any of the said prior art documents of aspartame type II crystals having the given X-ray characteristics and moisture content. For these reasons the novelty is acknowledged.

Obviousness (inventive step)

The claimed subject matter implies an inventive step if, for a person ordinarily skilled in the art, it is not obviously derivable from the state of the art. It must focus on previously unattainable size, structure, compositions, organizations methods of measurement and of changing the property of materials as well as application of the new properties.

In Nanotechnology, the results of the experimentation are mostly unpredictable and based on the presumption of a suggested outcome. If there is success in achieving the suggested outcome through experimentation, the resulting invention (the nanoparticle) can be said to involve an inventive step.

Obviousness or inventiveness is considered to be the second hurdle to a Nano technological patent. It bars a patent if a new invention is an obvious extent or an obvious change from a prior invention. A patent application of a microscopic device disclosed before the discovery of nanotechnology cannot possibly describe how to build the device on the nanoscale. Therefore, it does not render a nanostructure device obvious so it is patentable.[35]

Case Study[36]

[Decisions of the E.P.O. Enlarged Board of appeal]

In T0070199 [Fluid handling in micro rubricated analytical device]Case

When the miniaturization of a device is accompanied by an unpredictable effect, the result of the miniaturization should always be regarded as inventive regardless of the apparent obviousness of the means used to achieve it. The board is convinced that the prior art disclosed in the other documents cited by the applicant does not come closer to the invention and that these documents do not contain any more relevant information.

In T09151100 (Nanocrystalline Metals) Case

The method of the claim was distinguished from the continues electro-plating method of prior art essentially in that it comprised of passing direct current at pulsed intervals and under peak current density and timing conditions selected in the ranges set out the claim so as to deposited nanocrystalline material of size less than 100 nanometer on the cathode, instead of passing direct current in a continuous manner. The Board affirms that the skilled persons had no obvious reason to for see that the prior teaching could still be successfully extrapolated to structure smaller by at least two orders of magnitude, if not with the benefit of hindsight.

In T 0453/97 (Antireflective counting for use in Photolithography) Case

The technical problem underlying the subject matter of the claim as objectively defined in view of this nearest prior art is to still further reduce the optical reflectance of the antireflective film of titanium nitride disclose in prior art. The skilled person could not, in boards view, be expected to discover the claimed range in an obvious way in the course of routine experiments he would perform when putting in to practice the teaching of the prior art.

In T 0952/01 (Method of Coating a substance) Case

The prior art does not suggest the use of particles in the claimed size range of 20 to 70 nanometre because it recommends a preferred size range of 100 to 500 nanometre and thus clearly teaches away from the use of particle sizes below 100 nanometre.[37] Thus above two criteria i.e. Novelty and Inventive steps are very precisely found in nanotechnology so we can say that nanotechnological inventions are Patentable.

Challenges to Nanotechnology

Nanotechnology, more descriptively known as molecular manufacturing, involves the design, modelling, fabrication, and manipulation of materials and devices at the atomic scale. It is functioning through special control of matter at the level of molecules and rearranges them in to custom designs. When we talk about the future usage of nanotechnology, they seem to be limitless, however, while talking about utility and usefulness of multi-disciplinary field of nanotechnology, the challenges must also be kept in mind.

The emergence of new technologies continually forces us to ask, whether our laws provide proper balance consequences of those technologies,

and allowing us to reap the benefits? The development of nanotechnology as a molecular precision manufacturing technology is surprisingly out of regulatory system and we need to respond quickly to maintain the critical balance between dangerous and benefits. The development of nanotechnology will affect regulation in most areas from banking and commence to air safety and toxic waste.

The challenges to Nanotechnology can be divided as:

1. Challenges as to Patentability.
2. Challenges to Environment
3. Challenges to Health.

Challenges to Nanotechnology patents

First of all the distinction between discoveries and invention can become somewhat blurred in nanotechnology, where the principles of patent laws are to be tested. Main challenge is the limitation, which lies in the non-adaptability and absoluteness of the expiratory patent law. It must be understood that the law covering product and technology since the industrial revolution may not apply to the Nanotechnology. Can anybody get patent on an atomic level structure? How do you protect an atomic sized devices from being illegally copied? How will the patent policies evolve and affect the scope of Nanotechnology patents? These are the intellectual property questions require solution in order to make effective and efficient use of nanotechnological invention.[38]

In fact, most of the nanotechnology applications by corporations are targeting the improvements in the functioning of existing products which are maintaining market share, however they are not genuine and ground breaking inventions. Nanotechnology contains an aspect of molecular engineering and it is quite similar to the patents granted for chemicals and drugs however, the drugs are manufactured by the complex procedure by dealing with various chemicals whereas nanotechnology will contain nano-level material containing all the characteristics of useful products. Such method of using nanotechnology is a kind of arrangement of rearrangement of things at nano level and not an invention in true sense therefore proper system of patent or alike is required to extend protection to such unique technology. Moreover, looking towards small companies and start-ups, patents are among the only protections from infringement by large corporations. With the growth of a company, various issues are faced for maintaining secrecy of unique methods and therefore there is a strong requirement of patent protection. [39]

Furthermore, the interdisciplinary nature of nanotechnology creates a special case.[40] Lack of focused state of patent office is likely to result in :***(1)*** The improper rejection of patents due to a mistaken conclusion that the claimed matter is not new and ***(2)*** Overly broad patent by giving the owner excessive control over a particular area as had happened during the recent flood of information technology patents which overwhelmed the USPTO and resulted in cases such as the 'one click' amazon.com patent, which was criticized as too broad claim.[41] Apart from that, it is a basic rule of the patent law that obvious matters and basic scientific principles and mere discoveries are not considered for grant of patents. Therefore a basic challenge in the field of nanotechnology will be to decide the patentability of such inventions. Merely submission of smaller version will be difficult for the grant of patent unless it contains sufficient amount of novelty, utility and non-obviousness. Following are some points upon the applicability of these traditional bases of patenting to the nanotechnology inventions and discoveries.[42]

Patent Applicability

For obtaining patent, the invention must contain three basic aspects including novelty, non-obviousness and utility. It means the invention must be different and unique from the existing field of technology. This is very difficult in case of nanotechnological inventions due to its very vast coverage of the technological field.[43]

Requirement of Novelty

Novelty means something new which is not known before the date of patent application either by use or by documentation anywhere in the world. To decide this aspect, a prior art search is made for the national and international patent database available in patent offices. As nanotechnology contains a multidisciplinary nature, it would be a difficult task to make adequate search. Moreover, many nanotechnology inventions covers different fields of applications and due to this, the ability of a single examiner or technology group may not be sufficient to determine the novelty of an application.[44]

Requirement of Utility

The patent system requires that any invention for which patent protection is sought must be useful or functioning. The basics behind this concept is that only those inventions shall be granted patents which will serve the society with actual functioning of the invention against the grant of monopoly. Here the difference is required to be made between various inventions. All the fields of inventions cannot be compared at par. Comparing mechanical and engineering applications, having a defined purpose with chemical and biological inventions, the later has utility which is very difficult to convey and define. The reason for the same is utility of such inventions may be found at the later or future stage of its exploitation and if patents to such inventions are denied straight away due to absence of utility, it may be a case of great risk.[45] In nanotechnology, the types of application for each invention are theoretically limitless. Because of the scale impact and the interdisciplinary nature of the field, nanotechnology invention may be written across a wide range of applications. This indicates that there is a requirement of a wide range of fields for the proper drafting of nanotechnology patent applications and in the same way, there is also a need of proper team effort for minute examination of the patents mentioned above. If this requirements are not made, careful drafting of claim cannot take place, which is highly essential in gaining the optimal patent protection for the product.[46]

Requirement of Obviousness

Comparing with other two requirements, non-obviousness or inventive stem is a quite complicated subject in the field of patents. The term cannot be simple defined but it can be said that the invention is required to pass the requirement of obviousness even though it contains the requirement of novelty.[47]

To determine non obviousness in emerging technologies, the scope of prior art, and quality of the search is performed by the patent office. Basically, non-obviousness requires in-depth knowledge of the particular technology to get a sense of what 'one of ordinary skill in the art' would know in order to combine knowledge or prior art references. As it is discussed above, nanotechnology is a multidisciplinary field and it is difficult to define the scope of the prior art and person of ordinary skill in the nanotechnology and determining what is obvious or not will present unique challenges for the patent examiners and courts.[48]

Thus, the major issue in legal conflicts for patent claims coverage are the definitions used in the patent applications and in the world of nanotechnology, there is considerably confusion for various terms and on top of the same, there is not even a clear and generally used definition for the term 'nanotechnology' itself. Which is creating a challenge.[49] To overcome such challenges, patent applications should be examined by a team of examiners as opposed to single examiner as multiple experts can decide claim of patents in better way. Apart from that, a single and properly organized centre for nanotechnology patents is also expected to bring uniformity in respect of nanotechnology patents. Proper training may also be given to the patent officers to resolve such challenges. The patent offices are expected to be ready and open to accept wide claims in order to accommodate nanotechnology patents.[50]

Challenges to Environment

In spite of being such great technology, nanotechnology also has some environmental challenges which need to be solved. There are also various groups which are opposing nanotechnology because of environmental pollution and risks.

In addressing health and environment impact of nanomaterials we need to differentiate two types of nano structures. (1) Nanocomposites which are nano structural surfaces and nanocomponents where nanoscale particle are incorporated into a substance, material or device or in other words, "fixed" nano particles and (2) Free nanoparticles where at some stage in production or use in individual nanoparticles of a substance are present.

There seems to have conesus that, although one should be aware of materials containing fixed nano particles, the immediate concern is with free nano particles. As nano particles are very different from their everyday counterparts, there adverse effects cannot be derived from the toxicity of the macro sized material. These possess significant issues for addressing the health and environmental impacts of nano particles.

Nano pollution is generic name for all waste generated by nano devices or during the nano materials manufacturing process. This kind of waste is very dangerous because of its size. It can float in the air and might easily penetrate animals and plant cells causing unknown effects. Most human made nano particles do not appear in nature so living organism may not have appropriate means to deal with its nanopollutants and nano waste. Not enough data exists to know for sure if nanoparticles could have undesirable effects on the environment.[51] The relevant areas here are:

1. In free from, nanoparticles can be released in the air or water during production or production accidents or waste by-product or production and ultimate accumulate in the soil, water, or plant life.
2. In fixed from, where they are part of a manufactured substance or product, they will ultimately have to be recycled or disposed of as waste. It is not known whether nanoparticles will constitute a completely new class of nano-biodegradable pollutant. In case they do, it is not known how such pollutant could be removed from air or water because most traditional filters are not suitable for such tasks and their pores are too big to nanoparticles.[52]

Although in-depth research is required to ascertain harmful effects of the nanoparticles in the environment, it is the evident that nanoparticle in the free from will effete the environment and the ecology by accumulating in soil, water and vegetation, Nano silver particles a powerful bactericide used in many products and devices can kill beneficial bacteria in the nature to help down organic matter and keep the environment clean. On the other hand, harmful bacteria could become resistant to nano silver used in water purification and get their way into our body.

In this way, nanoparticles could have significant ecological impact because of bioaccumulation the increase of a pollutant from environment into organism through a food-chain, especially if the nanoparticles absorb smaller pollutants such as pesticide, or if they persist in the environment because they are too small to detect.[53]

Challenges to Health

Apart from creating environment risk, nanotechnology also have some effects to human health. The mere presence of nanomaterials i.e. materials that contain nanoparticles is not in itself a threat. It is only certain aspects that can make them risky, in particular their mobility and their increased reactivity. Only if certain properties of certain nanoparticles were harmful to living beings or the environment would be faced with a genuine hazard, in this case, it can be called Nano pollution.

There is a growing body of scientific evidence which demonstrate the potential for some nonmaterial to be toxic to human or environment. Smaller particle can have greater chemical reaction and biological activity due to its grater surface to the volume ratio. The extremely small size of nanomaterials can be taken by human body promptly causing serious health risks. They can also gain

access to the blood stream following inhalation or ingestion and they can also penetrate the skin. After entering into blood stream, nanomaterials can be transported around the body and taken up by organs and tissue including the brain, the heart, and the leaver, kidney, spleen, born marrow and nervous system which has effects on human tissue and cell cultures, resulting in increased risks on body.[54]

The health risks of nanoparticles are of particular concern for worker who may face occupational exposure to nanomaterials at higher levels and on a more routine basis, than the general public.[55] Studies of rats have found that discrete, nano meter-diameter particles were capable of crossing the animal's blood-brain barrier into the brain itself. Nanotechnology, it turns out has a dark size that no one in the industry wants to talk about. The nascent nanotechnology industry collectively cringed after a study showed that, fish exposed to nanoparticles suffered brain damage. Critics say that the human-hyped multibillion dollars nano industry has a dark side few want to talk about, Nano products are not subject to any special regulations. In part because little is known about the environment and health implications of nanotechnology, said by Kevin Ausman, Executive director, of the Centre for Biological and Environmental Nanotechnology at Rice university in Houston.[56]

Conclusion

Thus, nanotechnology, if not controlled under particular regulation, can create major issues relating to health hazard which would be hard to cure. Nanotechnology will be an important part of our lives and it will provide us with the ability to do things on an atomic and molecular scale. To get success, the companies that develop new discoveries and uses for nanotechnology will require a strong patent protection. With a carefully development of patent strategy, Indian can successfully meet with the challenges raised by the nanotechnology. Nanotechnology related research, development and commercialization will be important to transform India into a developed nation by 2020. Nanotechnology is the field of future. By taking into consideration the risk of nanotechnology to health and environment, a strong policy or law must be enacted to put some provisions related to control and prevention of nanotechnology pollution so as to get a sustainable development in 21st century. Indian intellectual property laws must have to be updated in order to meet the requirement of science and technology today so that new creations and inventions can be protected and a development in its true sense can be achieved.

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