
Critical Analysis of Issues and Challenges in Patenting Nanotechnology Inventions

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INTRODUCTION

Intellectual property is the foundation of all technology ventures, yet the laws governing and protecting Intellectual property rights are unfamiliar territory for most scientists. At international level, Intellectual Property Rights (IPRs) have traditionally been governed by several conventions- most prominently the Paris Convention for Patents and Trade Marks (1883) and the Berne Convention for Copy Rights (1886)- which are administered by the World Intellectual Property Organization (WIPO). The Trade Related Aspects of Intellectual Property Rights Agreement 1994 represents the most far reaching agreement towards global harmonization of Intellectual Property Rights. Nanotechnology is a young field that focuses on basic research and material science product. This paper will provide an insight to the laws in India governing Intellectual property rights in the field of science and technology especially nanotechnology and the issues and challenges surrounding nanotechnology inventions in patent law.

Intellectual property is the creative work of human intellect. The main motivation of its protection is to encourage and reward creativity. According to Article 2(viii) of the 'Convention Establishing the World Intellectual Property Organization (WIPO) 1967', intellectual property includes rights relating to-

(i)Literary, artistic and scientific works;
(ii) Performance of performing artists, phonograms and broadcasts;
(iii) Inventions in all fields of human endeavour;
(iv) Industrial designs
(v) Scientific discoveries
(vi) Trademarks, service marks and commercial names and designations;
(vii)Protection against unfair competition; and all rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

Intellectual property thus, includes copyright, trademarks, service marks, geographical indications, patents, utility models, plant varieties, industrial designs, trade secrets, layout design of integrated circuits, etc. Nanotechnology is the engineering of functional systems at the molecular scale.

When K.Eric Drexier popularized the word 'nanotechnology' in the 1980s, he was talking about building machines on the scale of molecules, a few nanometers wide motors, robot arms and even whole computers for smaller than a cell. Nanotechnology has now emerged as the most effective fields with respect to Intellectual property rights. In the field of nanotechnology Intellectual Property protection is available in manufacturing methods and computational techniques.

APPLICABILITY OF NANOTECHNOLOGY

Nanotechnology is applicable in the areas of:
Electronics- eg.the flat panel TV or Computer monitors are products of nanotechnology
Space – eg. nanomaterials are adopted as alternative materials in place of conventional materials such as Nanoparticles- based solar cell arrays
Defense- eg. Nanotechnology may play an important role in detection of harmful biological weapons.
Environment- eg. Use of nanomaterials as hydrogen storage or efficient oil filters may reduce vehicle pollution.

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Energy- eg. some metal hydride nanoparticles like nickel hydrides or high surface area, ultra light weight materials like aerogel are better options in improved batteries.
Sports – eg. Tennis ball using nano clay is able to fill pores in a better way and trap the air pressure inside.
Toys- eg. Eye movement of dolls, robot movements etc.
Textile- special threads and dyes used in textile industry are products of nanotechnology, use of silver nano particles in washing machines makes cloths germ free, nanotech fabrics, self cleaning necktie.
Cosmetics- eg. Nanoparticles based creams, nano based dyes.
Domestic Appliances- eg. Silver nano particles are used in refrigerators, air purifiers, water purifiers, washing machines.
Automobiles- eg. Nanoparticle paints for cars provide smooth, thin, attractive coating; using nano particle clay, better, light weight, less rubber consuming tyres are possible.
Biotechnology and Medical field- eg. Early detection of cancer is possible due to nanotechnology based analysis, biological labeling using fluorescent semiconductor nanoparticles or quantum dots.

The applicability of nanotechnology is spread over diverse fields such as physics, material science, engineering, chemistry, biochemistry, medicine and optics. As nanotechnology is applicable to other already established fields, there are challenges and issues surrounding the acquisition of intellectual property rights in the field of nanotechnology.

INTELLECTUAL PROPERTY RIGHTS LAWS AND NANOTECHNOLOGY

Over the past two decades the role of Intellectual Property in all fields of technology has exploded globally due to rules prescribed by Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS). The TRIPS Agreement requires member countries to make patents available for inventions, whether products or processes, in all fields of technology, without discrimination, subject to the standard patent criteria of novelty, inventiveness and industrial applicability. Article 27.3(b) of the TRIPS Agreement states that plants and animals as well as essentially biological processes may be excluded from patentability. However, World Trade Organization members must offer protection for plant varieties either by patents or by effective sui-generis system. Today, nanotechnology issues focus primarily on patents, with additional issues relating to trade secrets, copyrights, and semiconductor and integrated circuits layout designs.

PATENT

Patent law is all about inventions. An invention is what an inventor produces through his creative efforts as new knowledge in the form of a product or a process to make a product that did not exist at all till the time of his invention.

The grant of patent in India is governed by the *Patents Act*; 1970.The definition of a patent under the *Patent Act* 1970 is "patent means a patent for any invention granted under this Act". Section 2(1) (j) of the Act, "invention" is a new product or process involving an inventing step and capable of industrial application. '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 makes the invention non-obvious to a person skilled in the art.(section 2(1)(ja)). "Capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in industry (section 2(1) (ac)). A 'new invention' means any invention or technology which has not being anticipated by publication in any document or used in the country or elsewhere in the world before the date of filling of patent application with complete specification.

To be patentable, invention must be new, non-obvious and useful. The element of newness /novelty in an invention is dependent upon the state of prior art (the existing knowledge and similar inventions already known in the particular field). The invention must be non-obvious to a person skilled in the art to which the invention relates. The invention besides being new and non-obvious must also be useful.

Inventions not patentable under Patent Act 1970

Sections 3 and 4 of the Act state the inventions which cannot be patented. As per section 3, the following are not inventions within the meaning of this Act:

a) An invention which is frivolous or which claims anything obviously contrary to well established natural laws

b) An invention the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment

c) Mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature.

d) The mere discovery of a new form of known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use of a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

An explanation is provided for the purpose of this clause, stating that salt, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance, unless they differ significantly in properties with regard to efficacy.

This section was introduced as it was considered necessary to prevent pharmaceutical companies from 'ever greening' expiring or expired patents that has fallen into public domain, by adding insignificant and miniscule changes to the composition of their original compounds.

e) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance

f) The mere arrangement or rearrangement or duplication of known devices each functioning independently of one another in a known way

g) Omitted(2002)

h) A method of agriculture or horticulture

i) Any process for the medicinal, curative, prophylactic. Diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their product

j) Plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for the production or propagation of plants and animals.

This is in compliance with TRIPs Agreement which provided that protection for plant varieties may be provided either by patents or by an effective sui-generis system or by any combination thereof. India has chosen *sui-generis* system and enacted the *Protection of Plant Varieties and Farmers' Rights Act*, 2001.

Under this sub-section of the 1970 Act, micro-organism may be patented. Bio-technology research involves the use of micro-organisms. India does not have any specific legislation regarding bio-technological inventions, much less, micro-organisms. The *Biological Diversity Act*, 2002 governs applications for any intellectual property rights, in or outside India, for any invention based on any research or information on a biological resource obtained from India. Section 2(c) of the *Biological Diversity Act*, 2002 defines a biological resource as meaning plants, animals and micro-organisms or parts thereof, their genetic material and by-products(excluding value added products) with actual or potential use or value, but does not include human genetic materials.

k) A mathematical or business method or a computer programme per se or algorithms.

Since computer programme is governed by the Copyright Act 1957, it is excluded from the patent Act 1970. It was noted in the Copyright Act that computer implemented invention could be the subject of a patent. It states that a computer programme per se is not patentable; it would be patentable if the computer programme is part of a patentable process.

l) A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions.
m) A mere scheme or rule or method of playing game
n) A presentation of information
o) Topography of integrated circuits
The Semiconductor Integrated Circuits Layout-Design Act, 2000 deals with the layout design of integrated circuits.
p) An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component/s.
Section 4 of the Act denies patents for inventions relating to atomic energy.

No patent shall be granted in respect of an invention relating to atomic energy falling within subsection (1) of section 20 of Atomic Energy Act, 1962.

The general principles applicable to working of patented inventions as mentioned in Section 83 of the Act is that patents are granted to encourage inventions and to secure that inventions are worked in India on a commercial scale and that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

COPYRIGHT

Protect the right of creators of literary and artistic works to communicate, display, or perform those works in some medium, plus the right to make and sell the copies. Copyright is a bundle of exclusive rights which means that the right owner can prevent all others from copying his work, or doing any other acts which according to copyright law can only be done by him. Copyright subsists for a limited period. After the expiry of the copyright term the work falls into public domain.

The scope of copyright which was restricted only to the protection of literary and artistic works in the earlier days, has now been broadened to include not only literary and artistic works, but also dramatic and musical works, cinematograph film, and sound recording. In addition, neighboring rights which consist of the rights of the performers, the rights of producers of phonograms and the rights of broadcasting organizations are also covered by the copyright law. The reason why scope of the copyright has become so vast is the technological innovations which took place in the last two centuries. Technological innovations eg, computers, audio recording, video recording, reprography, cable television, satellite broadcasting and most recently Internet have posed challenges to copyright laws from time to time, and forced the nations to amend their laws.

The copyright law, today, not only protects the rights of the copyright owner and neighboring rights, but also deals with the subject of public interest and tries to strike balance between the two in this digital environment. The Intellectual Property right in respect of the work created is subject to the provisions of the *Copyright Act*, 1957 which is India's law on copyright. Copyrights are much more expensive and expediently obtained than patents, and are valid for the author's lifetime plus 50 years. A longer period of protection applies if the creation was work made for hire, which is generally the case in nanotechnology industry.

TRADE MARKS

Trade marks refer to a distinctive sign which identifies certain goods or services as those produced or provided by a specific person or enterprise.Legal protection is not offered to the technology, rather to the company goodwill and quality associated with the use of recognized name or symbol. In India, the Trademarks Act 1999 deals with the registration of Trademarks. Trademarks Act provides exclusive right to the registered trade mark owner for a period of 10 years which may be renewed indefinitely.

TRADE SECRETS

Trade secrets protect any technical or business information that gives the business a competitive advantage. It need not be completely novel or exclusive, but it must have a derived or potential economic value from being unknown. Legal protection under trade secret no longer applies when the information is disseminated publicly. There is no formal filing procedure to register trade secrets to obtain protection.

LAYOUT DESIGNS OF INTEGRATED CIRCUITS

Covers the layout designs of integrated circuits, the chips on which they are masked, and products that incorporate the chip. TRIPs specifically permit reverse engineering of integrated circuits.Semiconductor Integrated Circuits means a product having transistors and other circuitry elements which are inseparably formed on a semiconductor material and designed to perform an electronic circuitry function. The *Semiconductor Integrated Circuits Layout-Design Act* 2000 provides for the protection of semiconductor integrated layout designs in India. The purpose of the legislation is to protect the right in the creator of an electronic circuit on a semiconductor material for a period of 10 years.The term 'layout-design' means a layout of transistors, and other circuitry elements, and includes lead wires connecting such elements and expressed in any manner in a semiconductor integrated circuit. The Act defines 'registered layout-design' to mean a layout-design which is actually on the register.

Some of the current issues and challenges encountered in nanotechnology intellectual Property is briefly discussed below:

PROBLEMS IN PATENTING NANOTECHNOLOGY INVENTIONS

Nanotechnology have posed more problems and caused number of complex situations in patenting. The lack of expertise, capabilities and resources pose difficulties for the patent applicants and officials of patent office. Nanotechnology innovations are of multidisciplinary nature and multi-industry applications like physics, chemistry, biology, electronics, communication, energy etc. e.g. Carbon nanotubes have applications in electronics, energy, medicines etc. while Dendrimers are useful for medical, electronic and chemical industries.

The multidisciplinary and multi industry application of Nanotechnology fosters creativity and new approaches to technical challenges, the same poses challenges to the court and officials in determining patentability of Nanotechnology inventions.

The patent office's need to address which context is appropriate across many disciplines and industries incorporate all of them in decision making.

BROAD CLAIMS AND PATENTS ON BASIC INVENTIONS

An analysis of Nano patents show that many of them contain claims that are too broad, some very broad claims have been with respect to carbon nanotube patents- carbon nanotubes are tiny structures made up of rolled up layers of interconnected carbon atoms which may be classified as multiwall or single walled carbon Nano tubes.

Fall out of such broad claims has been patenting of inventions bordering closely on discoveries and patent on basic inventions or building block patents. This may lead to growth of patent thickets impeding downstream research in Nanotechnology which may lead to fragmentation of patent landscape. For country like India, the existence of such thickets and high licensing costs will have to be paid to the multiple patent holders would be a serious road block in developing domestic capacity.

DIFFICULTIES IN FULFILLING THE PATENTABILITY

In India patent is a product or process involving an inventive step and capable of industrial application. Inventive step is 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 non-obvious to a person skilled in the art. It is generally accepted that the properties of matter and other fundamental scientific discoveries are not patentable. An initial challenge for patent strategies is to determine how to obtain patent coverage that is based on discovery of inherent properties of materials. Simply submitting a

smaller version of a known structure would not be considered patentable without additional novelty or utility. Section 3(d) of Patent Act, 1970 and the explanation attached to it deals with the same. In India section 3(d) is likely to be problematic for Nanotechnology patents. Policy intervention will be needed in future to deal with Nanotechnology patents exclusively.

CHALLENGES IN REGULATING NANOTECHNOLOGY

Patent law is the primary area of law concerning technology. Patent system face great challenges in handling inter-disciplinary nanotechnologies consistent with their traditional core mission. These difficulties make it likely that any attempt to protect against uncertain human health and environmental risk, a task no patent system has ever successfully accomplished is likely to be particularly futile in case of Nano technological inventions. Potentially dangerous nanotechnology inventions raise a slightly different issue. Nanotechnology generally does not implicate immoral or illegal activity but whether an invention presents a safety risk, either to human health or to the environment. Although precedent in this area is sparse, such issues have been raised in patent cases occasionally. There are some statements in a couple of opinions indicating that the safety of an invention could raise utility concerns theoretically which is one of the basic requirements for grant of patent. [*Regulating nanotechnology through Intellectual Property rights*- Gregory N. Mandel, *see reference no*.7]

Nanotech products have come to market in the absence of public awareness and regulatory oversight. One concern is that the increased reactivity of nanoparticles could harm living tissue, perhaps by giving rise to "free radicals" that may cause inflammation, tissue damage or growth of tumours. Nanoparticles can be inhaled, ingested or pass through the skin. Once in the blood stream, nanoparticles can elude the body's immune system such as the blood-brain barrier. The very same properties that make engineered nanoparticles so attractive for development of targeted drug delivery systems- namely, their mobility in the blood stream and ability to penetrate cell membranes could also be qualities that make them dangerous.

The most important questions in the short term will be issues relating to patents. Biotechnology and pharmaceuticals are two segments of the industry that stand to gain a great deal from nanotechnology because treatments or even cures for many of the virulent illness may be possible through nanotechnology. Generic drug makers can cut a huge amount of cost by avoiding this and going directly to market, creating unfair competition if a patent does not block them.

Generic drug manufacturers such as Cipla in India produced the drugs for a fraction of cost, making it possible for Brazil to implement anti-AIDS programme. The patent-holders objected and tried to block generic makers. They claimed that they could not continue to research new drugs if they were not allowed to recover their costs. The question that arises is, if ever, public health and benefit should be prioritized above patents and other restrictions. If nanotechnology starts to deliver treatments for cancer or even all purpose frameworks for anti-viruses, these questions will be become paramount.

Nanotechnology has already excited many with its defense and weapons applications. But the flip side of super strong nanomaterials such as nanotubes is predominately carbon based. This means that they cannot be detected using metal detectors or chemical "sniffers". The only way to catch a person smuggling such a weapon would be exhaustive personal searches.

Futurist concerns arise from Nano-computation such as quantum computing, DNA computing and Nano-electronic computing may help unlock true artificial intelligence. But then the questions that will arise out of it will be how to treat artificial intelligence? The problem of self replication, if interfaces between humans and computers improve to a stage where they are hard to differentiate, the result it will have on human civilization and so on. The implications for national security and for personal privacy cannot be overstressed.

All these questions need to be tackled through discussion and debate by involving not only scientists and engineers but also thinkers, ethicists, lawyers, theologians and politicians as well.

CONCLUDING REMARK

As an emerging science, nanotechnology promises the Nano-scale manufacture of materials and machines made to atomic specifications. It is a field at the junction of chemistry, physics, biology, computer science and engineering. The impact of nanotechnology on our way of life is believed to reach profound and unimagined levels in the coming decades. The cross fertilization of technology is likely to lead to greater co-operation in the form of alliances and acquisitions among academic institutions, private companies and government. Science and Technology Policy 2003, reiterates India's commitment to participate as an equal and vigorous global player in generating and harnessing advances in science and technology for the benefit of all human kind. Therefore efforts should be to ensure that the Intellectual Property rights granted to the innovator's through various legislations relating to Intellectual Property Rights regime should be utilized so that science and technology uplifts the Indian people in particular and indeed all humanity in general.

The issue of control and ownership of nanotechnology is a vital issue because a single nano-scale innovation can be relevant for widely divergent applications across all industry sectors. In nanotechnology, current issues in patenting such as broad claims, basic inventions, and patentability criteria arises applications. This creates technical challenges to the officials of patent office, which at times results in refusal to the grant patent to nanotechnology innovations. The impact of which might be reduction in R& D Activities relating to nanotechnology based innovations. Moreover, the issue of emerging nanotechnologies and the potential impacts on the health, safety, environment and bio-diversity need to be studied. The regulatory discussions should include apart from the above issues, the broader socio-economic impacts, control and ownership of nanotechnologies.

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