scripted

Volume 6, Issue 2, August 2009

Legal Aspects of Nanobiotechnology Inventions: An Indian Perspective

Kanika Sharma and Archana Chugh[*]

Abstract

Nanobiotechnology results from the convergence of nanotechnology and biotechnology. It has a remarkable potential to abate problems and provide efficient solutions related to medicine, the environment, agriculture etc. Nanobiotechnology applications have had a remarkable global impact, especially in European countries and the United States of America. In India, the field holds immense importance particularly in the nanomedicine sector. The arrival of nanobiotechnology in India has raised a series of questions and challenges in terms of intellectual property protection. Therefore, it is of immense significance to analyse critically whether the Indian patent regime provides a proper environment for suitable intellectual property protection and commercialisation of nanobiotechnology in India.

[This article was presented at the SCRIPTed 'Governance of New Technologies' conference held in Edinburgh on 29-31 March 2009.]

DOI: 10.2966/scrip.060209.433

[*] Final year law student, Rajiv Gandhi School of Intellectual Property Law (RGSOIPL) and Assistant Professor, RGSOIPL, respectively.

1. Introduction

The "knowledge era" has witnessed a cascade of technological developments where each technology has significantly contributed in providing impetus for emerging technologies. Nanotechnology is one such novel and revolutionary branch of technology, where reduction in size has demonstrated magnificent results. Intersection with the field of biotechnology has given rise to nanobiotechnology. Involvement of living forms and the potential to meet human necessities have raised issues that are unique to nanobiotechnology. Nanobiotechnology has been defined in several ways, for example as "an interdisciplinary field of research and development that integrates engineering, physical sciences, and biology through the development of very small physical and biological devices using biomimetically inspired nano-fabrication techniques".[1] "Nanobiotechnology encompasses a wide range of applications on the molecular scale at the interface between the chemical, physical and biological sciences."[2]

1.1. Applications of Nanobiotechnology

Nanobiotechnology has several significant universal applications in the field of medicine, food and agriculture and environment and biodiversity conservation. For instance, the nanoparticles – due to their small size – have proved to be more efficient, target specific, water soluble[3] and stable tools in drug delivery compared with the conventional routes of drug administration. Carbon nano tubes provide better standards of food storage by inhibiting the growth of microbes. Nanosensors and nanofilters offer the prospect of a clean and healthy environment. As evident from these examples, nanobiotechnology aims at increasing health by introducing advances in therapeutics, diagnostics, surgery, etc by virtue of bio principles, modelled in a nano frame, at a nanoscale. Examples include nanotube syringes, polymer nanospheres, nanocrystals, nanocarriers for macromolecules etc.

However, plentiful applications of nanobiotechnology alone cannot establish the viability of the technology. The other key features required for a technology to achieve success include socio-ethical acceptability, economic feasibility and an intellectual property component which give it a commercial impetus. Nanobiotechnology is one such technology that needs attention in terms of the described parameters due to its strong association with the living organisms and, in

---

[1] Nano2Life – European Network of Excellence in Nanobiotechnology, " Nanobiotechnology of Biomimetic Membranes" (2006) available at http://www.nano2life.org/paper_of_month.php?pid=14 (accessed 30 Jun 09).

[2] The Royal Society and Royal Academy of Engineering, "Nanoscience and Nanotechnologies: Opportunities and Uncertainties" (2004) available at http://www.nanotec.org.uk/report/Nano%20report%20fin.pdf (accessed 27 Jul 09).

[3] R Bawa, "Nanoparticle-based Therapeutics in Humans: A Survey" (2008) 5 *Nanotechnology Law and Business*, 135-155.

particular, human welfare. Dilemmas persist with respect to defining nanobiotechnology whilst determining its scope and limitations. Nanobiotechnology has a futuristic character, where concrete results are required to support its admissibility. Due to diverse applications in the field of human welfare, it has caught the eye of the world at a very elementary stage which might give rise to social, ethical, economic and legal issues. Commercialisation of technology has intensified the need to siphon huge funds to conduct research, train manpower and human resources, ensure the application of regulatory and safety guidelines, whilst providing adequate patent protection. Biotechnology and nanotechnology have experienced patenting obstacles due to legislative and procedural ambiguities. It is, therefore, interesting – as well as challenging – to consider how the Indian patent regime will deal with the multidisciplinary dimension of nanobiotechnology.

The present paper focuses on representing the current scenario of nanobiotechnology in India in terms of identifying the challenges involved in the patenting of nanobiotechnology in light of obviousness and prior art. It also aims to analyse critically the nebulous provisions of the Indian *Patents Act 1970*, regarding the patenting of nanoparticles, their therapeutic and diagnostic uses and the methods of their administration. Besides comparative study of the patent laws of various countries concerning nanobiotechnology, other pertinent issues such as the adequacy of the Indian patent system for the protection of nanobiotechnology, amendments or flexibilities required in patent system for the interpretation of a nanobiotechnology patent in the right perspective will be also considered.

2. Legal Framework

The connotation of a legal framework is an "umbrella" cover, under which it has laws concerning issues such as the environment, food and drug regulation, and health and safety laws that are crucial in addressing legal disputes accruing from nanotechnology. Intellectual property protection cannot be considered in isolation as it forms an integral part of a well-knit web of other related laws. Nanoparticle toxicity remains one of the major concerns of nanobiotechnology, making it crucial to analyse the patenting issues in nanobiotechnology in close relation with other relevant laws. A brief comparative analysis of such laws across the United States of America and Europe would present an insight into their law, regulations and risk assessment of this technology.

In India, the *Insecticide Act 1968* does not explicitly encompass the term "nano" – leaving open the scope for condoning the health implications caused by the toxicity of nanoparticles. It does, however, make provision for toxic substances. In India, certain health provisions are dispersed under various laws – primarily the *Factories Act 1948* and the *Employees' State Insurance Act 1948*. Among major institutions, the National Institute of Pharmaceutical Education and Research (NIPER), focuses on "nanotoxicity" and is working towards framing regulatory guidelines. It further aims to set standards that can be employed to test nanotoxicity in nanomedicine.[4]

---

[4] J Mathew, "NIPER Developing Regulatory Guidelines for Nanomedicine" (2004) available at http://www.pharmabiz.com/article/detnews.asp?articleid=36215&sectionid=19 (accessed 25 Jul 09)

The United States of America has a *Toxic Substance Control Act 1976* (TSCA)[5] in place for the control of toxic substances and Occupational Safety and Health Administration (OSHA) is the body that monitors issues of occupational safety. The Food and Drug Administration in the United States of America has set up the Centre for Drug Evaluation and Regulation (CDER), which aims at framing guidelines for safety analysis of nanobiotechnology products.[6] Recently, the International Center for Technology Assessment (ICTA) petitioned the Environmental Protection Agency (EPA) to regulate the use of silver at nano scale under the *Federal Insecticide, Fungicide and Rodenticide Act 1947* (FIFRA).

2.1 Patent Law Regime

Innovation promotes market growth via enhanced competition and thus forms the basis of the economics of a patent system. In a market without a patent system, the effort, technical know-how and monetary investments of the few would be misappropriated by many. This can rapidly bring stagnation in the market and might block its expansion, finally resulting in market failure.

A patenting system appears to be a multifarious solution to such hindrances. The prospect theory of patents suggests that patenting in major technological areas provides directional assistance to the follow-up inventions, thereby reducing the possibility of wasteful inventions.[7] Schumpeterian theory suggests that innovation propels and lends dynamism to the economy that would be otherwise stagnant. Schumpter – also known as the father of economy of "technological innovation" – invites the inculcation of competition in this effort for technological growth. The jurisprudence of intellectual property law is based on the incentive/utilitarian theory complemented by others such as the Locke's labour theory on property. Rights derived from intellectual property are granted to the person to manifest the ideas emanating from his intellect. This is applicable for a specified term, in exchange for disclosure to the public. Knowledge is dissipated and contributes significantly towards evolution of the technological world. Additionally, the huge expense which commercialisation of a product demands is returned fairly to the inventor.[8]

The patent system derives its roots from the crying need for incentives for innovative research, imparting knowledge to the people and technology transfer. Important elements that are under consideration while patenting a technology are the criteria and subject matter. Statistics[9] suggests that out of the total nanotechnology patents across

---

[5] 15 USC §2602- §2628.

[6] N Sadrieh and P Espandiari, "Nanotechnology and the FDA: What are the Scientific and Regulatory Considerations for Products Containing Nanomaterials?" (2006) 3 *Nanotechnology Law and Business,* 3.

[7] E Kitch, "The Nature and Function of Patent System" (1977) 20 *Journal of Law and Economics*, 265-267.

[8] E Verkey, *Law of Patents History and Philosophy, Intellectual Property: A Canter through the Ages* (New Delhi: Eastern Book Company, 2005).

[9] OECD Report "Compendium on Patent Statistics" (2008) at 17, available at http://www.oecd.org/dataoecd/5/19/37569377.pdf (accessed 25 Jul 09).

the world, the United States of America has made the highest contribution of 41.8%, followed by Europe with 25.4%. BRIICS (Brazil, China, India, Indonesia, The Russian Federation and South Africa) has contributed 2.6%. As far as the field of contribution to the total number of nanotechnology patents is concerned, 14.8% are contributed by medicine and biotechnology. As will be described in the following sections, extensive research in nanobiotechnology in other jurisdictions and their respective patent provisions, issues, ambiguities in legal provisions, amendments etc, may act as relevant precedence for India to review its patent law – in order to make it more flexible and conducive for the nanobiotechnology patent applications. The criteria for patentability essentially consists in factors such as the novelty, non-obviousness (as known in the United States of America) or inventive step (as known in other countries like European Union and India) and utility (in the United states of America), capable of industrial application (India) or susceptible to industrial application (European Union) with written description and enablement requirements (Table 1, below.)

2.1.1 Novelty

As suggested by Table 1, the first criterion for which a patent application is scrutinised considers whether or not the invention is novel. Novelty may have an absolute, relative or territorial nature. India follows the absolute novelty norm. Presence of any prior art relevant to the invention in form of previous publication[10] anywhere in the world, previous communication to the government,[11] prior public use in India, public display,[12] public working,[13] prior knowledge (oral or otherwise) is screened to confirm or deny the newness of the invention. In the Indian *Patents Act 1970*, section 2(j) lays down the novelty criteria that pose challenges to emerging technologies – especially nanobiotechnology – which is considered to be a mere reduction in size of existent inventions. The *Manual for Patent Practice and Procedure of India* suggests that the anticipatory disclosure should be contained in one single document. Novelty has been defined and standards have been laid down in various court judgments like in the case of *Monsanto Company v Coramandal Indag Products*,[14] where the invention was found to be anticipated by public knowledge of the formula by virtue of its publication in an international journal. In an another case, *Kay Laboratories, Bombay v Hindustan Lever Ltd*,[15] the process for preparing plant growth stimulant was alleged to be anticipated by prior publication. Nanobiotechnology inventions are problematic in two ways. Firstly, they are anticipated by prior art – they are thus not considered as novel due to the pre-existing technologies from which these are believed to derive. For example, traditional medicines (such as ayurvedic preparations which make use of nanoparticles) are believed to be present in the public domain. Secondly, they fail to meet the threshold

---

[10] *Patents Act 1970*, s 29.

[11] *Ibid,* s 30.

[12] *Ibid,* s 31.

[13] *Ibid,* s 32.

[14] AIR 1986 SC 712.

[15] 1988 PTC 31Mum.

of inventive step and can be also rendered non-obvious on the basis of being a consequence of mere reduction in size.

Interestingly, in India, Ayurveda is a popular alternative, traditional medicine system which has been shown to have a superimposition with modern day nanomedicine in certain applications. It is believed that the Ayurvedic bhasm which is used to treat diseases composes of various metal nanoparticles that aid in effective medical treatment of a disease. The recent nanobiotechnology is a mere effort in the direction of unfolding such archaic compositions. In December 2007, an international conference on ayurvedic bhasm and nanomedicine was organised in in the Biotech Park, Lucknow, India, to give effect to research collaborations between India and the United States of America[16] in this regard. Although several conferences and seminars on nanotechnology have been held in India in the past, this conference is regarded as the first step towards recognition of nanobiotechnology in India. It is noteworthy that the traditional medicine born out of Ayurveda has to its merit 20 patents granted in India.[17]

In the United States of America, 35 USC §102 discusses novelty and loss of rights and stipulates that an invention is considered to be anticipated by knowledge or use in the United States of America, by publication anywhere in the world or public use or sale in the United States of America not more than one year prior to the application for patent in the United States of America. This is a grace period which is unlike that in India. The landmark cases with respect to "*novelty*" in the United States of America include *In re Best*,[18] where the Court held that where the United States Patent and Trademark office (USPTO) alleges identity with the relevant prior art, the burden of proof is on the applicant to prove that there is no such similarity. In another case, *In re Spada*,[19] it was held that, by showing the differences between claimed invention and prior art, a *prima facie* case of obviousness can be rebutted.

The novelty criteria set up by the European Patent Convention (EPC) renders any state of art made available to the public by oral or written description or use or any other form prior to the patent application.[20]

2.1.2 Nanobiotechnology Classification

Apart from the pre-existing nature of the technology, another challenge is posed by the interdisciplinary nature of nanobiotechnology. The state of art is more likely to be scattered across various disciplines. In consequence, it does not satisfy the requirement of being present in one document. This problem can be dealt with to an extent by developing a classification system for nanobiotechnology. The Indian patent

---

[16] "International Conference on Ayurveda Bhasm and Nanomedicine, at ACS – Bioinformatics" available at www.ascbioinformatics.com/index.html (accessed 13 Mar 09).

[17] http://www.ccras.nic.in/PatentsObtained/20081031_PatentsAndProcesses.htm (accessed 13 Feb 09).

[18] 562 F.2d 1252, 1255, MPEP 2112.01.

[19] 911F.2d 705, 709.

[20] *European Patent Convention 1973*, Article 54.

system still lacks its own proper classification code for nanotechnology, with nanobiotechnology as its subclass.

USPTO has classified nanotechnology in class 977 under 35 USC §8, "Classification of Patents" whereas the European Patent Office (EPO) has carved out a Y01N tag for nanotechnology. A more specific, Y01N2 tag has been devoted to nanobiotechnology. Under the International Patent Classification, nanotechnology is placed under B82B class.[21] Unlike the nano classifications developed in US and EU patent regime, the absence of a nanobiotechnology patent classification system in India makes patent landscaping cumbersome and patents may be issued without divulging the invention area as "nanobiotechnology". This affects future patents in the field.

Further, such challenges increase the onus on the examiner considering the patent applications: the dearth of skilled, aptly-qualified and trained examiners may result in the granting of poor quality patents. In India, there are 133 examiners from diverse technical backgrounds, for example twelve from biotechnology, five from computer science, twelve from electronics and telecommunication engineering, and none from nanotechnology.[22] This problem can be circumvented by the generation of human resource and manpower in this emerging area of technology.

2.1.3 Generation of Human Resources Skilled for Nanobiotechnology Inventions

Institutes like the Life Science Foundation of India have recently introduced a diploma course in nanobiotechnology – advertised in Current Science,[23] a leading national journal of science. Several other universities are providing post graduate level (MTech) courses in nanotechnology (e.g. the Indian Institute of Science, National Chemical Laboratory at Pune and the Indian Institute of Technology at Mumbai, Kanpur, Chennai, Guwahati and Delhi, etc).[24]

To add to the apathy of nanobiotechnology patents is the paucity of databases that consolidate all of the dispersed prior art which is likely to be relevant. Development of such databases by the nanobiotechnology experts – coupled with periodic update of the present databases such as "ekaswa A" and "ekaswa B" ("ekaswa" means patents in Hindi) – would certainly aid in propelling a better examination system. This could have a significant role in structuring the nanobiotechnology invention-based patents.

2.1.4 Inventive Step/ Non-obviousness

The second criterion that the patent application is required to meet involves non-obviousness or inventive step (see Table 1, below). In the Indian patent law,

---

[21] Available at http://www.wipo.int/classifications/fulltext/new_ipc/ipc7/eb82b.htm (accessed 25 Jul 09).

[22] *Annual Report of the Office of the Controller General of Patents, Designs, Trademarks, Geographical Indications Intellectual Training Institute and Patent Information System, India* (2006-2007).

[23] "Nanobiotechnology Course: Life Science Foundation India" (2008) 95 *Current Science*, 417.

[24] Available at http://www.indiaedu.com/career-courses/nano-technology-courses/ (accessed 25 Jul 09).

"inventive step" is defined under the *Patents Act 1970,* s 2(ja).[25] Non-obviousness is more crucial and likely to pose obstacles in patenting for nanotechnology in general. In the United States of America, non-obviousness is dealt with under 35 USC§ 103 and has been established by a series of cases beginning from the *Graham's Triology* – derived from three cases[26] – and has been discussed recently in *KSR v Teleflex.*[27] Apart from these cases, the first case that raised the question of non-obviousness with respect to nanotechnology is that of *In re Kumar*,[28] where the Board had held the claimed invention of "aluminium oxide particles" as unpatentable because it was obvious in view of a prior patent (the Rostoker Patent). The Board opined that there was an overlap between the particle range of Rostoker patent (5-15nm) and Kumar's patent (4-16nm (claim 19)). The petition was vacated.

In Europe, the question of inventive step was raised in case T0070/99,[29] which involved flow cytometry using a device bearing micro-size pores. It was alleged that the device lacked novelty and involved a mere reduction in size deriving from already existing technology. It was thus held to be obvious or in lack of an inventive step.

In terms of inventive step, India's patent law provisions are much closer to European patent law provisions (Article 56) than those in United States of America.

2.1.5 Capable of Industrial Application

The third criterion for patentability is whether the subject is "capable of industrial application" according to the Indian *Patents Act 1970*, s 2(j). It may initially seem that this criterion would pose no problems for the patenting of nanobiotechnology inventions. On analysis, however, it is clear that utility is very crucial for nanobiotechnology-based inventions. Nanobiotechnology falls under the class of "unpredictable" arts like biotechnology – one of its predecessors. There is the possibility of huge variation in the laboratory results and actual results when technology such as nanobiotechnology is put to use. In the laboratory stage, it is not possible to determine the possible impact of external factors on products born out of a technology. Inoperability of such products may render them non-patentable as they would fail to comply with the utility requirements.[30] In addition, the problem solving approach applied in both Europe and India would render them as not being inventions (thus rendering the problem insolvable). The case of *EMI Group North America Inc* v

---

[25] *Patents Act 1970*, s 2(ja) states that an "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both that makes the invention not obvious to a person skilled in the art.

[26] *Graham v John Deere,* 52 US 248 (1851); *Calmer Inc v Chemical Co,* 383 US 1 (1966); *United States v Adams,* 383 US 39 (1966).

[27] *KSR v Teleflex,* 550 US 398 (2007).

[28] 418F.2d 1361 (Fed. Cir. 2005).

[29] *Trustees of The University of Pennsylvania v Affymetrix, Inc.* (Case T0070/99) decided on 23 Jan 03 by the Boards of Appeal of the European Patent Office.

[30] D Almeling, "Patenting Nanotechnology: Problems with the Utility Requirement" (2004) *Stanford Technology Law Review,* N1, available at http://stlr.stanford.edu/STLR/Articles/04_STLR_N1

(accessed 27 Jul 09).

Cypress Semiconductor Corp[31] provides a better insight into the requirement. The applicant claimed a patent for an invention that lacked utility. The invention in question was a vapour-induced explosion mechanism.

In the United States of America there is an analogous requirement – namely the "*utility*" requirement as under 35 USC § 101. In terms of this section, India differs both from United States of America (which has the term "utility" instead of capable of industrial application) and Europe (which employs a standard of "susceptible to industrial application"). Consequently, the scope and, hence, effect of these similar provisions may vary. For instance, utility can be categorised as specific and substantial utility or credible utility, whereas the Indian patent system does not deal with such aspects explicitly.

2.1.6. Patentable Subject Matter

The *Patents Act* 1970, section 3 lists inventions that are not patentable. The major provisions that are relevant within the area of nanobiotechnology in the Indian *Patents Act* 1970 include sections 3(b),[32] 3(d)[33] and 3(i).[34] The high permeation ability of nanoparticles in the bodies of humans and animals can result in more environmental damage is caused by nanobiotechnology than any other known technologies (nanotoxicology). The Indian *Patents Act 1970,* section 3, may also form a barrier to nanobiotechnology-based patenting due to speculations about nanotoxicity caused by the use of nanoparticles. As an instance, the case of *Plant Genetic Systems/Glutamine Synthetase Inhibitors*[35] involved an invention where genetic engineering was applied to plants to render them herbicide resistant. It was held that the unchecked use of technology to alter natural traits which caused prejudice to other living organisms and adversely affected the environment was not patentable.

Also, nanobiotechnology has to be analysed in the light of environmental jurisprudence across various jurisdictions. The Indian constitution provides for a right to life under Article 21. The article is very broad and capable of imbibing various related rights including the right to live in a healthy and wholesome environment as

---

[31] 268 F.3d 1342 (Fed. Cir. 2001).

[32] *Patents Act 1970,* s 3(b) states that an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.

[33] *Patents Act 1970*, s 3(d), amended by Patents (Amendment) Act, 2005 states that the mere discovery of a new form of a 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 for 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.

Explanation – for the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

[34] *Patents Act* 1970, s 3(i) states that any process for the medicinal, surgical, 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 products.

[35] [1995] EPOR 357.

has been laid in a series of cases.[36] The "polluter pays" principle[37] and the "precautionary" principles[38] governing the environment have been judicially recognised in the form of precedent for future issues arising from conflicts between the environmental implications of technologies such as nanotechnology and the right to a healthy environment. The Indian *Patents Act 1970*, section 3 also renders inventions non-patentable on moral grounds.

For example, when a miniscule chip is slid into the body for the purpose of monitoring a tumour and/or to control its growth, a constant surveillance is apprehended. This threatens the right to privacy. Such issues are likely to cloud over the possibility of patenting such inventions. The same has been held in the Harvard oncomouse case.[39]

With regard to Indian *Patents Act 1970*, section 3(d), the ambiguity resides in the "particle size" being included in non-patentable subject matter. In case of nanobiotechnology, the novelty of technology is substantially derived from the reduction in size. The foremost ambiguity is lack of a universal definition of nanobiotechnology. The word "nano" encompasses inventions of 100nm in size or smaller. The pharmaceutical industry – likely to be the biggest beneficiary sector from nanobiotechnology-aided research – is based on drug targeting. Nanoparticle efficacy or accuracy of methods using nanoparticles for drug delivery is significantly governed by particle size which may vary as different drugs are effective with different particle size. Therefore, fixing a size limit of 100 nm may rule out the patenting of such particles under the "nano" regime. Interestingly, such provisions in other jurisdictions are not expressly present. In India, the first case (though not specific to nanobiotechnology) has brought section 3(d) or the Indian *Patents Act 1970* to the notice of practitioners, researchers and the public. In *Novartis AG v Union of India*,[40] the constitutional validity of this subsection under Article 14 (equality before law) was the bone of contention. The issue was the lack of a standard for determination of the efficacy and quantification of enhancement of efficacy. Section 3(d) of the Indian *Patents Act* 1970 is a unique provision. It is difficult to compare this section to the law of other jurisdictions as it considers particle size change to be same unless the properties differ significantly with regard to efficacy.

However, non-patentable inventions have been described under Article 53(a) of the EPC 1973.[41] Similar provisions also find a place in Article 27(2)[42] of the Trade

---

[36] E.g. *Virender Gaur v State of Haryana,* 1995(2) SCC 577.

[37] *Indian Council for Enviro Legal Action v Union of India (Bicchri case),* AIR 1996 SC 1446.

[38] *Vellore citizens' Welfare Forum v Union of India,* AIR 1996 SC 2715.

[39] *Harvard Oncomouse* [1991] EPOR 525.

[40] (2007) 4 MLJ 1153.

[41] The article states that inventions the publication or exploitation of which would be contrary to "*ordre public*" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

[42] Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of 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 their law.

Related Aspects of Intellectual Property (TRIPS). "*Ordre public*" has been derived from French law and is present in the Anell and Brussels Draft respectively.[43] In the United Kingdom, the case of *Ivax Pharmaceuticals UK Ltd v Akzo Nobel*[44] considered a polymorphous steroid (tibolone) which was used for hormone replacement therapy in women. It was found to exist in more than one crystalline form. Akzo claimed three subsequent patents on the steroid – the third patent involved a change in particle size of the subject of the prior patent claim. Ivax alleged a lack of novelty and obviousness.

Analysing the case in Indian patent regime set up, same would be rendered unpatentable unless the particle size differed in its properties with enhanced efficacy. Since nanomedicine is the biggest sector of nanobiotechnology, patentability of drugs would revolve around reduction in particle size to ensure better efficacy, such contraventions with provision 3(d) is likely to occur. In another example, Abbott Pvt Ltd was selling the HIV drug Kaletra under brand name "alluvia". To overcome the storage problems of the drug, Abbott claimed a heat-stable form of the same drug. A pre-opposition has been filed by the organization known as Initiative for Medicines, Access and Knowledge, in terms of the Indian *Patents Act 1970*, section 3(d).[45]

Further, some applications of nanomedicine include nano syringes for drug release and injection of the substance in the cell. Nano-engineered prosthetics enhance the biocompatibility of artificial bones. Nano detectors detect slightest signals associated with malignancy. Nano vectors can carry chemotherapeutic drugs to tumour sites. Nano crystals can be tagged to proteins/DNA for their identification and localization in pathways. Nano chips can control delivery of drug dosage. Nano carriers can be used in gene therapy. Nano pore sequencing can be employed in the detection of single nucleotide polymorphism and the diagnosis of pathogens. Nanoimplants can replace damaged sensory organs. As described earlier, in order to be classified as "nano", the size has to be less than 100 nm.[46] In the field of nanomedicine, sometimes a better efficacy is obtained with a molecule larger than 100 nm but less than 1000 nm (mathematically, 1 micron = 1000 nm). In such situations, it becomes challenging to classify them as nanopharmaceuticals. Nanoparticles – due to their small particle size and proportional increase in surface area – enhance the solubility in blood and bioavailability, thereby abating the need for adjuvant or co-solvents and reducing the dosage. The presence of nanoparticles prevents biochemical reactions of the drug. Additionally, the exposure time to the drug is also prolonged. Innovation in nanomedicine mainly focuses on the delivery methods that make use of the above

---

[43] UNCTAD-ICTSD, *Patents: Ordre Public and Morality*, (Cambridge: CUP, 2005), at ch 19.

[44] [2006] EWHC 1089 (Ch).

[45] R Mukherjee, "Booster Shot: US Body Opposes Abbott's Patent in India, Europe" (2007) available at http://www.articlearchives.com/pharmaceuticals-biotechnology/pharmaceuticals/1670476-1.html (accessed 27 Jul 09).

[46]The term nanotechnology covers entities with a controlled geometrical size of at least one functional component below 100 nanometres 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 (EPO definition), available at http://www.epo.org/topics/issues/nanotechnology.html (accessed 25 Jul 09).

described inherent properties of nanoparticles or nanocarriers. This improves the administration of drugs. It is speculated that established players in the pharmaceutical sector would make use of these nano-based novel drug delivery systems in conjunction with drugs whose patents have expired, thereby introducing new products. Such acts would restrict the entry of generic players in the market.[47]

Some of the nanotechnology patents by Indian entities include those for: development of one dose a day of ciprofloxacin using nanotechnology; tumour-targeted taxol delivery in the Phase II clinical trial stage; improved ophthalmic delivery using smart hydrogel nanoparticles**;** oral insulin formulation using nanoparticle carriers; liposome based Amphotericin B formulation; first produced smart hydrogel nanoparticles for drug delivery applications (US Patent 5847111); tumour-targeted delivery of Taxol using nanoparticles (US Patent 6,322,817); inorganic nanoparticles as non-viral vectors for targeted delivery of genes (US Patent 6555376), etc**.**

It is to be noted that India and Europe do not permit the patenting of therapeutic, surgical and diagnostic methods. Recently, amendments have been proposed for the European patent law in this regard (dealt in detail in the later section). Its reflection in the Indian Patent regime is awaited. Section 3(i) of the Indian *Patents Act 1970* deals with the medical exclusion or exemption of medical method patents similar to that under Article 27.3(a) of TRIPS, which reads that members may also exclude from patentability: "... diagnostic, therapeutic and surgical methods for the treatment of humans or animals".

The Indian medical and healthcare industry has seen a boom in the product patent regime. Medical devices are patentable primarily because it is believed that medical devices involve huge cost of production and great degree of precision is required, however, medical methods are not patentable, though, both the cost and the technology involved demands for patentability. The medical process patent regime is in urgent need of consideration since the cost of production of a new therapeutic, surgical or diagnostic method – and the time spent in developing a new method – are both much less than the costs involved in producing a drug with high therapeutic efficacy. Both of these factors contribute to enticing investments in the areas where either the government funding is lacking or diseases are less common.

In the modern world, the advent of novel technologies such as nanobiotechnology has influenced to a greater extent the patentability issues involved in medical method patents. The fear that dominant players with patented drugs may extend their presence in the market beyond the patent term by taking patents over several methods of administration of drugs would persist. As can be explained in case of a nanoparticle used for drug administration, there is a possibility of multi-patenting. The patent may be over the process of preparing the nanoparticles; the nanoparticles themselves; the process of transfer of these particles into the patient's body; the medical devices used; and the processes of the nanoparticle. The pertinent question is the distinct classification of methods as medicinal, surgical, curative, prophylactic, diagnostic and therapeutic and the subject matter that each of them encompasses. Cosmetic methods are another category about which the Indian *Patents Act* is silent. There also exists

---

[47] D Harris et al, "Strategies for Resolving Patent Disputes over Nanoparticle Drug Delivery Systems" (2004) 1 *Nanotechnology Law and Business,* 1-18.

ambiguity regarding whether cosmetic methods are included in any of the above-mentioned processes. It is argued that exempting medical methods from the purview of patentability is, on the one hand, in favour of public policy, whereas, on the other, allowing patents in this field would draw unwarranted ethical, moral and practical problems and may also fail to fulfil the industrial applicability criteria. It is contended though that such medical methods by their character are not industry-specific but human- or animal-specific. The argument that their patentability should be restricted on the grounds of non-compliance with the industrial applicability criteria is therefore negated. The recent trend suggests that the doctors who get patents over medical methods enforce them against the companies who manufacture medical devices[48] as in the case of *Medtronic v Michelson*,[49] where there was a breach of contract by the defendants.

In the United States of America, under 35 USC § 101, a patent may be obtained for any new and useful process, machine, manufacture or composition of matter. Accordingly, the patentability of medical method patents is not excluded. It is also contended that medical and surgical methods may be placed in the category of a process – an art which is a patentable under 35 USC § 101.[50] But in the United States of America and other jurisdictions where medical methods are patentable, the number of patents granted is relatively small because of challenging enforcement issues. It is difficult to monitor infringement in cases of medical method patents, as the use of such patented methods is not easy to assess. Even the patients are not aware of the methods used due to confidentiality of documents that are, anyway, silent on the methods being used.[51]

The debate began with the case of Dr Samuel Pallin, who claimed to have made a "V"-shaped self healing incision which he subsequently patented. Later, Dr Pallin sued Dr Singer for infringement of his patent. Interestingly, maximum medical method patents that are being filed in the United States of America and Australia[52] are by foreign nationals as they are unable to seek similar patent protection in their own countries. Therapeutic methods are also excluded from patentability whereas non-therapeutic methods are not. In cases where both therapeutic and non therapeutic methods are not severable from one another, the method is rendered as non-patentable. The methods used to diagnose human or animal conditions may be termed as diagnostic methods irrespective of whether such a condition strictly falls into that category. Diagnostic methods may be of two types:

- Those practiced on a living body; and
- Those whose performance takes place outside the body.

---

[48] T Baldas, "As Medical Patents Surge, so do Lawsuits" available at http://www.law.com/jsp/article.jsp?id=118457679163116 (accessed 25 Jul 09).

[49] No. 01cv2373 W.D. Tenn. (2005).

[50] *Martin v Wyeth Inc,* 96 F. Supp 689 at 695 (D.Md. 1951).

[51] S Miller, "Should Patenting of Surgical Procedures and other Medical Techniques by Physicians be Banned?" (1996) 36 *The Journal of Law and Technology*, 255-272.

[52] L Storer, "Medical Method Patent Litigation Polarises the Medical Community" (2008) available at http://www.veintherapynews.com/content/view/101/2/ (accessed 25 Jul 09).

Although review is demanded of diagnostic methods which do not involve the human body, diagnosis under *in vitro* condition may be patentable. In the case of surgical methods not restricted to operation; its ambit extends to cover the manipulation, relocation and transformation of the body structure. Methods giving way to such effects are not patentable. Similarly, with surgical methods, no distinction is made between minor or major surgery. Repositioning is also said to be a surgical method.

Europe bars patentability of medical method patents under Article 54(4), but recent amendments regarding patentability of medical methods have been suggested. Amendments primarily focus on the diseases related to psychiatry and the elderly. Such methods may be patentable under Article 52(5), provided the cost of development is over 25000 Euros. The setting up of an Ethics Committee was also suggested to gain a deeper insight into the ethical issues which might likely arise due to a relaxation in the exclusion provision. The Indian patent law can take hints from such committees to overcome any ethical or moral issues which may be foreseen. The recommended amendments would more closely concentrate on patenting of the techniques of carrying out a procedure and not the new uses of already-known drugs and chemicals.[53]

The critical question here is that with a large number of patients in India, would it be justified to allow a monopoly over a technique or process of treatment? On the other hand, the need for greater investment in the medical sector is highly demanded and only allowing patents would revolutionise the sector by making new, efficient and economic methods of treatment available to the people. A strong contradiction is observed between the medical method patents and medical ethics.[54] Nanobiotechnology may further add more complications owing to its potential capacity to develop highly efficient, more precision-based products, devices and methods. A comparison of patentability of medical methods (diagnostic, surgical and therapeutic) is provided in Table 2, below.

It was held in the case of *Pfizer Inc v The Commissioner of Patents*[55] that medical methods were excluded from patentability as they fall under "manner of manufacture" in countries like New Zealand. With the exception of Australia and the United States of America, all the other countries consider medical, surgical and therapeutic methods as non-patentable subject matter. This is not because these do not qualify under the industrial applicability requirement of patentability, but rather because they are considered to be against public morality. Health is the crux of the wellbeing of a nation. Monopolising it is considered to be against public policy. However, the paucity of funds, especially in developing countries, poses hindrance in curing diseases. Thus, a review of the medical methods is highly necessitated. The patent legislation of a few countries (like Canada) does not expressly exclude medical method patents. Amendments to such laws are required, such that they explicitly mention the respective exclusions and attain consonance with Article 27.1 of TRIPS

---

[53] A West, "A Proposal to Amend the Medical Exclusion within Patent Law to Provide for Patentability of Certain Methods of Treatment" (2007) 29 *European Intellectual Property Review*, 492-499.

[54] T Tolloczko, "Surgical Patents and Patients-Ethical Dilemmas" (1995) 11 *Science and Engineering Ethics*, 61-69.

[55] [2005] NZLR 362.

and provide minimum level of patent protection. In the case of the *Unilever Limited (Davis1) Application*,[56] an *obiter* view suggested that any method of surgical treatment – whether curative, prophylactic or cosmetic – is not patentable. Therapy includes both curative and preventative treatment. A balancing test is often used to consider the ethical issues surrounding a medical method and the public interest, societal benefits and the cost of developing of the method.[57]

The dilemma in the present context is whether methods using nanoparticles constitute diagnostic, surgical or therapeutic methods.

3. Conclusions

Nanobiotechnology has achieved remarkable success in research and development, innovation, legal protection and commercialisation in western countries. Legislation and regulations are in place to assess risk, comply with safety measures and regulate the outcomes of such research. With a promise of widespread application, nanobiotechnology research is still at an early stage of development in India. This technology raises issues which are in conflict with intellectual property rights protection and non-commercial laws (such as the environmental laws or privacy rights). In the absence of consonant patent law provisions, nanobiotechnology will encounter challenges with respect to the criteria of novelty, inventive step, being capable of industrial application and eligibility of subject matter under Indian *Patents Act* 1970, section 3. The use of ecomarks on nanobiotechnology products are proposed to ensure environmental safety and consonance. This would further help in dealing with the proposed obstacles to nanobiotechnology products in light of Indian *Patents Act 1970*, ssection 3(b). Amendments to the Indian *Patents Act 1970*, s 3(i) can be imported from the European jurisdiction which has proposed significant amendments to their provisions similar to Indian *Patents Act 1970*, section 3(i) regarding medical methods. The examination guidelines for the patent applications relating to medical inventions in the UK Intellectual Property Office, August 2008 would be useful in dealing with patent applications pertaining to Indian *Patents Act 1970*, section 3(i). According to the market and societal needs, efforts can be made to amend the existing provisions as and when the need arises by maintaining a flexible approach and importing precedence from other jurisdictions. The draft Manual should breed more guidelines and should be updated regularly. Since patent law is technology-specific, providing guidelines to examiners for assessment of patent applications is a good practice and should be encouraged as it would aid in the issuing of better quality nanobiotechnology patents. Documentation and consolidation of scattered prior art in the form of a database is necessitated. Ethics should be given weight in relation to ignorance. Nanoethics committees or the inclusion of nanoethics under the present bioethics committee should be considered as inventions that may be rendered non-patentable in India on ethical and moral grounds.

---

[56] [1983] RFC 219.

[57] The balancing test was discussed in *Harvard Oncomouse* case and *R v Leland Stanford/ Modified Animal* [2002] EPOR 2.

The emergence of recent concepts such as access to knowledge (A2K) propounds accessibility of knowledge to all on the basis of justice and equity. Such contentions raise a voice against the monopolistic character of patent rights This gives birth to the most acute dilemma which strikes at the very root of the patent law jurisprudence. It remains to be seen what impact such movements will have on emerging technologies such as nanobiotechnology under the Intellectual Property regime in India.