



# Patenting of Nanotechnology Inventions: Analyzing Section 3 of Indian Patent Act, 1970

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**Abstract:** *Recently there has been a perception, especially amongst the foreign multinational pharmaceutical companies that Indian Patent Act doesn't provide the adequate protection to inventions. Their belief basically flows from the fact that while inventions are patentable in developed jurisdictions like USA, Japan, European Union, etc but when it comes to secure the same inventions in India they become non-patentable. This raises questions like 'Is Indian Patent law unnecessarily rigid and narrows down the patentability of inventions' and whether it is compliant to the TRIPS agreement. Taking the judgment in the Novartis case as base and looking forward to the future inventions technology like nanotechnology, the author tries to analyse these question.*

**Key Words:** *TRIPS, Indian Patent Act, Law, Novartis, Nanotechnology.*

## I. INTRODUCTION

Inventions are the drivers of the change that separate one era from another. Inventions are the solutions an inventor finds in response to prevailing problems faced by the societies. The fact that solutions provided by invention can be used for the mankind as a whole after the disclosure on working of the invention brought forth the need to reward the inventor in order to motivate the inventorship. This brought various theories, the natural theory, labour theory, Schumpeter's theory, etc to justify and secure the reward to the inventor for the investment of his labour, skill, time and effort towards bringing the inventions. John Locke's labour theory is one such theory that justifies the effort-reward equation to uphold the validity of the limited time patent rights by the State to the inventor. Based on the principle of *quid pro quo*, patent rights recognise the inventors' right to exclude all others from exploiting his invention. While the history of patent rights goes back to 14th century; the modern roots towards a globally accepted uniform protection of IPRs can be traced to post World War II period.

With the increase in the global trade post World War II, it became a great concern, especially for the developed nations to ensure the protection of the intellectual property rights across the jurisdictions. So when the World Trade Organisation got established in 1995, one of the agreements to be made was TRIPS which contains general principles and a comprehensive policy framework within which the members can draft their legislations recognising the Intellectual Property Rights in their jurisdictions. Preamble to TRIPS recognises the sovereignty of the member States by allowing them to tailor their IP legislations in consonance with their respective public policies and allows certain measures that can be taken only under certain circumstances whereby they can override the recognised protection. All such measures shall be incorporated within the IP legislations and can be adopted during the prevalence of those conditions only.

## II. STANDARDS OF PATENTABILITY: A PRIMER ON TRIPS PROVISIONS

The subject matter of patentability is described in Article 27(1) which generally lays that both processes and products be patentable if they are, novel, involve an inventive step and are capable of industrial application. Clauses (2) and (3) of the same article recognize the sovereignty of the member states, allowing them to exclude certain inventions as non-patentable. Clause (2) allows excluding those inventions, the commercial exploitation of which may have adverse impact on the public order, morality, human, plant or animal life, health, or those which may prejudice the environment in general. The other allowable exclusions are those where the inventions are relating to the diagnostic methods, therapeutic or surgical methods relating to treatment of animals or humans. Plants and animals in part or whole and the essential biological processes associated with the life also fall under the allowable exclusions to patentability. However, clause (2) of Article 27 comes with a rider providing that such exclusion to patentability shall not be available merely on the ground that local law prohibits the commercial exploitation of such inventions. It is from this freedom of sovereignty that leads to differing provisions in respect of patentability standards and the levels of protection to inventions. Different provisions give differing interpretations leading to conflicts over the subject matter of patent and its protection. In Indian context, the decision in Novartis is the right place to explore this further.

## III. THE JUDGMENT IN NOVARTIS

On April 1, 2012, the Supreme Court of India upheld the decision of the patent office in rejecting the patent claim on the application filed by the Novartis AG for their drug Glivec. The court construed strictly the legislative intention expressed in very clear terms of the section 3(d) of the Patent Act, 1970. The application for the beta crystalline form of the imatinib mesylate was found to be anticipated by a prior disclosure contained in 1993 application. The court found that in the absence of an increased



efficacy, the provision contained in the section 3(d), imposed a clear bar upon the novelty of the claimed invention. While the resentment amongst the pharma companies still persists, the court neither implied nor imposed a blanket ban upon the novelty upon the different forms of the same substance. Neither does the provision of the Section 3(d) deviate from the general criteria of patentability contained in the TRIPS agreement. Section 3(d), in fact, establishes a high bar of novelty to be crossed. Thus, if a substance which is already claimed in an earlier application (prior art) and which is later found to be existing in any other form and which is more beneficial or efficient over the previous form mentioned in the prior art; must, in the light of section 3(d) prove its increased efficacy in order to be patentable. Many substances are known to occur in different forms and if they do not differ in utility, the patent grant then becomes unjustified because there is no incremental benefit passed onto the society by the inventor.

This question is important in deciding the patentability of the nanotechnology inventions involving elements already disclosed in the prior art. The only difference is that of scale at which they are manipulated through human effort to bring in desired effects which can later be claimed as novel or more efficacious; or through manipulation of different materials altogether. To understand this better it is better to have a working knowledge of the nanotechnology inventions and the patentability requirements under TRIPS.

#### **TRIPS patentability requirements:**

TRIPS simply lay general conditions for the patentability of inventions and what can be excluded there from under certain circumstances. These requirements are a must to satisfy quid pro quo principle which is akin to consideration if we hold a patent as a social contract between an inventor and the State/society. The general requirement for an invention to be patentable is that it must be<sup>1</sup>:

1. Novel;
2. Involves an inventive step (non-obviousness); and
3. Is capable of industrial application.

#### **A primer on nanotechnology:**

There exists an array of definitions attempting to define nanotechnology each focussing either upon the size range of the elements involved; the change in properties owing to size range, the functions or effects observed at nanoscale<sup>2</sup> besides other approaches. The common feature to all the definitions is the manipulation of nanoscale elements to bring in different effects to produce useful properties. European Patent Office (EPO), for example, has provided the following definition:

*“The term nanotechnology covers entities with a controlled geometrical size of at least 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 method for controlled analysis, manipulation, processing, fabrication and measurement with a precision below 100 nanometres”<sup>3</sup>*

This definition stresses the need to limit the size of the elements manipulated to a specific range of 100 nm to exhibit the effects produced by both the inventions and the processes in order to be patentable. Nanotechnology is a multidisciplinary technology with potential applications in almost all the major sciences. In fact, nanotechnology takes in various elements from various fields including living elements from biological sciences. This ability to blend in elements from various sciences at nanoscale brings forth a set of problems that question the patentability of these inventions under particular fields of inventions, searching the prior art, priority dates, etc. Satisfying the requirements of novelty, non-obviousness and industrial application becomes a complex task. The challenge poses complex questions to be answered while comparing the size of nanotechnology inventions and processes with those under the pool of existing inventions of the prior art. The two such obvious questions those crop up are; one, are these inventions novel just because the size of elements involved has been brought within nanoscale? And two, is the inventive step still non-obvious when some effects which are already claimed in prior art are produced by manipulation of elements at nanoscale? As far as the third requirement of patentability is concerned, many jurisdictions have recognised even the economical advantage gained through nanotechnology inventions as satisfying this requirement. At one hand the TRIPS require that these three requirements shall be strictly satisfied independently; at the other the utility of a promising technology cannot be overlooked just because the legal framework restricts its patentability. Similar situation arises, when we look at the section 3(d) of the Indian Patent Act, its phraseology makes it increasingly difficult not only the different forms of same substances to be patentable but also it sets high bar on the requirements of patentability to be satisfied for emerging technologies. Before commenting upon or concluding anything about section 3(d), it is better to analyze the entire section 3 to see, if it restricts and yet leaves any room for the patentability of nanotechnology inventions? Before that, we need to see the legal positions obtaining in USA and EU towards enabling the patenting of nanotechnology inventions.

#### **IV. PATENTING OF NANOTECHNOLOGY INVENTIONS IN US AND EU:**

Discoveries are not patentable under the US patent law<sup>4</sup> for the obvious reason that what is claimed belongs to nature and that there is no human skill and effort involved. The distinction between the two has been made by Purchas LJ, in *Genentech Inc.*,<sup>5</sup> in following words:

<sup>1</sup> Article 27 read with preamble to TRIPS agreement

<sup>2</sup> Reference scale – 1 meter = 1000 mm; 1mm = 1000 µm; 1 µm = 1000nm; or 1nm = 10<sup>-9</sup>m

<sup>3</sup> Available at, '<http://www.epo.org/focus/issues/nanotechnology.html>'

<sup>4</sup> Per section 101 which states, “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title;”



*“there may be a critical distinction to be drawn between a claim to new knowledge or to a discovery “as such” which is not patentable under section 1(2) of the 1977 Act and a claim to a method embracing a discovery which may well be an invention which is patentable”.*

The requirement of novelty raises a fundamental question striking at the very patentability of the nanotechnology inventions. Simply reducing the size of invention to molecular level does not satisfy the novelty requirement.<sup>6</sup> Novelty can be judged by searching the prior art to see if the invention is anticipated. To be anticipated, the entire invention need not be contained in a single application, but doctrine of inherency can be applied to fill in the gaps. In many jurisdictions, the novelty requirement has been toned down by special nanotechnology directives or policies and as a result if one of the elements or dimensions involved in the invention or process falls within the nano range, the novelty requirement is to be checked along with the inventive step requirement. This is natural for the nanotechnology inventions where the novelty consists in manipulating the components at nanoscale amidst the quantum forces to bring in the desired effects blended with the inventive step that consists in the very arrangement of the atoms amongst a set of forces different from those that occur at normal level. In re Kumar<sup>7</sup>, the first ever nanotechnology patent to be granted, the application was rejected as lacking inventive step. The question of novelty was never raised over the manufacturing of alumina particles of nanoscale dimension whose utility lay in polishing the ultra smooth metal surfaces. The Federal Circuit upheld the patent on holding that despite an apparent overlap in size of the manufactured alumina particles with prior art<sup>8</sup>, the inventive step lay in the certainty brought by the pyrolysis process in increasing the weighted average of particles so manufactured below that of prior art. Also in Photodegradable Cellulose Ester Tow<sup>9</sup>, the EBOA10 upheld the novelty of invention reasoning that a generic disclosure in an earlier application did not take away the novelty in the claim for specific increased photo-degradability due to addition of nano form of Titanium dioxide. Similarly, the EBOA held the nickel nano crystals of size less than 11 nm produced by the process of electro-deposition as novel<sup>11</sup>.

The industrial application requirement is also called utility requirement which ensures that inventions patented shall provide a real life solution through an executable process, to the mankind and are not harmful. It is however not necessary that at the time of filing the application all the possible uses be known. Usually, a research is carried under given context and known objects beforehand so industrial application for which that invention is to be used is already known. But in nanotechnology the constituent elements from different fields blend together to bring unpredicted results and processes and products, the harmlessness of which cannot be guaranteed. So far we have seen that nanotechnology is bringing an unexplored arena of inventions with promising technologies at the horizon. This can be seen from the various nanotechnology missions and initiatives undertaken by the governments in many developed and developing countries to enable and promote nanotechnology. Indian government has also adapted a mission on nanotechnology towards promoting research in nanotechnology. But a question arises is the Indian patent law wide enough to allow patentability of nanotechnology inventions. Post Novartis, the general view is that Indian patent law is too narrow. It is worth here to analyse a few relevant provisions of section 3 of the Indian Patent Act, 1970 which describes what are not inventions.

## V. SECTION 3 – THE PATENT ACT, 1970

### *Section 3 – The following are not inventions within the meaning of this Act:*

*Section 3(a) – an invention which is frivolous or which claims anything obviously contrary to well established natural laws;*

This section ensures usefulness of claimed inventions to ensure quid pro quo in the form of grant of patent. An invention made by joining two parts is frivolous and hence non patentable when manufactured in one part if it still provides the same utility. In India, *Malshelkar Committee Report*<sup>12</sup> recommended that “every effort should be made to prevent the grant of frivolous patents and evergreening” because they extend unjustified monopoly. The second part of this section assumes greater importance because nanotechnology brings forth new interaction of forces at quantum level and may bring in new conditions and equations which may deviate from the presently established scientific laws. This section supplements in general what is specifically disabled by section 3(d).

*Section 3(b) – an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;*

<sup>5</sup> [1989] RPC 147, 208

<sup>6</sup> Bishwanath Prasad Radheyshyam v. Hindustan Metals Ltd., AIR (1982) SC 1444

<sup>7</sup> 418 F 2d 1361

<sup>8</sup> Rostoker’s Patent (No. US 5389194 A)

<sup>9</sup> T 0006/02

<sup>10</sup> Extended Board of Appeals

<sup>11</sup> Nanocrystalline Metals, T 0915/00

<sup>12</sup> Report of Technical Expert Group of Patent Law Issues, 2006



This section is the legislative version of the TRIPS provision recognising sovereignty of States tailoring the law as per local public policy. However, the public policy is to be distinguished from the public opinion as was held in the Plant Genetic Systems/ Glutamine Synthetase Inhibitors<sup>13</sup> wherein the patent over genetically engineered plants and seeds to make them more resistant to herbicides, was refused to be revoked on the opposition by a large number of concerned farmers. The scientifically verifiable facts shall only be the basis of the public policy to deny a patent claim. Where a modified form of a human protein to be used for easing the childbirth was objected on the morality and slavery grounds, the benefit of invention weighed towards allowing the patent<sup>14</sup>. The situation obtaining in India is not so different from the decision cited above so this subsection is not grained against the nanotechnology patents. However, there are many unanswered issues related with the health and unless these are dispelled on the scientific grounds, members can impose limitations upon patenting on nanotechnology inventions.

*Section 3(c) – the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;*

The claims under nanotechnology patent applications are based on novelty and inventive step/s involved that arises from the combination of atomic forces at nanoscale. But a question arises that are not the forces those bring the claimed effects are intrinsic and peculiar to that scale? Isn't it then a discovery of scientific principles which are not the subject matter of patents according to the Article 27? Also when living things are manipulated as constituent elements to bring in the desired effects, isn't it again a validly justified bar on patenting? Not so long ago, Biotechnology patents have already cleared much way for the nanotechnology patents on this last question. The judgement in *Dimminaco A.G. v. Controller of Patents & Designs*<sup>15</sup> paved the way for patents on biotechnology inventions upon which the nanotechnology patents can now easily leverage their validity. Thus, in India, it is possible for the living forms to be used as invention content, of course within a framework with limitations.

*Section 3(d) – 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.*

The explanation makes clear that 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. It is this subsection that apparently has caused dismay in the recent past and can come in way of patentability of the nanotechnology inventions as well. The obvious question to ask is that if two substances having the same atomic composition but with different molecular arrangement at macro level, are not patentable then how it can be possible to make a claim over the same when it is *manufactured* with atomic manipulation. This subsection can give way if an increased efficacy is shown to be provided by such manipulation. One question that needs to be answered clearly is that does efficacy translate to economic efficiency? The decision in Novartis did not consider the stability of the beta form of imatinib mesylate and thus increasing the shelf life of the molecule as enhanced efficacy was answered in negative. The beta form with increased shelf life still provided the same functional utility as provided by the alpha form. The judgment can now be seen in the nanotechnology context as correct when we juxtapose the decision in *Elan Pharma International Ltd. V. Abraxis Biosciences Inc.*<sup>16</sup>, the first patent infringement suit on nanotechnology invention, wherein Elan was successful in showing that amorphous form used by the *Abraxis* required the crystalline form of the surface modifiers used in its patented drug delivery system. In Novartis also, out of the three methods of manufacturing beta crystalline form two methods required alpha form as ingredient in free base while the third method required the beta form itself! Now when alpha form is disclosed in a previous application, the beta form (as the stand was then taken) builds upon the alpha form. Supreme Court seems to have upheld the principle of *quid pro quo* as the weighing stone for the patent rights over the claim of Novartis extending its patent rights secured through another form of the same substance which could not be manufactured without using the first form as input! It thus, requires a little stretch of logic that this subsection is clearly a barrier to patentability in the absence of an increased efficacy.

*Section 3 (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;*

This innocuously sitting subsection poses strong challenge to patentability of the nanotechnology inventions. When read with the earlier subsection, it almost closes the door to patentability of nanotechnology inventions. It checks that claimed nanotechnology invention does not simply bring in an aggregated effect equalling the effects of all those atoms and molecules that have been manipulated as components of the invention. This requirement is little difficult to achieve except where the properties and effects of the constituents change or bring in additional effects at nanoscale. In fact this section has already taken in its first casualty – rejection of the application of *Abraxis Bioscience's* drug *Abraxane*, used in the treatment of breast, pancreatic and other cancers. The application for the drug *Abraxane* which is actually the paclitaxel molecule packed inside a nanotube to avoid some side effects and enhance site-availability has been rejected on failure to satisfy the requirements of both the subsections (d) and (e). The decision on the latter subsection seems to be based on the obvious aggregation of the properties of the already patented paclitaxel and its packaging inside a nanotube. This section can pose greater challenge to patentability of the nanotechnology inventions.

<sup>13</sup>1995 EPOR 357

<sup>14</sup>Howard Florey/Relaxin, (1995) 162 OJ EPO 388

<sup>15</sup>IPLR 2002 July, 255

<sup>16</sup>case number C.A. 06-00438, decided on 17 August 2007



*Section 3(f) – the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;*

This requirement can come in the way of patentability of those abstract nanotechnology devices which can achieve different functionality through different arrangements or replication of duplication of the units.

*Section 3 (i) – 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;*

This sub-section is likely to affect processes in a similar way the previous sub-section can affect the inventions. Inventions involving biotechnology elements as manipulated constituents within claimed inventions. Morality and public policy may also add up as barriers to this subsection.

*Section 3 – (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 production or propagation of plants and animals;*

This subsection bars the patentability of plants and animals as a whole and as nanotechnology involves elements below 100 nm, inventions involving plants and animals as a whole remain outside the definition of nanotechnology. The enabling provisions is contained in the excepting part that allows the micro organisms to be used as manipulated components of the nanotechnology inventions. So whatever is enabled in the *Diamond v. Chakraborty* and *Dimminaco A.G v. Controller of Patents and Designs* remains still extendible and available to nanotechnology inventions.

## VI. CONCLUSION

Indian government is promoting the nanotechnology research through the Ministry of Science and Technology. The Department of Science and Technology has initiated a program called Nano Mission in 2007 as a capacity building measure on nanotechnology awareness and provide infrastructure development in this area. Various departments under various ministries are conducting research in various areas like, defence, semiconductor chips, rice and other crops. Despite a clear thrust to promote this new promising and emerging technology it remains to be seen how the patent protection can be granted to the in-house and other inventions. Under the present situation obtaining under the Indian Patent Act, 1970, there is high uncertainty about the patentability of nanotechnology inventions. There is a need for an exclusive enabling directive which can bring an umbrella of recognition and protection over the nanotechnology inventions. The first step in that direction can be coming out with a clear and inclusive definition of nanotechnology to provide a general direction to nanotechnology research. Being an emerging technology, the initial patents play a vital role as these provide an edge to build upon and extend the technology. The other step can be enabling the in house working mechanism of the patent offices to process the nanotechnology applications.