

Patenting Nano Technology – An Intellectual Imbroglia

¹Dr.M.Madhuri Irene, ²Dr.Srinivas Borra

¹Associate Professor, ICAFI LAW SCHOOL, ICAFI foundation for Higher Education - IFHE (A Deemed to be University), Hyderabad, Telangana.

²Legal Advisor Venkateshwara Hatcheries Ltd,

Abstract

Humanity, having crossed primitive stone age, agrarian age, industrial age and Information age, has been galloping into 'Nano age'. Over the past few years, this little word 'Nano' with big potential has been rapidly insinuating itself into the world's consciousness, and conjured up speculation about a seismic shift in almost every aspect of science and engineering.

The newly emerging science of nanotechnology, the first new field in the present century has a peculiar trait that this field is ambitious, at the outset, to patent the basic ideas in many of the most important fields of inventions over the past century like computer hardware, software, the internet and even biotechnology.

The opulence of Nanotechnology as a science is marked with the great inflow of abundant inputs from many disciplines like physics, chemistry, electronics, biology and engineering etc. It is construed to be a science with great magnitude and potential to create new materials with specific properties and devices with wide ranging applications in medicine, electronics and energy production. But it appears that nanotechnology is at a speculative early stage; only a few nanotech inventions have so far actually made it into commercial products. There are about more than 2000 consumer products in the market which are developed containing Nano-particles and using nanotechnology. But the expectations surrounding the field are immense, ranging from a utopia of free energy and abundant materials to astounding alarm of probable industrial and environmental hazards.

This Article comprehends the significance of the application of Patent rights in nanotechnology products and devices, and how private domain taking away the nanotech-regime from public regime, how distinct the nanotech patents are from other patents, and patentability exemptions and exclusions, examines critically whether the supposed Nano-world is becoming the paradise of privileged rich or penurious common people.

Key Words: Nanotechnology, Patent rights, engineering, National Institute of Standards and Technology

I. INTRODUCTION

The beginning of nanotechnology can be said to have taken place in the imagination of humans, through alchemists who hoped to combine materials to create compounds never before created. Science fiction also contributed to humankind's imagination with Dick Tracey's (a cartoon-strip character from 1950s-60s) wrist watch he could use as a communication device, decades before the cell phone.¹

The twentieth century, now came to an end, has been one of rapid technological innovation and consequent social and legal change. From railroads to space travel, from computers to nuclear power and genetic engineering, new technologies have emerged in succession, each promising to upset settled expectations and change society's established patterns of human interaction. By consequence, in the past few decades many have come to believe that it is necessary to begin thinking about the impact of new technologies before they arrive. Such forward thinking has been applied to fields as diverse as space travel, artificial intelligence, and genetic engineering, with constructive results for the legal debate. Now a new technology, little more than a blip on the horizon, promises or threatens to create changes far more drastic than any of those mentioned is Nanotechnology.²

It is known to everyone that Richard Feynman's erudition on "There's Plenty of Room at the Bottom" stirred the scientific thinking on Nanotechnology in 1959, who confidently declared that doing things on an atomic level cannot be avoided, and suggested that atoms could be manipulated one at a time to form combinations which would be useful. In 1974, NorioTaniguchi, a Japanese Scientist coined the term "nanotechnology".

In 1981, invention of the Scanning Tunneling Microscope (STM);

¹ Victoria Sutton, Nanotechnology Law and Policy – Cases and Materials, Carolina Academic Press (2011) N.C. US. Pp.15

² Frederick A. Fiedler Glenn H. Reynolds, Legal Problems of Nanotechnology: An Overview, 3 S.Cal.Interdisc.L.J. 593 (Winter 1994)

In 1986, establishment of Foresight Nanotech Institute to study nanotechnology;

In 1988, Robert F Curl, Jr. Sir Harold W. Kroto and Richard E. Smalley discovered another carbon form – C₆₀ – a fullerene – named “Buckyballs”:

In 1991, Sumo Iijima discovered the carbon nanotube; all testified the inevitable emergence of nanotechnology.

The evolution of this new scientific refulgence is decorated by the rich and resourceful paper publications of: –

David Frost, a student of MIT, paper on ‘Regulation of Nanotechnology’ in 1989,

Frederick A. Fiedler and Glenn H. Reynolds, paper on “Legal Problems of Nanotechnology: An Overview” in 1994,

Glenn H. Reynolds continued publications in 2002 and 2003 on legal and regulatory issues of nanotechnology,

Michael Crichton published in 2002 a novel, “Prey” a fictional account of Nano machines which were self-replicating, and threatened the humans who created them. This novel was responsible for introducing much of the public to the nanotechnology issues and the question of regulation and risk.

In 2003, the U.S. Congress passed the “21st. Century Nanotechnology Research and Development Act, P.L. 108-153, 108th. Congress. 117 Stat. 1923, 15 U.S.C. 7501, December 3, 2003. This Statute’s stated purpose was to “authorize appropriations for nanoscience, Nano engineering, and nanotechnology research, and for other purposes.” This statute is unique in that it addressed the legal, ethical and societal issues and provided for funding to support those research efforts. This was derived from lessons of the past from emerging technologies where law and ethics were often afterthoughts.

In the United Kingdom, the Royal Science/Royal Academy of Education report, ‘Nanoscience’s and Nanotechnologies: Opportunities and Uncertainties’, was published in October 2004, and is recognized as a landmark publication. The report pointed out that there was a lack of knowledge about the risks to health and environment of nanoscience and nanotechnology. The Report made specific recommendations about the research needs necessary to address these risks. Among those recommendations was the need for a multidisciplinary research program addressing exposure, hazard and risk; and the establishment of a research centre to have a focus nanotechnology

research, activities and international interest in nanotechnology.

In 2006, the U.S. Environmental Protection Agency announced that it would proceed with its first regulation of nanotechnology. The proposal was for a “Toxicological Study Nominations of the Nano forms of Silver and Gold to the NATIONAL Toxicology Program (NTP) at 72 Fed. Reg. 14,816 (March 29, 2007)³

Rapid technological advances and commercialization within the emerging field of nanotechnology will challenge traditional regulatory regimes. The promising nanotechnology phenomenon has attracted extensive scientific and commercial interest.

Thus the evolving nanotechnology attained the status of enabling technology and turned ubiquitous, all embracing and intruding engineering technology. In fact, it is other technologies that are embracing nanotechnology rather than nanotechnology encompassing other technologies.

A. Nanotechnology- learning the task

Nanotechnology – the technology of the smallest objects – is slowly but surely progressing. The first products making use of nanotechnology are appearing on the market, amongst others: tennis racquets, ski wax, and sun burn crème. The European Patent Office has granted about 80,000 patents on inventions in the field of nanotechnology. Hitherto, European academic literature has had hardly any attention for the patenting of nanotechnology. This is remarkable in view of the fact that nanotechnology raises new and important questions of law, as well as questions relevant for the development of nanotechnology industry in Europe. Well-known examples of nanotechnology are Nano-carbon tubes and Bucky-balls for making extremely rigid constructions, quantum dots which can be applied as markers for labelling purposes, and *dendrimers* that may be used for drug delivery purposes. The EPO defines nanotechnology as follows:

“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 to make 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.”

³ Victoria Sutton, Nanotechnology Law and Policy – Cases and Materials, Carolina Academic Press (2011) N.C. US.(Pp.15-17)

This process, thus, serves as a kind of an “existence proof” for nanotechnology. Of course, putting these natural molecular machines to work is in effect, nothing new, as every living being does so constantly. But, where nanotechnology differs is, in the fact that it attempts to transcend the realm of the natural. Full-fledged nanotechnology successfully exercises complete control over the physical structure of the matter, akin to what is done by a word processor over the form and content of textual matter.⁴

Using nanotechnology, production would be carried out by large numbers of tiny devices, operating in parallel, in a fashion similar to molecular machinery already found in living organisms. These nano-devices wouldn't have to be made out of protein or other substances extractable from the natural environment, but can be constructed out of whatever fashion is most suited to their task. Popularly known as ‘assemblers’, these miniscule devices would be capable of manipulating individual molecules rapidly and precisely. Instead of weaving cloth this method would seize individual atoms using selectively sticky manipulator arms, and then “plug” those atoms together until chemical bonding occurs.

By repeating these steps according to a programmed set of instructions, a nano technological approach would be able to synthesize materials faster, and at a lower cost.

Besides such efficient and powerful manufacturing capabilities, there exist more sophisticated applications. For instance, specially designed Nano devices, the size of bacteria might be programmed to destroy arterial plaque, or fight cancer cells, or repair cellular damages caused by aging. Finishing with these tasks, the element shall be induced to self-destruct, or remain in a surveillance mode, or cause, in some cases, to integrate with the body cells itself. In addition to treating diseases, the technology would be exceptionally useful in producing drastically enhanced mental, physical and sensory abilities. Substantial changes in human morphology would be possible and even copying thoughts and memories, and actually storing them, would soon be reality, thanks to nanotechnology.⁵

⁴ Kirthi Jayakumar, Patents Nanotech – Challenges to Indian Patent Regime, http://www.indialawjournal.org/archives/volume3/issue_2/article_by_kirhti.html

⁵ Kirthi Jayakumar, Patents Nanotech – Challenges to Indian Patent Regime, http://www.indialawjournal.org/archives/volume3/issue_2/article_by_kirhti.html

II. NEED FOR PATENTS IN THE NANO WORLD

Nanotechnology has been projected to be a ‘transformative technology’ that has the potential to revolutionise varied industries such as health, information technology, energy, food, defence etc.⁶

This is because a single nanotechnology invention has applications across varied industries.⁷

Further, nanotechnology deals with the understanding and control of matter at the sub-atomic level whereby matter exhibits unexpected properties that are different from the properties exhibited by bulk material. For instance, carbon, which is a good conductor, turns into a bad conductor, at the Nano scale.⁸

Manipulation of matter at the Nano scale maybe useful across varied industries since matter at the Nano scale forms the basic building unit of all products in all industries. By being able to control the properties of matter at the sub-atomic level, one will be able to control the properties of all products across all industries. Cross-industry application of nanotechnology highlights the immense potential that this field holds.⁹

It has been estimated that nanotechnology has the potential to grow into a one trillion dollar industry in the next few decades. In light of the immense potential that the burgeoning field of nanotechnology holds, it is imperative for the patent regime to

⁶ Graham Reynolds, “Nanotechnology and the Tragedy of Anticommons: Towards a Strict Utility Requirement”, *University of Ottawa Law & Technology Journal*, Vol. 81, 2009; Ted Sabety, “Nanotechnology Innovation and the Patent Thicket: Which IP Policies Promote Growth?”, *Alb. L. J. Sci & Tech*. Vol. 15, 2005, at p.479.

⁷ ETC Group Report, Nanotech’s “Second Nature” Patents: Implications for the Global South, ETC Group Special Report – Communiqués No. 87 and 88, *available at* <http://www.nanowerk.com/nanotechnology/reports/reportpdf/report7.pdf>, (last accessed 24 October 2015).

⁸ Stefan Huebner, ‘The validity of European Patents in Germany’, *Nanotechnology Law and Business* (2008), *available at* https://srhuebner.com/uploads/media/nanotechnology_validity_huebner_nlb.pdf, (last accessed on 31 October 2015).

⁹ H. Shand & K. Wetter, “Trends in Intellectual Property and Nanotechnology: Implications for the Global South”, *Journal of Intellectual Property Rights*, Vol. 17, 2007, at p. 111.

respond favourably to this new technology. This is because patents incentivise innovation and investment and play a crucial role in determining the growth trajectory of a particular field of technology.¹⁰

Against the backdrop of a global knowledge marketplace,¹¹ it is crucial for technology developers to use the tool of patent law in order to ensure that the gap between the laboratory and the marketplace is bridged. From the sovereign's perspective this bridging is important as it would provide the sovereign an edge over other competitors.¹²

Consequently, it is crucial to examine whether the existing patent landscape is well equipped to keep pace with the rapid technological advancement that is colouring the field of nanotechnology.¹³

A. Transformation of Patent Law to accommodate new technological inventions

Tweaking the Requirements of Novelty and Non-Obviousness:

As per Trade Related Aspects of Intellectual Property Rights (TRIPS) the patent system is geared towards providing a technology neutral protection to all kinds of innovations.¹⁴

Patent protection is provided to inventions that fulfil the three pronged criteria of novelty, non-obviousness and usefulness. In USA, the requirements are novelty, non-obviousness and usefulness and in UK these requirements are referred to as novelty, realisation of inventive step and industrial application.¹⁵

Sometimes, the existing principles of patent law might not fit well with technological advancements,

¹⁰ M. Rimmer & Alison McLennan, *Intellectual Property and Emerging Technologies*, 2012 at p. 25.

¹¹ Madies & Prager, *Patent Markets in the Global Knowledge Economy*, 2014 at p.96.

¹² High Level Expert Group, 'Mastering and Deploying Key Enabling Technologies', European Commission, available at http://ec.europa.eu/enterprise/sectors/ict/files/kets/hlgworkingdocument_en.pdf, (last accessed 31 October 2015).

¹³ Pallavi Kishan, patent law and nanotechnology: examining the patent landscape in www.rslr.in/.../3/.../4._patent_and_nanotechnology.pdf

¹⁴ Indrani Barpujari, "The Patent Regime & Nanotechnology: Issues & Challenges", *Journal of Intellectual Property Rights*, Vol. 15 2010 at p. 207.

¹⁵ Luca Escoffier, 'Nanotechnology under the Magnifying Lens, from a European and US perspective', TTLF Working Papers, available at http://www.law.stanford.edu/sites/default/files/publication/205107/doc/slspublic/escoffier_wp3.pdf, (last accessed 31 October 2015).

resulting in the need for tweaking the existing principles in order to bring new technological innovations within the net of patent protection.

For instance, as per the general principle, a mere miniaturisation of a product does not clear the hurdles of novelty and non-obviousness.¹⁶

As observed by the US court, "an invention may not be patentable where the sole element of novelty is a difference in size."¹⁷

If we use this general principle related to downsizing of traditional products, a majority of nanotechnology inventions,¹⁸ would not be able to satisfy novelty and non-obviousness. As a result of this, the requirements of novelty and non-obviousness have been diluted to a certain extent in order to bring nanotechnology inventions within the umbrella of patent protection. Departing from the general rule, a nano scale miniaturisation is considered to fulfil the requirements of novelty and non-obviousness. The primary reason for this is that the laws of physics that apply at the Nano scale are fundamentally different.¹⁹

The laws of quantum physics take over as a result of which Nano scale particles exhibit unexpected properties, different from their macro scale counterparts.²⁰

These unexpected changes in properties are called 'quantum effects'.²¹

¹⁶ Indrani Barpujari, "The Patent Regime & Nanotechnology: Issues & Challenges", *Journal of Intellectual Property Rights*, Vol. 15 2010 at p. 207.

¹⁷ Ibid

¹⁸ Nanotechnology: The Industrial Revolution of the 21st Century, Accenture Foundation- Future Trends Forum, available at <https://www.fundacionbankinter.org/documents/11036/16211/Publicacion+PDF+IN+FTF+Nanotecnologia/03fd2b3c-0807-4cb3-a1fe-d2b2af21aed9>, (last accessed 31 October 2015).

¹⁹ Andrew Wasson, "Protecting the next small thing: Nanotechnology and the reverse doctrine of equivalents", *Duke Law & Technology Law Review*, Vol. 10 No. 2, 2004.

²⁰ Patenting Nanotechnology: Exploring the Challenges, WIPO Magazine, 2011 available at http://www.wipo.int/wipo_magazine/en/2011/02/article_0009.html (last accessed 31 October 2015); Also See ETC Group, Commodity Markets: The Implications for Commodity Dependent Developing Countries, Trade- Related Agenda, Development And Equity, available at <http://www.etcgroup.org/files/publication/45/01/southcentre.commodities.pdf>, (last accessed 20 October 2015).

²¹ A Tiny Little Primer on Nano-Scale Technology and the Little Bang Theory, ETC Group, 2009,

Ergo, by their very nature, nanotech inventions exhibit properties that are not witnessed at the macro scale.²²

B. Analysing the Stretch of the Patent Net in case of Traditional Products.

Another crucial question that arises with respect to patenting nanotechnology inventions which are miniaturised versions of their macro-sized traditional counterparts is that whether the patent rights given on a traditional product without specifying any size could be regarded as being infringed by its miniaturised nanotech invention.²³

The reverse doctrine of equivalents²⁴ which states that Where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way but nevertheless falls within the literal words of the claim the reverse doctrine of equivalents maybe used to restrict the claim and defeat the patentee's action for infringement,²⁵ may be used in order to excuse the literal infringement of traditional product patents by nanotech inventions. Further, author Andrew Wasson will put forth a two pronged argument to suggest that the net of patent protection granted to a traditional product without any size specification does not extend to its nanotech counterpart. Firstly, the traditional product and the nanotech counterpart are fundamentally very different not only in terms of size but also in terms of properties. The patent holder of a macro scale product could neither have envisaged the properties that a nano scale version of his product would have exhibited nor the technical issues that would be involved in actually bringing the nanotech counterpart into existence. Secondly, until the inventor of a macro scale product comes up with a technical solution to apply the laws of quantum

physics and come up with a Nano scale counterpart, the idea of making a miniaturised version of the macro scale product, exhibiting different properties would in fact just be an abstract idea which is not covered by the net of patent protection.²⁶

Thus, the requirements of novelty and non-obviousness have been diluted in order to aid patent law adapt to new technological advancements. Further, the rights of a patent holder on a traditional product with no size specification cannot be regarded as infringed by its miniaturised nanotech counterpart.²⁷

III. NANOTECH PATENTABILITY – EXEMPTIONS & EXCLUSIONS

The range of potentially patentable subject matter is vast, particularly in the U.S. , where essentially 'any non-naturally occurring product or process is eligible for patent protection. Essentially, there are four requirements to be complied with for patent application that are uniquely important for nanotechnology: -

A. The Utility Requirement:

Sec. 101 of 35 U.S.C. provides that an invention must have a definite, immediate, and demonstrable utility to meet the utility requirement as established by the Supreme Court in *Brenner vs. Manson*, 383 U.S. 519, 534 (1966). The USPTO applied the Brenner standards to biotechnology patent applications and required human clinical data to demonstrate biotechnology invention utility.²⁸ The USPTO also issued a series of interim utility guidance for comment between 1995 and 1999,

available at <http://www.etcgroup.org/content/tiny-little-primer-nano-scale-technology-and-little-bang-theory>, (last accessed 31 October 2015).

²² Jordan Paradise, "Claiming Nanotechnology: Improving USPTO efforts at classification of emerging nano enabled pharmaceutical technologies", Vol. 10, 2012, at p. 175.

²³ Nanotechnology and Patents, WIPO, available at <http://www.wipo.int/patent-law/en/developments/nanotechnology.html>, (last accessed 7 November 2015).

²⁴ *Graver Tank & Manufacturing Company v. Linde Air Products Company*, 339 U.S. 605.

²⁵ Andrew Wasson, "Protecting the next small thing: Nanotechnology and the reverse doctrine of equivalents", *Duke Law & Technology Law Review*, Vol. 10 No. 2, 2004.

²⁶ Lisa Abe, *Nanotechnology Law: The legal issues*, ICE Technology Conference 2005, available at, <http://www.fasken.com/files/Publication/1db6f3c3-a757-4067-af7c-901a5498ecd8/Presentation/PublicationAttachment/d755b60-42ff-44e8-9e57-582e2a83b8f7/NANOTECHNOLOGY.PDF>, (last accessed 31 October 2015); Marko Schauwecker, *Nanotechnology Inventions in US Patent Law*, TTLF Working Papers, available at http://www.law.stanford.edu/sites/default/files/publication/205786/doc/slspublic/schauwecker_wp_nanotech.pdf, (last accessed 25 November 2016).

²⁷ Pallavi Kishore, *Patent Law and Nanotechnology: Examining the Patent Land Scene in Miniature World*, www.rslr.in/.../3/.../4._patent_and_nanotechnology.pdf

²⁸ *Ex parte Balzarini*, 21 U.S.P.Q. 2d. 1892, 1897 (Bd. Of Pat. App. & Interferences 1991).

which addressed the rising concerns regarding the legality and morality of issuing gene patents.

Revised Utility Examination Guidelines;

Request for Comments, 64. Fed. Reg. 71,440 (1999);

Revised Utility Examination Guidelines;

Request for Comments, Correction, 65 Fed.Reg. 3.425 (2000).

These guidelines required the applicant to “explicitly identify, unless already well-established a specific. Substantial and credible utility, for the claimed invention. The guidelines were intended to provide examiners a basis for rejecting a gene patent application disclosing only theoretical utility.

Final utility guidance was issued in January 5, 2001, “Utility Examination Guidelines, 66 Fed. Reg. 1,092 (2001) which requires that examiners “review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any ‘specific and substantial utility’ that is credible, based on the view of one of ordinary skill in the art and any record evidence.’ Failure to meet the utility requirements of guidance will result in rejection under Sec.101 for lack of utility and under Sec. 112 (1) for failure to teach how to use the invention.

Still, the guidance is criticized for not establishing distinctions between the classic discovery versus invention. According to The USPTO, “an inventor’s discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.”²⁹

U.S. Law does allow the government to block the patenting of an invention in certain rare situation, in which publication of a description of the invention would endanger national security.³⁰

B. The Inherency Requirement: 35 U.S.C. Sec. 102.

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.³¹

²⁹ PTO Finalizes Guidelines For Examiners on Utility Requirement, 61. Pat. Trademark & Copyright. J. (BNA) 252 (January 12,2001)

³⁰ 35 U.S.C. Sec. 181. For example, a cryptographic system used by U.S. Security or Military agencies).

³¹In re Best, 562 F. 2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.³²

Simply put, the fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.³³

C. The Written Description Requirement: 35 U.S.C. Sec. 112.

The written description requirement is codified at 35 U.S.C. Sec. 112 (1), “Written Description” Requirement, 66 Fed. Reg. 1,099, (2001). The published guidance for examiners in evaluation biotechnology patents requires the following procedure:-

- i) Compare what the applicant possesses and what the applicant claims;
- ii) Determine whether there is sufficient written description to inform a skilled artisan that the applicant is in possession of the claimed invention as a whole;
- iii) For special claims, determine whether the application –
 - a) Includes a reduction to practice;
 - b) Is complete based on the drawings; or
 - c) Identifies sufficient distinguishing characteristics to show the applicant was in possession of the claimed invention; and
- iv) For genus claims, determine whether application (i) described a representative number of species by reduction to practice, drawings, or disclosure of identifying characteristics; or (ii) disclosed functional characteristics correlated with structure or a combination of identifying characteristics that indicate the inventor was in possession of the claimed invention.

For example, these heightened written description requirements for biotechnology patents, may not require the exact DNA sequence to meet the written description requirement, but it appears likely that the

³² Ex parte Levy, 17 USPQ 1461, 1464 (Bd. Pat. App. & Inter. 1990)

³³ Schering Corp. vs. Geneva Pharm., 68 USP 2d 1760 (CAFC 2003)

USPTO will only grant and the Federal Circuit, U.S. Court of Appeals, will only enforce patent protection to the extent of the scope of the invention at the time of the invention.

The guidance indicates that, in general, as knowledge and skill in the relevant art improve, the written description requirements may begin to relax.³⁴

D. The Enabling Requirement: 35 U.S.C. Sec. 112.

The Federal Circuit, U.S. Court of Appeals, has reinforced the enabling requirement by invalidating broad biotechnology claims requiring “undue experimentation.” In 1999, in *Enzo Biochem, Inc. vs. Calgene, Inc.*, 188 F. 3d. 1362 (Fed. Cir. 1999), the Federal Circuit, U.S. Court of Appeals returned to the *Wands* Factors from *In Re Wands*, 858, F.2d 731 (Fed.Cir.1988), in determining where there was “undue experimentation”. The *Wands* factors³⁵ are:-

- i) The quantity of experimentation required;
- ii) The amount of guidance provided;
- iii) The presence or absence of working examples;
- iv) The nature of the invention;
- v) The state of prior art;
- vi) The relative skill of those in the art;
- vii) The predictability of the art; and
- viii) The breadth of the claims.

But the purpose of this provision is to prevent the dissemination of information not to deny the inventor patent protection per se, and the inventor is entitled to government compensation for any losses that result from an inability to patent the invention.³⁶

Sec. 287 (c) also limits the ability of patent owners to enforce certain disfavoured classes of patents, such as patents that claim medical procedures, or business methods. (Sec.273). But the U.S. has declined to enact any subject matter specific limitation on patentable subject matter, even attempts to ban the patenting of genetically engineered mammals

³⁴ See. Margaret Sampson, *The Evolution of the Enablement and Written Description Requirement under 35 U.S.C. 112 in the Area of Biotechnology*, 15. Berkeley Tech. L.J. 1233. 1266 (2000)

³⁵ Victoria Sutton, *Nanotechnology Law and Policy – cases and materials*, (2011) Carolina Academic Press, N.C. US, pp. 347-348)

³⁶35 U.S.C. Sec. 183.

(including human beings) and human cloning have failed to win Congressional approval.³⁷

In contrast, other countries explicitly rule out the possibility of patenting certain types of subject matter, often on moral grounds. For example, under the European Patent Convention surgical, therapeutic and diagnostic procedures are not considered patentable.³⁸

The European Union classifies as patentable certain inventions involving human cloning, germ line modification and embryonic stem cells.³⁹

For a time, the European Patent Office even refused to issue patents that claim human genes, a longstanding practice in the U.S., but the moratorium was lifted in 1999 in line with the directive of the European Commission for harmonizing biotechnology patents in the European Union.⁴⁰

Until 2005, Indian law did not allow product patents on substances capable of use as a medicine, drug or food, but this policy was terminated to comply with international treaty obligations.⁴¹

E. Laws of ‘Nature and Natural Phenomena’ and patentable Inventions

Prior to 1980, there was considerable uncertainty in the U.S. as to the extent to which patent protection would be available for biotechnology-related innovations. In particular, it was unclear whether living organisms were patentable subject matter. Some feared that even inventions based on the constituent parts of living organisms, such as recombinant biomolecules and biotechnological processes, would be found ineligible for patent protection. However, these concerns were largely dispelled by the landmark decision in “*Diamond vs.Chakraborty*” wherein the Supreme

³⁷ Robin S., (2006) *The Human use of Humanoid Beings: chimeras and patent law*, Nat.Biotechnol. 24, 517-519; and Dewar, H. (June 2002) *Human Cloning Ban Sidetracked: Senate Vote Deals Amendment Second Setback in a Week.*, Washington Post, 19,A.4)

³⁸ Art. 53 of European Patent Convention (EPC)

³⁹ See Directive 98/44/EC of the European Parliament and of the Council of 6 July, 1988, on the legal protection of biotechnological inventions.)

⁴⁰Abbott, A and Hellerer, U., (2000) *Politicians seek to block human-gene patents in Europe*. Nature 404, 802)

⁴¹ Patents (Amendment) Act, 2005. – repealing Sec.5 of of Patents Act, 1970)

Court held that a genetically engineered microorganism can be patented.⁴²

Subsequent decisions by the Courts and U.S. Patent and Trade Marks Office (USPTO) have expanded upon that principle, establishing that genetically modified plants and non-human mammals are also eligible for patent protection, as are genetic sequences and other biotechnology-based inventions.⁴³

In an oft-quoted passage from Chakrabarty, the Court stressed that Congress intended the realm of potentially patentable subject matter to encompass ‘anything under the sun that is made by man’. This language, expansive as it is, nonetheless evokes the key caveat under U.S. law, that to be patentable an invention must be of human origin. By contrast, the Court has repeatedly emphasized that ‘laws of nature, natural phenomena and abstract ideas’ are not patentable.’ Although the discovery of a previously unrecognized principle of nature might warrant a Nobel Prize, in and of itself it will not provide the basis for a patent. The court has characterized fundamental scientific discoveries, such as $E=mc^2$ and the law of gravity, as ‘manifestations of ... Nature, free to all men and reserved exclusively to none.’⁴⁴

Gene Patents increasingly have become the subject of public criticism.⁴⁵

Whereas naturally-occurring genes as they exist in the body are considered un patentable ‘products of nature’, various forms of human intervention, such as purifying a genetic sequence from its native environment, converting an m RNA to a cDNA, or chemically synthesizing a gene, are considered sufficient to confer patentability upon isolated or recombinant poly-nucleotides. Patent law generally treats isolated poly-nucleotides in the same manner as it would any other newly invented molecular compound.

The principle that purification of a naturally-occurring biological material from its native environment can render the purified product patentable has a long history. For example, in 1873 Louis Pasteur received a patent that claimed ‘yeast’,

⁴² Diamond vs. Chakrabarty, 447 U.S. 303 (1980)

⁴³ J.E.M.Ag.Supply Inc. vs. Pioneer Hi-Bred International Inc., 534 U.S. 124, 143-46 (2001); *Exparte Allen*, 2 USPQ2d 1425 (Bd.Pat.App & Inter 1987); and *Animals-Patentability* (April 21, 1987) 1077 Off. Gaz. Pat. Office-24; and USPTO Utility Examination Guidelines, 66 Fed.Reg. 1092 (2001)

⁴⁴ Diamond vs. Chakrabarty case)

⁴⁵ Chrichton, M. (2007) Patenting Life, Editorial, *New York Times* 23 February, p. A.23) (<http://www.whoownsyourbody.org/>).

free from organic germs of disease, as an article of manufacture.⁴⁶

Since then, the courts have upheld the validity of claims directed to purified adrenalin and prostaglandin, noting that the isolated forms of these molecules do not exist in nature and have substantial therapeutic utility.⁴⁷

Purified native proteins are also routinely patented.⁴⁸

IV. CONCLUSION

Patents play a crucial role in determining the growth trajectory of a particular field of technology. In order to ensure that the patent regime responds favourably to nanotechnology patent claims, the requirements of novelty and non-obviousness have been tweaked whereby a mere Nano scale miniaturisation of a product would be considered to cross the hurdles of novelty and non-obviousness. This is because of the unexpected and unique properties exhibited by Nano scale matter as a result of the operation of laws of quantum physics at the Nano scale.

For instance, gold as bulk material is an excellent conductor. However at the Nano-level, it turns into a semi-conductor.⁴⁹

Further, the patent system is geared towards spurring innovation. However, it might end up having the exact opposite effect of stifling innovation due to the formation of patent thickets which refers to a web of overlapping patent rights requiring those who want to use the patented subject matter to obtain the permission of multiple patent holders. A patent thicket has been formed in the field of nanotechnology due to reasons like the grant of overlapping patent rights over basic building blocks of nanotechnology by patent offices. Patent thickets stifle innovation as they hold the potential to result in tragedy of anti-commons. If the patentees holding overlapping patents refuse to grant such licenses to

⁴⁶ U.S. Patent No. 141,072.

⁴⁷ *Parke-Davies & Co vs. H.K.Mulford Co.* 189 F. 95, 103, (S.D.N.Y. 1911) *In re Bergstrom*, 427 F 2d 1394, 1397 (C.C.P.A. 1970)

⁴⁸ *Amgen vs. Chugain*, 927 F.2d 1200 (Fed.Cir 1991) – alleging infringement of US Patent No. 4,677,195, which claims purified erythropoietin); and *Scripps Clinic and Research Inst. Vs. Genentech, Inc.*, 927 F. 2d 1565 (Fed. Cir.1991 – alleging infringement of U.S. Reissue Patent No. 32,011, which claims purified Factor VIII.C)

⁴⁹ Stefan Huebner, ‘The validity of European Patents in Germany’, *Nanotechnology Law and Business* (2008), available at https://srhuebner.com/uploads/media/nanotechnology_validity_huebner_nlb.pdf, (last accessed on 31 October 2015).

those who seek them, the basic building blocks of nanotechnology would remain locked from the reach of other inventors, leading to their underutilisation. Patent thickets might also impede second generation innovation and they might provide soil for the germination of problems like royalty stacking and double marginalisation. Ergo, in order to ensure that the field of nanotechnology is not stifled in its infancy, there is a need for all stakeholders to encourage the formation of patent pools and to support the development of standard nanotech terminology.

These solutions would mitigate problems related to granting overlapping patents. Further, the suggested solutions would ensure that prior art searches in the field of nanotechnology are streamlined, expenses and risks related to obtaining licenses from multiple patentees are minimised and the burden of litigation related to being sued due to the failure of identifying multiple patentees holding patents over basic building block of nanotechnology, is reduced significantly. In addition to the development of standard nanotechnology terminology by patent offices and formation of patent pools, there is a need for an experimental exception to be recognised by law in the field of nanotechnology in order to enable inventors use patented nanotechnology building blocks for further research and invention. Ergo, the field of nanotechnology holds the key to revolutionise varied industries and in light of the immense potential that the burgeoning field of nanotechnology holds, it is imperative for the patent regime to respond favourably to this new technology.

Nanotechnology patents bear watching. They have characteristics that may well make them fundamentally different than patents in any other industry in the last two decades. How the market responds to these characteristics will determine whether and how the law must step in and tailor the rules of patent law to the needs of this nascent industry. It will also give us broader insight into the role of patents in enabling technologies.

Nanotechnology is a natural experiment that can teach us whether we have learned anything since the days of the Wright brothers about how to license and enforce patents without restricting innovation, or whether the absence of early patent protection for the enabling technologies of the last century was merely a series of fortunate events. (with apologies to Lemony Snicket).⁵⁰

REFERENCES

[1] A Tiny Little Primer on Nano-Scale Technology and the Little Bang Theory, ETC Group, 2009, available at

⁵⁰ Mark A Lemley, Patenting Nanotechnology, 58 Stanford Law Review 601.)

http://www.etcgroup.org/content/tiny-little-primer-nano-scale-technology-and-little-bang-theory..

[2] Amgen vs. Chugain, 927 F.2d 1200 (Fed.Cir 1991) – alleging infringement of US Patent No. 4,677,195, which claims purified erythropoietin);

[3] Scripps Clinic and Research Inst. Vs. Genentech, Inc., 927 F. 2d 1565 (Fed. Cir.1991 – alleging infringement of U.S. Reissue Patent No. 32,011, which claims purified Factor VIII.C)

[4] Andrew Wasson, “Protecting the next small thing: Nanotechnology and the reverse doctrine of equivalents”, Duke Law & Technology Law Review, Vol. 10 No. 2, 2004.

[5] ETC Group Report, Nanotech’s “Second Nature” Patents: Implications for the Global South, ETC Group Special Report – Communiqués No. 87 and 88, available at <http://www.nanowerk.com/nanotechnology/reports/reportpdf/report7.pdf>,

[6] Ex parte Balzarini, 21 U.S.PQ. 2d. 1892, 1897 (Bd. Of Pat. App. & Interferences 1991).

[7] Frederick A. Fiedler Glenn H. Reynolds, Legal Problems of Nanotechnology: An Overview, 3 S.Cal.Interdisc.L.J. 593 (Winter 1994)

[8] Graham Reynolds, “Nanotechnology and the Tragedy of Anticommons: Towards a Strict Utility Requirement”, University of Ottawa Law & Technology Journal, Vol. 81, 2009; Ted Sabety, “Nanotechnology Innovation and the Patent Thicket: Which IP Policies Promote Growth?”, Alb. L. J. Sci & Tech. Vol. 15, 2005.

[9] Graver Tank & Manufacturing Company v. Linde Air Products Company, 339 U.S. 605.

[10] H. Shand & K. Wetter, “Trends in Intellectual Property and Nanotechnology: Implications for the Global South”, Journal of Intellectual Property Rights, Vol. 17, 2007..

[11] High Level Expert Group, ‘Mastering and Deploying Key Enabling Technologies’, European Commission, available at http://ec.europa.eu/enterprise/sectors/ict/files/kets/hlgworkingdocument_en.pdf,

[12] Indrani Barpujari, “The Patent Regime & Nanotechnology: Issues & Challenges”, Journal of Intellectual Property Rights, Vol. 15 2010.

[13] Indrani Barpujari, “The Patent Regime & Nanotechnology: Issues & Challenges”, Journal of Intellectual Property Rights, Vol. 15 2010.

[14] Jordan Paradise, “Claiming Nanotechnology: Improving USPTO efforts at classification of emerging nano enabled pharmaceutical technologies”, Vol. 10, 2012,

[15] Kirthi Jayakumar, Patents Nanotech – Challenges to Indian Patent Regime, http://www.indialawjournal.org/archives/volume3/issue_2/article_by_kirhti.html

[16] Lisa Abe, Nanotechnology Law: The legal issues, ICE Technology Conference 2005, available at, <http://www.fasken.com/files/Publication/1db6f3c3-a757-4067-af7c-901a5498ecd8/Presentation/PublicationAttachment/da755b60-42ff-44e8-9e57-582e2a83b8f7/NANOTECHNOLOGY.PDF>,

[17] Marko Schauwecker, Nanotechnology Inventions in US Patent Law, TTLF Working Papers, available at http://www.law.stanford.edu/sites/default/files/publication/205786/doc/slpublic/schauwecker_wp_nanotech.pdf,

[18] Luca Escoffier, ‘Nanotechnology under the Magnifying Lens, from a European and US perspective’, TTLF Working Papers, available at http://www.law.stanford.edu/sites/default/files/publication/205107/doc/slpublic/escoffier_wp3.pdf,

[19] M. Rimmer & Alison McLennan, Intellectual Property and Emerging Technologies, 2012 Madies & Prager, Patent Markets in the Global Knowledge Economy, 2014 at p.96.

[20] Margaret Sampson, the Evolution of the Enablement and Written Description Requirement under 35 U.S.C. 112 in the Area of Biotechnology, 15. Berkeley Tech. L.J. 1233. 1266 (2000)

[21] Nanotechnology and Patents, WIPO, available at <http://www.wipo.int/patent->

- law/en/developments/nanotechnology.html, (last accessed 7 November 2015).
- [22] Nanotechnology: The Industrial Revolution of the 21st Century, Accenture Foundation- Future Trends Forum, available at <https://www.fundacionbankinter.org/documents/11036/16211/Publicacion+PDF+IN+FTF+Nanotecnologia/03fd2b3c-0807-4cb3-a1fe-d2b2af21aed9>, (last accessed 31 October 2015).
- [23] Pallavi Kishore, Patent Law and Nanotechnology: Examining the Patent Land Scape in Miniature World, www.rslr.in/.../3/.../4._patent_and_nanotechnology.pdf
- [24] Parke-Davies & Co vs. H.K.Mulford Co. 189 F. 95, 103, (S.D.N.Y. 1911) In re Bergstrom, 427 F 2d 1394, 1397 (C.C.P.A. 1970)
- [25] Patenting Nanotechnology: Exploring the Challenges, WIPO Magazine, 2011 available at http://www.wipo.int/wipo_magazine/en/2011/02/article_0009.html¹
- [26] Robin S., (2006) The Human use of Humanoid Beings: chimeras and patent law, *Nat.Biotechnol.* 24, 517-519; and Dewar, H. (June 2002) Human Cloning Ban Sidetracked: Senate Vote Deals Amendment Second Setback in a Week., *Washington Post*, 19,A.4)
- [27] Stefan Huebner, 'The validity of European Patents in Germany', *Nanotechnology Law and Business* (2008), available at https://srhuebner.com/uploads/media/nanotechnology_validity_huebner_nlb.pdf,
- [28] Victoria Sutton, *Nanotechnology Law and Policy – Cases and Materials*, Carolina Academic Press (2011) N.C. U.S