

**PATENTING NANOTECHNOLOGY:  
A STUDY OF SOME BASIC ISSUES**

*Dissertation Submitted to Jawaharlal Nehru University in Partial  
Fulfillment of the Requirements for Award of the Degree of*

**MASTER OF PHILOSOPHY**

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January 4, 2010

**DECLARATION**

I declare that the dissertation entitled **PATENTING NANOTECHNOLOGY: A STUDY OF SOME BASIC ISSUES** submitted by me in partial fulfillment of the requirements for the award of the degree of **MASTER OF PHILOSOPHY** of Jawaharlal Nehru University is my own work. The dissertation has not been submitted for any other degree of this University or any other university.

**Meenakshi Chaudhary**

**CERTIFICATE**

We recommend that this dissertation be placed before the examiners for evaluation.

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**Dr. V. G. Hegde**  
Supervisor

**Dedicated**  
**To**  
**My Maaji**

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-Meenakshi Chaudhary

## ABBREVIATIONS

|              |  |
|--------------|--|
| <b>AFM</b>   | <b>Atomic Force Microscope</b>                                       |
| <b>AIDS</b>  | <b>Acquired Immune Deficiency Syndrome</b>                           |
| <b>APNF</b>  | <b>Asia Pacific Nanoforum</b>  |
| <b>BCD</b>   | <b>Binary-Coded Decimal</b>  |
| <b>CKMNN</b> | <b>Centre for Knowledge Management of Nanoscience and Technology</b> |
| <b>CPU</b>   | <b>Central Processing Unit</b>                                       |
| <b>CSIO</b>  | <b>Central Scientific Instruments Organization</b>                   |
| <b>CSIR</b>  | <b>Council for Scientific and Industrial Research</b>                |
| <b>CT</b>    | <b>Carbon Nanotube</b>   |
| <b>DBT</b>   | <b>Department of Biotechnology</b>                                   |
| <b>DCL</b>   | <b>Descarboethoxyloratadine</b>                                      |
| <b>DNA</b>   | <b>Deoxyribonucleic Acid</b>   |
| <b>DNT</b>   | <b>Dendritic Nanotechnologies</b>                                    |
| <b>DRDO</b>  | <b>Defence Research and Development Organisation</b>                 |
| <b>DST</b>   | <b>Department of Science and Technology</b>                          |
| <b>DVD</b>   | <b>Digital Videodisc</b>   |
| <b>EPC</b>   | <b>European Patent Convention</b>                                    |
| <b>EPO</b>   | <b>European Patent Office</b>  |
| <b>ETC</b>   | <b>Action group on Erosion, Technology and Concentration</b>         |
| <b>EU</b>    | <b>European Union</b>  |
| <b>FDA</b>   | <b>Food and Drug Administration (USA)</b>                            |
| <b>GATT</b>  | <b>General Agreement on Tariffs and Trade</b>                        |
| <b>GM</b>    | <b>Genetically Modified</b>  |
| <b>HIV</b>   | <b>Human Immunodeficiency Virus</b>                                  |
| <b>IBM</b>   | <b>International Business Machines Corporation</b>                   |
| <b>IBRD</b>  | <b>International Bank of Reconstruction and Development</b>          |
| <b>IMF</b>   | <b>International Monetary Fund</b>                                   |
| <b>IP</b>    | <b>Intellectual Property</b>   |
| <b>IPC</b>   | <b>International Patent Classification</b>                           |
| <b>IPR</b>   | <b>Intellectual Property Rights</b>                                  |
| <b>ISO</b>   | <b>International Organization for Standardization</b>                |
| <b>ITO</b>   | <b>International Trade Organization</b>                              |



|                        |   |
|------------------------|---|
| <b>IUF</b>             | <b>International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers' Associations</b> |
| <b>IWGN</b>            | <b>Interagency Working Group on Nanoscience Engineering and Technology</b>  |
| <b>JPO</b>             | <b>Japan Patent Office</b>  |
| <b>LDC</b>             | <b>Least Developed Country</b>  |
| <b>MDGs</b>            | <b>Millennium Development Goals (UN)</b>  |
| <b>MEMS</b>            | <b>MicroElectroMechanical Systems</b>   |
| <b>MIT</b>             | <b>Massachusetts Institute of Technology</b>  |
| <b>MNC</b>             | <b>Multinational Corporation</b>  |
| <b>MOSTI</b>           | <b>Ministry of Science, Technology and Innovation (Malaysia)</b>  |
| <b>NANOTEC</b>         | <b>National Nanotechnology Center</b>   |
| <b>NASA</b>            | <b>National Aeronautics and Space Administration (USA)</b>  |
| <b>NIH</b>             | <b>National Institute of Health</b>   |
| <b>NNI</b>             | <b>National Nanotechnology Initiative</b>   |
| <b>NSF</b>             | <b>National Science Foundation (USA)</b>  |
| <b>NSTC</b>            | <b>National Science and Technology Council</b>  |
| <b>NSTDA</b>           | <b>National Science and Technology Development</b>  |
| <b>NSTI</b>            | <b>Nano Science and Technology Initiative</b>   |
| <b>OECD</b>            | <b>Organisation for Economic Co-operation and Development</b>   |
| <b>PCT</b>             | <b>Patent Cooperation Treaty</b>  |
| <b>R&amp;D</b>         | <b>Research and Development</b>   |
| <b>RM</b>              | <b>Ringgit Malaysia</b>   |
| <b>RNA</b>             | <b>Ribonucleic Acid</b>   |
| <b>ROM</b>             | <b>Read-only memory</b>   |
| <b>SANI</b>            | <b>South African Nanotechnology Initiative</b>  |
| <b>SR</b>              | <b>Strategic Research</b>   |
| <b>STM</b>             | <b>Scanning Tunnelling Microscope</b>   |
| <b>TIO<sub>2</sub></b> | <b>Titanium Dioxide</b>   |
| <b>TRIPS</b>           | <b>Trade-Related Aspects of Intellectual Property Rights</b>  |
| <b>TS</b>              | <b>Technical Specification</b>  |
| <b>TSM</b>             | <b>Teaching, Suggestion or Motivation</b>   |
| <b>UNESCO</b>          | <b>United Nations Educational, Scientific and Cultural Organization</b>   |
| <b>UK</b>              | <b>United Kingdom</b>   |

|              |  |
|--------------|--|
| <b>U.S.</b>  | <b>United States of America</b>                  |
| <b>U.S.C</b> | <b>United States Code</b>                        |
| <b>USPTO</b> | <b>United States Patent and Trademark Office</b> |
| <b>WHO</b>   | <b>World Health Organisation</b>                 |
| <b>WIPO</b>  | <b>World Intellectual Property Organisation</b>  |
| <b>WTO</b>   | <b>World Trade Organization</b>                  |
| <b>µm</b>    | <b>Micrometre</b>                                |
| <b>mm</b>    | <b>Millimetre</b>                                |

## GLOSSARY

- Atom** : An atom is a particle of matter that uniquely defines a chemical element. It consists of a nucleus surrounded by one or more electrons. Each *electron* is negatively charged. The nucleus is positively charged, and contains particles *protons* and *neutrons*.
- Bang** : An acronym referring to a convergence of technologies whose operative units are Bits, Atoms, Neurons and Genes. The technologies are Information technology, Nanotechnologies, Cognitive neuro-science and Biotechnology. It is Known as **NBIC** (nan- bio- info- cogno) by the US government and **CTEKS** in Europe (Converging Technologies for the European Knowledge Society).
- Biosensor** : A sensor structure that targets biological analytes or a sensor based on the use of biological molecules.
- DNA** : It is a nucleic acid found within the nucleus of each cell, carrying genetic growth, division, and function. DNA consists of two long strands of nucleotides twisted into double helix and held together by hydrogen bonds.
- Electron** : The subatomic particle with one negative charge and a mass that is roughly 1/2000 the mass of a proton.
- Gray Goo** : Eric Drexler introduced the term in his 1986 book *Engines of Creation: The Coming Era of Nanotechnology*. Gray Goo refers to the obliteration of life that could result from the accidental and uncontrollable spread of self- replicating assemblers.
- Microbicide** : A pharmaceutical agent capable of killing viruses or pathogens.
- Micron** : A measurement equal to one thousand nanometres.
- MEMS** : Microelectromechanical Systems, referring to structures at the micron scale that transduce signals between electronic and mechanical forms.
- Molecular Manufacturing** : Methods of creating products by means of molecular machinery, allowing molecules-by-molecule control of products and by-products through positional chemical synthesis.
- Molecule** : A collection of atoms held together by strong bonds. It usually refers to a particle with a number of atom small enough to be counted (a few to a few thousand).
- Nano** : It is derived from the Greek word “nanos” meaning dwarf; it implies the scale of the nanometer, one billionth.
- Nanometer** : A measurement equal to one billionth of a meter.

- Nanoparticle** : A small piece of matter composed of an individual element or a simple compound of elements, typically less than 100 nanometers in diameter
- Nanoscience** : A discipline in which the authors of this book work, involving scientific understanding and investigation of nanoscale phenomena.
- Periodic Table** : It is a complete list of all known chemical elements arranged in columns and rows according to chemical properties. Russian chemist Dimitri Mendeleev produced the first list in 1869. Mendeleev's list proposed about 60 elements.
- Quantum Dot** : It is a nano-scale particle (a few hundred to a few thousand atoms) with extraordinary optical properties that can be customized by changing the size or composition of the particle.
- Quantum Mechanics** : A system of mechanics based on quantum theory that explains phenomena observable at the atomic level (<50nm), phenomena that differ from those observable on larger scales.
- Replicator** : A system able to build copies of itself when raw materials and energy are provided.
- Self Assembly** : A method of integration in which the components spontaneously assemble, typically by bouncing around in a solution or gas phase until a stable structure of minimum energy is reached.
- Supramolecule** : A system of two or more molecular entities held together and organized by means of intermolecular binding interactions.
- Toxicology** : The branch of medical and biological science studying the nature, adverse effects, detection, and treatment of poisons on living organisms.
- Ultrafine Particles** : It means nanoparticles with size smaller than 100 nm.

# **CHAPTER I**

## **INTRODUCTION**

**CHAPTER – I**  
**INTRODUCTION**

Nanotechnology refers to the manipulation of matter at the nano-scale of atoms and molecules, where size is measured in billionth of meters (1 nanometre = 1 billionth of metre). It refers to those areas of science and engineering where phenomena that take place at the nano-metre scale are used in the design, characterization, production and applicability of materials, structures, devices and systems. The nano-scale refers generally to the measurement between 1 and 100 nm. A molecule of DNA, e.g. 2.5 nm wide, a human hair is 80,000nm wide. It is this manipulation at the nanometre scale that distinguishes nanotechnology from other technologies.

At the nano-scale rules of classic physics no longer apply and instead quantum effects are observable. This means that a substance in nano-scale can behave totally different from the same substance at a larger scale. Nanotechnology also makes possible “Bottom-up” manufacturing. The real power of nano-scale is the convergence of diverse technologies. So nanotechnology is not a single technology but a range of technologies converging at the nano-scale including biotechnology, informatics, genomics, neuroscience, robotics and information technology. It has the potential to radically transform many sectors of industry from pharmaceuticals to computers and from energy to chemicals. For developing countries nanotechnology has the potentials in the form of improved water purification, energy systems, health care, food production and communications.

However, a number of scientific and toxicological studies warned that engineered nanoparticles could pose unique risks to human health and safety. Nanoparticles as a class are more toxic due to their smaller size and quantum properties. Nanoparticles demonstrate different toxicity than larger version of the same compound. A large number of products containing invisible, unregulated and unlabelled nano-scale particles are

already commercially available (including food products, pesticides, cosmetics and more) and thousands are in pipeline.

Nanotechnology has been described as the transformational technology of the 21<sup>st</sup> century. It will revolutionize manufacturing across all industry sectors and eventually impact the production of every human made object. According to the U.S. National Science Foundation, by 2015 the annual global market for nano-related goods and services will be \$1 trillion, making it one of the fastest growing industries in history. Governments across the world are impressed by its potentials and are making huge investment in this field. The economic implication of nanotechnology has ensured that research and development in this field has become a national priority for the industrialized world.

Patents are strongest form of intellectual property protection and are essential to the growth of nanotechnology as research in this area requires huge amount of investment. The world's largest multinationals, leading academic laboratories and nanotech start-ups are all rushing to patent nanotechnology inventions. They are trying to obtain patent on nanotechnology inventions as much as they possibly can. For example, 8,630 nanotech-related patents were issued by the United States Patent and Trademark Office in 2003 alone, an increase of 50% over the previous three years. Patent offices all around the world are facing many problems in this field due to the astounding surge of patent applications in this field. The filing of large number of patent applications in this area has increased the burden on the examiners who lack relevant expertise in this area. As a result a large number of overcrowding and overlapping patents are being issued in this area.

Most of the nanotechnology patents are being granted on the basic invention which will stifle innovation in this field. The Intellectual property landscape in nanotechnology is fragmented and somewhat chaotic. As a large number of broad patents of poor quality are being granted in this area by the patent offices around the world shows that a large number of patent litigation will occur in this area. In fact, the nanotechnology patent litigation has already begun. Nanotechnology patent thickets are already causing concern

in the United States and European Union and many other countries. To deal with this situation in October 2004, the United States Patent and Trademark Office created new classification of nanotechnology patents—Class 977—which help examiners among others, search prior art. In January 2006, the European Union office began classifying nanotechnology patents as –nanotechnology subclass (Y01n).

Nanoscale technologies are poised to become the strategic platform for global control of manufacturing, food, agriculture and health in the immediate years ahead. Nano-scale engineering offers the potential to transform existing materials and designing entirely new ones which mean multiple raw material options for industrial manufactures. Some applications of nanotechnology could increase global demand, while others lead to a decrease in demand for specific commodities. Applications that result in reductions or increases in the demand for commodities could have potentially far reaching socio-economic and other effects in developing countries, any change in material demand will affect their economies.

Nanotechnology inventions have application in virtually all areas of human life. Nanotechnologists argue that nanotechnology applications will address specific needs of the developing countries. The debate about the impact of nanotechnology is polarized. However, there is other side to this debate. Some scholars argue that nanotechnology will reinforce the divide not only between rich and poor but will also create south-south nanodivide.

### **Review of Literature**

The term 'nanotechnology' has been used since the mid-1980s to label a vision described by physicist Richard Feynman in his classic talk, "There's Plenty of Room at the Bottom", about futuristic control of matter on an atomic level. He speculated about manipulating atoms to construct machines, storing enormous amount of information on microscopic level. He suggested that miniature manufacturing systems could build yet



more manufacturing systems (Feynman 1961). The idea that nanomachines can build with atom-by-atom control is the foundation of the Feynman vision of nanotechnology.

The revolutionary Feynman vision of a powerful and general nanotechnology based on nanomaterials that build up atom-by-atom control, promises great opportunities and, if abused, great dangers. This vision made nanotechnology a buzzword and launched the global nanotechnology race. A vastly broadened definition enabled specialist from diverse fields to infuse unrelated research with the Feynman mystique. The resulting nanoscale technology funding coalition has obscured the Feynman vision by misunderstanding its promise, and fearing that public concern regarding its dangers might interfere with research funding (Drexler 2004).

Nanotech is still in early stage of research. Ownership and enforcement of IPRs in the emerging field of nanotechnology will become increasingly important as application move from the R&D phase into the commercial marketplace. As the next 'technological revolution', nanotechnology will be a key technology for economic development in the 21<sup>st</sup> century. The field of nanotechnology is currently one of the most active on an international basis, with respect to number of patent applications. Patents will cast a larger shadow over nanotechnology than they have over any other modern science at a comparable stage of development. The ownership of nanotechnology patents is too fragmented, risking the development of patent "thicket"(Lamely 2005). Companies that hold pioneering patents could potentially put up toll on entire industries. Nanotechnology is still in its infancy, 'Patents thickets' on fundamental nano-scale materials, tools and processes are already creating thorny barriers for would be innovators (Shand and Wetter 2007).

Lamely asserts that nanotechnology 'is the first new field in a century in which people started patenting ideas at the outset'. In contrast to most other major enabling technologies of the 20<sup>th</sup> century (such as computer hardware, software, the internet, and even biotechnology), the most basic ideas and fundamental building blocks in nanotechnology are either already patented or may well end up being patented (Lamely

2005). Patent on basic inventions create problems because they are inclined to cover larger areas than final products. Patents on upstream "building block " materials or on initial experimental protocols can restrain downstream research that depends upon those tools as essential inputs to experimentation and efforts to translate basic science into useful drugs ( Zekos 2006a).

In order to obtain a patent certain statutory requirements must be satisfied; the invention must be novel, non-obvious and useful. While nanotechnology falls squarely within the traditional doctrines of patent law in many respects, it also raises unique questions. It is well settled that pure miniaturization are obvious in the light of prior art, but it is an open question whether nanoscale miniaturizations will clear the non-obviousness hurdle by virtue of the fundamentally different laws of physics at play at such small dimension (Wasson 2004). To the extent that these are 'foundational' patents—that is, seminal breakthrough inventions upon which later innovation are built research in the developing world could be shut down. Nanotech patent thickets are already causing concern in the U.S. and EU and many other countries. Researchers in the global south are likely to find that participation in the 'nanotech revolution' is highly restricted by patent tollbooths, obliging them to pay royalties and licensing fees to gain access (ETC Group report 2005b).

U.S. National Nanotechnology Initiative have propagated that nanotechnology will bring next 'industrial revolution. Therefore, for developing countries it might be a signal to embark on nanotechnologies as soon as possible, achieving in a few years for what industrialized countries have needed centuries. Schummer is of the view that such hopes rest on the understanding of the historical industrial revolution, according to which some technological innovations alone would have moved the economies of European countries in the 19<sup>th</sup> century. Many of today's historians of economy rather hold to the "dependency theory" according to which "one country's industrial revolution is another country's under development and these are two sides of the same coin of world capitalist development". If nanotechnologies have a potential for a legitimate industrial revolution—which is doubtful

because of their unclear identity-the dependency theory predict that, all else equal, they would reinforce the divide between the rich and poor (Schummer 2007).

Nano-scale engineering offers the potential to transform existing materials and design entirely new ones. New, nano-engineered materials could mean that industrial manufactures will have multiple raw material options. Most of the world's critical resources, particularly metals, are found in developing countries and that their economies essentially depend on mining and exporting these materials to industrialized countries. Nanotechnology will drastically affect the economies of developing countries and thus on increasing economic gap between poor and rich countries (ETC GROUP 2005a).

Maclurcan argues that like many past technologies, nanotechnology could be both relevant and appropriate to sustainable practices in developing countries. However, there is also a danger in viewing nanotechnology as a 'solution' to challenges before developing countries. In some cases its application may undermine alternative, more appropriate approaches to dealing with the problems at hand. He suggests that throughout nanotechnology's ongoing evaluation process, both risk assessment and global contextualization of nanotechnology's promises must be recognized as universal requirement in order for debates to progress on mutual ground (Maclurcan 2005).

Invernizzi and Foladori argue that attempts to list nanotechnology applications which may benefit people in poorer nations can be seen as only a starting point in a much larger and important debate which seeks to challenge the dominant socio-economic hierarchies in which nanotechnology development and application actually occur. By recognizing these historical mistakes and realities, the nanotechnology community can help to avoid repeating the mistakes of the pharmaceuticals and biotechnology industries to help nanotechnology become a tool which can alleviate disparity rather than widen it (Invernizzi and Foladori 2005).

## **Definition, Rationale and Scope of the Study**

The focus of the study is to explore nanotechnology by analyzing the patenting issues in this field. Nanotechnology is still in its infancy. Rapid commercialization of this technology will challenge traditional patentability criteria. While it has attracted much attention with respect to its scientific and business potential, there has been limited debate on the broader legal aspects of this technology. The current intellectual property trends related to nanotechnology is somewhat fragmented and chaotic. Several broad and overlapping patents are being granted on nanotechnology inventions which could severely retard the development of this technology.

Its proponents are forecasting that it will address the specific needs of the developing countries. However, the potential disruptive effect of this technology on the developing countries, has received far less attention. Currently, nanotechnology innovations and intellectual property are being driven from the North and promote the interests of dominant economic groups. Intellectual property (IP) will play a major role in deciding who will gain access to these technologies and at what price. This study will also analyse whether nanotechnologies meet specific needs of the developing countries and how their impact is affected by intellectual property rights. This study will not discuss following issues that are beyond its scope: IP and Antitrust law, Impact of nanotechnology on trade and commodity market, Environmental issues.

### **Research Questions**

The study seeks to address the following research questions:

- What are the various definitions of nanotechnology?
- Is nanotechnology really unique or is just the same like other technology?
- Do the standard patent criteria apply to Nanotechnology?
- To what extent nanotechnology would be able to meet the specific needs of the developing countries?

## **Hypotheses**

The research paper seeks to test the following hypothesis:

1. The existing patentability criteria need to be redefined to accommodate and protect the unique nature of nanotechnology.
2. There is a need for a common definition, terminology and classification for nanotechnology.

## **Research Methods**

The study would be based mainly on the primary and secondary data published by public, private research institutes and organizations. In order to arrive at a better understanding of the subject; interviews will be conducted with the academics and experts on the subject of research. The secondary sources will include books, articles, and internet sources.

## **Tentative Chapters**

### **Chapter One: Introduction**

This will be introductory in nature and will deal with the theme of the present work. Apart from this it will also reflect on the methodology, justification for choosing the topic and the objectives and limitations of the work

### **Chapter Two: Understanding Nanotechnology**

This Chapter will examine the basic conceptual framework of Nanotechnology.

### **Chapter Three: Intellectual Property Rights and Nanotechnology**

This Chapter identifies the current issues and challenges encountered in nanotechnology patents. The chapter will also discuss the applicability of the Trade-related Intellectual Property Rights Agreement with respect to current and future nanotechnology applications. The comparative study of the United States patent law and the European

patent law will be done. The problem of patent thickets, anticommons, patent trolls will also be discussed.

#### **Chapter four: Nanotechnology and Developing Countries**

This chapter aims to analyze the debate about the possible impact of these technologies on the economies of developing countries. It will also discuss the challenges that are being faced by the developing countries in nanotechnology research and development with particular reference to India.

#### **Chapter Five: Conclusion**

This chapter contains the summary and conclusion of the study.

## **CHAPTER II**

# **UNDERSTANDING NANOTECHNOLOGY**

## CHAPTER – II

### UNDERSTANDING NANOTECHNOLOGY

#### **1. Introduction**

Fifty years ago, physicist Richard P. Feynman, in his famous speech to the American Physicist Society said that “The principles of physics, as far as I can see, do not speak against the possibility of maneuvering things atom by atom.....It would be, in principle, possible for a physicist to synthesize any chemical substance that the chemist writes down.....The problems of chemistry and biology can be greatly helped if our ability to see what we are doing, and to do things on an atomic level is ultimately developed—a development which I think cannot be avoided”.<sup>1</sup> Feynman vision marked the beginning of what is now known as nanotechnology. His vision of ‘total nanoscale control’ which was not taken seriously at that time is now known as “the original nanotechnology vision”.<sup>2</sup>

Feynman vision motivates the researchers and played an important role in the development of this technology. Some argues that Feynman vision, which promises a technology of unprecedented power with commensurate dangers and opportunities, made nanotechnology a buzzword and launched the global nanotechnology race (Drexler 2004:21). This can be realized from the fact that the technology which was just an imagination a few decades ago has now been described as a major technological breakthrough.

Nanotechnology refers to the development and application of materials, devices and systems with fundamentally new properties and functions because of their structures in

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<sup>1</sup> Feynman (1959).

<sup>2</sup> National Science and Technology Council (1999), “ Nanotechnology: Shaping the World Atom by Atom”, for greater details see [Online:web] Accessed on 12 July 2009, URL:<http://www.wtec.org/loyola/nano/IWGN.Public.Brochure/IWGN.Nanotechnology.Brochure.pdf>



the range of about 1–100 nanometres. But, this is not the only definition of nanotechnology. There are numerous definitions to describe what nanotechnology is. A vastly broadened definition of ‘nanotechnology’ enabled specialists from diverse fields to infuse unrelated research with the Feynman mystique. Drexler argues that debate regarding nanotechnology and its prospects has been muddied by multiple definitions used to describe the term (Drexler 2004:121).

Today, nanotechnology is growing at a fast pace. Worldwide countries are making huge investment in nanotechnology research. Industry analysts say that it will revolutionize manufacturing across all industry sectors and have a huge impact on human life. It has been heralded as the ‘new industrial revolution. Nanotechnologists are promoting this technology by stating that it will transform the human life as it is capable of achieving such results which were not possible before. At the same time, concerns are also being raised about the potential risks associated with this technology.

In the context of this debate the following questions arises: How to define nanotechnology? What are those unique characteristics possessed by this technology which makes it so special? Is it really unique or is just the same like other technologies? In order to find out the answer to these questions it is essential to understand the basic features of this technology. This chapter traces the history of nanotechnology and the various definitions used to describe this technology. It also outlines the basic characteristics of this technology and will discuss the potential benefits and risks associated with this technology.

## **2. Evolution**

Nanotechnology is new, but research on nanometer scale is not new at all. For example, in the 4<sup>th</sup> Century A.D., the Romans applied gold and silver nanoparticles to colour glass cups. The resulting effect were red in transmitted light and green in reflected light-a sophistication not produced again until medieval times (Maclurcan 2005:3). From the time of the Greeks, Philosophers attempted to describe what matter is. Aristotle (350 BC)

characterized matter as made of four elements—earths, water, fire, and air. In the 5th century BC, Democritus provided the first realistic model of matter by proposing that matter was made up of particles at the smallest levels that were indivisible—atoms. For most of the 20<sup>th</sup> century, scientist focused on gross chemical interactions of the molecules when they studied chemistry (Wejnert 2004: 2-3). It was only after the introduction of term nanotechnology that scientists started to think of the manipulation at the level of atoms and molecules to construct devices and machines.

The concept of nanotechnology was first enunciated by the American physicist Dr Richard Feynman in his talk '*There's Plenty of Room at the Bottom*'.<sup>3</sup> He asked 'Why cannot we write the entire 24 volumes of the Encyclopedia Britannica on the head of a pin?' According to Feynman, there was no question that there was enough room on the head of a pin to put all of Encyclopedia Britannica there: there was not just enough room, but plenty of room at the bottom. He pointed out that the head of the pin is 1.6 mm across, and if you magnify the head of the pin by twenty-five thousand times, the area would be equal to the area of all pages of the Encyclopedia Britannica. According to him all that was necessary was to reduce the size of all the writing in the encyclopedia by twenty-five thousand times (Feynman 1959).

Feynman did not use the term nanotechnology but accurately described its potential by suggesting that miniature manufacturing systems could build yet more manufacturing systems. According to him this objective could be achieved by building things atom by atom control. The term nanotechnology was first used by Professor Norio Taniguchi (1912-1999) of Tokyo University, in 1974 at the International Conference on Production Engineering in Tokyo. He used the word 'nanotechnology' to describe ultra fine machining—the processing of a material to nano-scale precision- work that he started in 1940.<sup>4</sup>

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<sup>3</sup> He gave this visionary lecture to the annual meeting of the American Physical Society at the California Institute of Technology, Pasadena, California in December 1959. He became a Nobel Laureate in 1965.

<sup>4</sup>For greater details see [Online:web] Accessed on 26 March 2009, URL:[http://en.wikipedia.org/wiki/Norio\\_Taniguchi](http://en.wikipedia.org/wiki/Norio_Taniguchi)

It took over twenty years to fully meet the Feynman challenge. Gerd K. Binnig and Heinrich Rohrer at IBM's Zurich Research Laboratory invented a Scanning tunnelling microscope (STM) in 1981 that enable researchers to see and manipulate atoms for the first time.<sup>5</sup> Just a few years later, Gerd Binnig was also involved in the invention of the Atomic force microscope (AFM) at IBM in Zürich, Switzerland. Today, they are the requisite tools used by the researchers to observe and manipulate matter at the nano-scale (ETC Group report 2003:18).

In 1981 Eric Drexler published the first technical paper on molecular nanotechnology in the Proceedings of the National Academy of Sciences. He established fundamental principles of molecular design, protein engineering, and productive nanosystems. He concluded by saying that the development of the ability to design protein molecules would make possible the construction of molecular machines. These machines could build second-generation machines able to perform extremely general synthesis of three-dimensional molecular structures, thus permitting construction of devices and materials to complex atomic specifications (Drexler 1981: 5278).

Another breakthrough in the field of nanotechnology came with the discovery of new shapes for molecules of carbon, the quintessential element of life. In 1985 Robert F. Curl Jr., Harold W. Kroto and Richard E. Smalley discovered *Buckminsterfullerenes* (fullerenes). Buckyballs are perfect spheres, made of sixty carbon atoms arranged like the pentagons and hexagons that make up the surface of a soccer ball. They are named after R. Buckminster Fuller, the inventor who promoted the geodesic dome as the ideal architectural structure.<sup>6</sup>

In 1986 K. Eric Drexler published a popular book "Engines of Creation", which popularized the concept of an all embracing manufacturing technology based on molecular manufacture. In his book he postulated the idea of nanomachines built of more

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<sup>5</sup> The researchers won a patent on the microscope in 1982 and a Nobel Prize in Physics in 1986.

<sup>6</sup> "The Nobel Prize in Chemistry in 1996", The Nobel Foundation, 9 October 1996, [Online: web] Accessed 10 June 2009, URL: [http://nobelprize.org/nobel\\_prizes/chemistry/laureates/1996/press.html](http://nobelprize.org/nobel_prizes/chemistry/laureates/1996/press.html).

than just proteins-would do all that proteins can do, and more. He called those nanomachines 'assemblers'. He postulated the possibility that assemblers would let us build almost anything that the laws of nature allow to exist, including more assemblers. According to him the consequences of this will be profound, because our crude tools have let us explore only a small part of the range of possibilities that natural law permits. Assemblers will open a world of new technologies. He also cautioned about the possible dangers that accompany this kind of technology. Primarily, Drexler warns of the "gray goo," an amalgamation of self-replicating nanobots that would consume everything in the universe in order to survive (Drexler 1986).<sup>7</sup> Drexler's ideas gained greater publicity with the first designed protein produced at Du Pont in 1987.

Feynman vision was famously realised in 1990, when Don Eigler and Erhard Schweizer of IBM's Almaden research centre in San Jose, California, U.S., wrote their company's name using the scanning tunnelling microscope (STM) to manipulate individual xenon atoms. These were adsorbed on the surface of nickel, creating letters five atoms high and achieving a data storage density over 100 times greater than Feynman's conservative estimate for what might be needed to write with atoms (Ball 2009: 59).<sup>8</sup>

Although research leading toward nanotechnology was progressing, it was fragmented and uncoordinated. Developing nanotechnology is fundamentally an engineering project, not of natural science, and as such it required a cooperative effort. To begin this process, the Institute for Molecular Manufacturing was founded in 1991 Palo Alto, California (U.S.). Its initial project was funding the first textbook in the field, *Nanosystems:*

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<sup>7</sup> Drexler feared that the assemblers will be capable of replicating themselves. Assembler-based replicators will therefore be able to do that entire life can, and more. He feared that from an evolutionary point of view, this poses an obvious threat to people, to the rich fabric of the biosphere and all that we prize. According to him dangerous replicators could easily be too tough, small, and rapidly spreading to stop (Drexler 1986).

<sup>8</sup> Feynman supposed that "instead of reproducing all the information directly in its present form, we write all the information content in a code of dots and dashes to represent the various letters. Each letter represents six or seven "bits" of information; that is, you need only about six or seven dots or dashes for each letter. Let us represent a dot by a small spot of one metal, the next dash, by an adjacent spot of another metal, and so on. Suppose, to be conservative that a bit of information is going to require a little cube of atoms 5 times 5 times 5---that is 125 atoms". He estimated that in such a case we need hundred and some odd atoms to make sure that the information is not lost through some process. He stressed that to achieve these result there is need to make the electron microscope 100 times better (Feynman 1959).

*Molecular Machinery, Manufacturing, and Computation*, by K.Eric Drexler, which won the award for best computer-science book of the year. Nanosystems has gone far to put the theory of molecular manufacturing on sound technical footing-although scientific debate about the achievability and the best routes to developing nanotechnology has continued. Directly after the publication of this book, Drexler founded the Foresight Institute, whose stated goal is to "ensure the beneficial implementation of nanotechnology".<sup>9</sup>

Advances in scanning probe microscopy, electron microscopy and other analytical techniques enabled the new materials with nanostructure-dependent properties to be developed. Another breakthrough came with the discovery of carbon nanotubes in 1990 by Sumio Iijima, a physicist at NEC Research Labs in Japan. Nanotubes come in single- and multi-walled forms, and the single-walled form is essentially a long cylinder of carbon with half of a buckyball on either end. Single-walled nanotubes are estimated by some to be the strongest and most flexible material yet discovered. The Carbon nanotubes unique atomic configuration makes them mechanically very strong and highly electrical conductive (Maynard 2007:2). In the year 2001 Mitsui & Co. of Japan announced its plans for mass-manufacture of carbon nanotubes.

In 1998, Zyvex, the first molecular nanotechnology company, was established in U.S. and that marked the beginning of private nanotechnology venture capital companies. In 2000, one step further ahead was made, when Lucent and Bell Labs, together with Oxford University created the first DNA motor, the first nano-biotechnology gadget (Burgi and Pradeep 2006:646). By looking at the reality of nanotechnology, the National Science and Technology Council (NSTC) of U.S. created the Interagency working Group on Nanoscience Engineering and Technology (IWGN) in 1998. In January 2000 at the same institute President Bill Clinton announced \$500 million worth of funding in support of the U.S. government's investment in nanotechnology research and development. It was

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<sup>9</sup> Peterson, Chris (1995), "Nanotechnology: From Concept to R&D", [Online:web] Accessed on 28 July 2009, URL: <http://www.foresight.org/Hotwired.all.files/index.html>.

the Feynman vision which motivated the U.S National Nanotechnology Initiative (NNI). Due in part to Richard Smalley's leadership, the U.S. launched the NNI in 2000<sup>10</sup>.

### **3. Definitions and Terminology**

The word 'nano' is derived from the Greek nanos, meaning 'dwarf', and as a prefix means 'one-billionth' - in case of nanotechnology, to be precise, one billionth of a metre. If you take 1 millimetre and divide it by 1000 you get 1 micrometer and if you divide 1 micrometre by 1000 you get 1 nanometre. Objects measured in nanometres are on the scale of single molecules and atoms: for example, a human hair is approximately 10,000 nm (nanometer) thick. Below 10 nm is the quantum level, where matter starts to behave like waves and the world becomes notoriously unpredictable (Johansson 2003:3).

Nanotechnology is an emerging family of technologies including 'nanosciences' and 'nanotechnologies' enabling the manipulation of matter at the nanoscale (Drexler 1991). Nanoscience is defined as the study of phenomena and manipulation of physical system that produce significant information, with critical boundaries that do not exceed 100nm in length at least in one direction. Therefore, nanotechnologies focus on the design, characterization, production, and application of nanoscale systems and components (Uskokovic 2007:44).

One of the problems facing nanotechnology is the confusion and disagreement among experts about its definition. Nanotechnology is an umbrella term used to define the products, processes, and properties at the nano/micro scale that have resulted from the convergence of the physical, chemical, and life sciences (Morrow et al. 2007:806). Currently there is no single, internationally agreed, definition of technology. The definition of nanotechnology varies around the world. In Europe and U.S., the term 'nanotechnology' is frequently used to describe the science of atomic scale phenomena. The U.S. National Nanotechnology Initiative defines nanotechnology as "research and

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<sup>10</sup> For greater details see "National Nanotechnology Initiative", see [Online:web] Accessed on 28 April 2009, URL: <http://www.nano.gov/>

technology development at the atomic, molecular, or macromolecular levels, in the length scale of approximately 1 to 100 nm range, to provide a fundamental understanding of phenomena and materials at the nanoscale and to create and use structures, devices, and systems that have novel properties and functions because of their small and/or intermediate size”.<sup>11</sup>

Some experts consider the NNI definition of nanotechnology overly rigid; it excludes numerous devices and materials of micrometer dimensions, a scale that is included within the definition of nanotechnology by many nanoscientists. Nanotechnology represents a cluster of technologies, each of which may have different characteristics and applications. Moreover, the size limitation of less than 100 nm is rarely critical to a drug company from a formulation or efficacy perspective, because the desired or ideal property (e.g., reduced toxicity, lower dose) may be achieved in a size range greater than 100 nm (Morrow et al. 2007:807).

The UK Royal Society makes a distinction between ‘nanoscience’ and ‘nanotechnologies’ “where nanoscience is the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales” and “nanotechnologies are the design, characterisation, production and application of structures, devices and systems by controlling shape and size at nanometre scale” (Royal Society and Royal Academy of Engineering 2004:5).

Nanotechnology can also be described as passive and active nanotechnology. Passive nanotechnology, like sunscreens containing nano-sized titanium particles, is characterised by nanostructures whose “presence alone adds a significant increase to the performance of the system”. Whereas, the structures belonging to active nanotechnology carry out more complex functions, like performing movements. The later is consistent with common definition of machines, therefore, important exponents of active nanotechnology are known as “nanomachines” (Zech 2009:150).

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<sup>11</sup> Ibid.

There are also some ethical definitions of nanotechnology. According to Schummer there are at least three different ways in which nanotechnology has been defined and each one shapes perception of ethical issues in a radically different manner. The first definitional approach, called *nominal definition*, defines nanotechnology by providing necessary and sufficient conditions. The definition states that nanotechnology is the investigation and manipulation of material objects in the 1-100 nanometre range so as to explore novel properties and develop new devices and functionalities that essentially depend on the 1-100 nanometre range (Schummer 2006: 218).

The second definitional approach, called *teleological definition*, defines nanotechnology by its future goals. These goals can be values such as health, wealth, and security, or relative values such as smaller, faster, harder, cheaper-but this remains very unspecific. The third approach, called *real definition*, refers to a list of particular research topics that usually appear under the umbrella of nanotechnology in governmental research programmes, in nanotechnology research centres, in nanotechnology journals and nanotechnology conferences. For example, microscopy, quantum chemistry, molecular biology etc. (Schummer 2006: 219).

There are a number of national and international organizations that are developing terminology for nanotechnology. In September 2008 the International Organization for Standardization (ISO)<sup>12</sup> published Technical Specification ISO/TS 27687, "Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate". This is the first of a planned series of ISO documents on nanotechnology terminology and definitions. The specification refers to core terms such as the nanoscale (size range from approximately 1 nm to 100 nm) and nano-objects, which include nanoparticles, nanoplates, nanofibres, nanotubes, nanorods, nanowires and

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<sup>12</sup> ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. ISO is a network of the national standards institutes of 162 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO is a non-governmental organization that forms a bridge between the public and private sectors. ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society. For greater details see [Online:web] Accessed on 10 August 2009, URL:<http://www.iso.org/iso/home.htm>



quantum dots (Bard 2009: 5). Because nano-objects in general – and nanoparticles in particular often occur in large groups, and are likely to interact for reasons of surface energy, ISO included different assemblies of particles under the term “Nano-objects”. ISO states that these terms “are not restricted to physical size and shape (Grobe et al. 2008:7).

In June 2005, ISO formed a new Technical Committee to help focus the world’s attention on standards that would support the growth of nano-related industries. The scope of that committee, ISO/TC 229 – *Nanotechnologies*, includes standardization in the areas of terminology and nomenclature; measurement and instrumentation; material specifications; and health, safety and the environment. ISO Technical Committee (TC) 229’s work is being coordinated with the work of other organisations, including the Organisation for Economic Co-operation and Development (OECD) Working Party on Nanotechnology, which has incorporated into its work programme a project to “develop a framework for internationally comparable and validated statistics, according to agreed definitions and classifications”. In advance of this, ASTM International<sup>13</sup> had published a similar terminology standard: ASTM E2456 - 06 “Standard terminology relating Nanotechnology” (Bard 2009:5).

## **4. Characteristics of Nanotechnology**

### **4.1. Significance of Nano-scale**

Nanotechnologies have one thing in common: They all involve matter that is on the scale of the nanometre (nm). Atoms and molecules are nano-scale materials. The nano-scale generally refers to measurements between 1 and 100nm. A molecule of DNA, for

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<sup>13</sup> ASTM International, originally known as the American Society for Testing and Materials (ASTM) formed in 1898. It is one of the largest voluntary standards development organizations in the world-a trusted source for technical standards for materials, products, systems, and services. Standards developed at ASTM are the work of over 30,000 ASTM members. These technical experts represent producers, users, consumers, government and academia from over 120 countries. Participation in ASTM International is open to all with a material interest, anywhere in the world. See [online:web] Accessed on 10August 2009, URL: <http://www.astm.org/ABOUT/aboutASTM.html>

example, is 2.5 nm wide. Everything on nano-scale is invisible except with the aid of “Scanning Tunneling” and “Atomic Force” microscopes. Without these fundamental tools, first developed by IBM in the 1980s, it would be impossible to “see” and manipulate matter on the nano-scale (ETC Group Report 2005a: 9). The essence of nanotechnology is scale. At the nano-scale, elements can perform very differently than they do when they are on a larger scale. The nanoscale is unique because it is the size scale where the familiar day-to-day properties of materials like conductivity, hardness, or melting point meet the more exotic properties of the atomic and molecular world such as and quantum effects. The change of properties between macroscopic and nano-sized objects is called scale-effect (Zech 2009:149).

The two main reasons for this change in behaviour are an increased relative surface area, and the dominance of quantum effects. An increase in surface area (per unit mass) will result in a corresponding increase in chemical reactivity, making some nanomaterials useful as catalysts to improve the efficiency of fuel cells and batteries. As the size of matter is reduced to tens of nanometres or less, quantum effects<sup>14</sup> can begin to play a role, and these can significantly change a material’s optical, magnetic or electrical properties different from those of the same material at larger scale (Royal Society and Royal Academy of Engineering 2004:5). These effects can give materials very useful physical properties such as high capacity for storing or transferring heat, and can even modify biological properties, with silver for example becoming a bactericide on a nanoscale. For example:

- Carbon in the form of graphite (i.e. pencil lead) is soft and malleable but, at the nano-scale, carbon can be stronger than steel and is six times lighter.

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<sup>14</sup> Quantum mechanics states that matter at the very smallest dimensions can behave as waves. The effect of quantum mechanics is that when relatively few atoms are combined into a particle that is smaller than approximately 10 nm, the electrical, optical, chemical or magnetic properties may differ markedly from those of equivalent larger particles. At this size the physical, chemical and biological properties of the materials may differ substantially from the properties of bulk material. This makes it difficult to predict what causes a certain effect which means that materials at nanoscale may display unexpected properties that do not occur at larger scale (KEMI 2008:8-12).

- Zinc oxide, which appears white and opaque on the micron-scale, is transparent at the nano-scale.
- Nano-scale copper is a highly elastic metal at room temperature, stretching to fifty times its original length without breaking (ETC Group Report 2005a: 9).

Therefore, by tailoring the structure of materials at the nano-scale, it is possible to engineer novel materials that have entirely new properties never before identified in nature. All matter, living and non-living is made up of “raw materials” that are the chemical elements of the Periodic Table<sup>15</sup>, which are the stuff of everything else, including the genetic building blocks of life (ETC Group Report 2003:14). Therefore, nanotechnology raw materials are the elements of the periodic table. In effect, nanotechnology provides scientists with an expanded periodic table, and the expansion is exponential. It is not the case that every substance exhibits one set of properties associated with the realm of classic physics and a second set of properties associated with the nano-scale. Within the nano-scale realm too, a substance’s fundamental properties can change. For example, some nanoparticles of gold are inert while other nanoscale gold, of a different size, is highly reactive (ETC Group Report 2005a: 9-10).

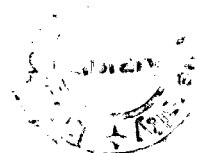
#### 4.2. Nanotechnologies Enable Technological Convergence

The basic components of both living and non-living matter exist at the nano-scale (e.g., atoms, molecules, and DNA). Therefore, it is now possible to converge technologies and scientific disciplines to an unprecedented degree. Since all materials and all processes operate from bottom-up (Beginning with atoms that combine to form molecules and all large structures), proponents of convergence believe that they can control events on the macro-scale by manipulating events at the nano-scale. With possible applications across

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<sup>4</sup> Dmitri Mendeleev is often considered the “father” of the periodic table. Mendeleev is best known for his work on the periodic table; arranging the 63 known elements into a Periodic Table based on atomic mass, which he published in *Principles of Chemistry* in 1869. The periodic table of the chemical elements is a tabular display of all known chemical elements, approximately 117 at present. The symbols for each chemical element (usually the first letters in its name) are arranged in columns and rows, grouped according to chemical properties. See [Online:web] Accessed on 9 August 2009, URL:[http://en.wikipedia.org/wiki/Periodic\\_table](http://en.wikipedia.org/wiki/Periodic_table)

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all industry sectors, nano-enabled technological convergence is poised to become the strategic platform for manufacturing, food, agriculture and health in the immediate years ahead (ETC Group report 2005a:10). Nanotechnology enables one to engineer at the nanoscale and thereby perhaps to reconfigure everything molecular. From the point of view of nanotechnology, what used to be separate domains of biomedicine, information technology, chemistry, photonics, electronics, robotics, and materials science come together in a single engineering paradigm (Nordmann 2004b: 12).

The ETC Group<sup>16</sup> uses the term “BANG” to describe convergence. Bits (Information technology controls Bits), Atoms, Neurons (Cognitive Neurosciences enables control of the mind by manipulating Neurons) and Genes add up to a little BANG theory-the technological quest to control all matter, life and knowledge. According to little BANG theory, neurons could be re-engineered so that our minds “talk” directly to computers or to artificial limbs; viruses can be engineered to act as machines or, potentially, as weapons; computer networks can be merged with the biological networks to develop artificial intelligence or surveillance systems. Therefore, technological convergence will improve human performance in the work place, on the playing field, and on the battlefield (ETC Group Report 2005c:8).

Converging technologies are enabling technologies and knowledge systems that enable each other in the pursuit of a common goal. Enabling technologies prepare the ground for a wide variety of technical solutions. Because they unlock vast potential and open the door to radically novel technological developments; they are also referred to as “key technologies.” When referring to the potential of nanotechnology one speaks of it instead as a key or enabling technology. An enabling technology enables technological development on a broad front. It is not dedicated to a specific goal or limited to a particular set of applications, but has unlimited potential (Nordmann 2004:12, 19). So,

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<sup>16</sup> The ETC Group, formerly known as Rural Advancement Foundation International (RAFI), is an international civil society organization dedicated to “the conservation and sustainable advancement of cultural and ecological diversity and human rights”. The full legal name is ‘Action Group on Erosion, Technology and Concentration’. See [Online:web] Accessed on 20 March 2009, URL: <http://www.etcgroup.org/>.

nanotechnology is not just a single technology but a combination of many technologies which converge at the nano-scale.

## **5. Manufacturing Approaches to Nanotechnology**

### **5.1. Bottom-up Manufacturing**

Nanotechnology also makes possible bottom-up manufacturing. Bottom-up manufacturing involves the building of structures, atom-by-atom or molecule-by-molecule. It promises a better chance to obtain nanostructures with less defects and more homogeneous chemical composition (Cao 2004:9). The wide variety of approaches towards achieving this goal can be split into three categories: chemical synthesis, self-assembly, and positional assembly. Large numbers of atoms, molecules or particles are used or created by chemical synthesis, which can then be used either directly in products in their bulk disordered form, or as the building blocks of more advanced ordered materials. The process by which the molecules fall into the desired place is called “self-assembly” (Royal Society and Royal Academy of Engineering 2004:27-31).

Self assembly is a bottom-up production technique in which atoms or molecules arrange themselves into ordered nanoscale structures by physical or chemical interactions between the units. Although self assembly has occurred in nature for thousands of years, for example the formation of salt crystals and snowflakes, the use of self assembly in industry is relatively new. There is an economic and environmental interest in processes through which materials or product components essentially form themselves, creating less waste and using less energy (Royal Society and Royal Academy of Engineering 2004:27-31).

Positional assembly is the only technique in which single atoms or molecules can be placed deliberately one-by-one. It involves the use of tiny robots or similar manipulating devices to precisely position molecular building blocks for bonding (Bastani and Fernandez 2002:474). Nanotechnology borrows from living organisms its goals of

constructing machines by organising atoms and molecules into particular configuration it creates work of greater complexity by performing operation in parallel. The scale and complexity of this effort of nanotechnology will likely to remove boundaries that have long been existed between various scientific and engineering disciplines and between various technological fields (Castro 2004:141).

## 5.2. Top-down Manufacturing

Top-down manufacturing involves starting with a larger piece of material and etching, milling or machining a nanostructure from it by removing material (as, for example, in circuits on microchips). This can be done by using techniques such as precision engineering and lithography<sup>17</sup>. Top-down methods offer reliability and device complexity, although they are generally higher in energy usage, and produce more waste than bottom-up methods (Royal Society and Royal Academy of Engineering 2004: 28). Any technology that manipulates matter on nanoscale using “top-down” techniques can be denoted as nanotechnological. In the opinion of Uskokovic, it is natural to expect that the encounter of the “top-down” and “bottom-up” manufacturing system at the nanoscale will result in nano productivity that will mark a new era (Uskokovic 2007: 46).

## 6. Generations of Nanotechnology Products and Processes

The commercial production of nano-scale applications has already begun. There are an estimated over 1200 companies around the world operating in the nanotechnology industry. Four overlapping generations of new nanotechnology products and processes (called “nanoproducts”) have been identified which have potential for development in the interval 2000– 2020: passive nanostructures, active nanostructures, systems of nanosystems, and heterogeneous molecular nanosystems. The first generation products developed mainly after 2000 consist of passive nanostructure (Renn and Roco 2006:

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<sup>17</sup> Lithography is the practice of scanning a beam of electrons in a patterned fashion across a surface covered with a film. The purpose of lithography is to create very small structures by etching of material on to that surface to produce the desired device. It is used in nanotechnology for creating artifacts. See [Online:web] Accessed on 26 August 2009, URL: [http://en.wikipedia.org/wiki/Electron\\_beam\\_lithography](http://en.wikipedia.org/wiki/Electron_beam_lithography)

156). Thus, the commercial production of 'first generation' nano-scale applications has already begun with applications including functioning scientific tools such as atomic force microscopes and the creation of simple nano-scale compounds and composites for use in sunscreens, cosmetics, coatings, and paints, stain resistant clothing, and faster computer memory (Bowman and Hodge 2006: 1061).

The Second generation of products started after 2005, consists of active (evolving function) nanostructures, for example, new transistors, amplifiers, targeted drugs and chemicals, actuators, molecular machines, laser-emitting devices, and adaptive structures. An 'active' nanostructure changes its state in time during its operation (Renn and Roco 2006:156). Based on the existing trends, this second generation development might be viewed as mid way between the existing 'science fiction' and more futuristic 'science fiction' (Bowman and Hodge 2006:1062).

The 'third generation' is expected after 2010 and the advancements in this generation contrast the first and second generation and are a longer-term ideal (Bowman and Hodge 2006:1063). It is the most elaborate, challenging and speculative of the nanotechnology frontiers. This third generation has been coined 'molecular manufacturing', and will, if it eventuates, see the creation of computer directed nano-scale robots capable of precise manipulation of atoms to form complex atomic devices and machine (Hodge et al. 2005:3). K.Eric Drexler in his book "Engines of creation" argued that nanomachines called 'assemblers' will be capable of building anything molecule by molecule. He defined 'molecular assembler' as a device resembling an industrial robot arm but built on a microscopic scale. A general-purpose molecular assembler will be a jointed mechanism built from rigid molecular parts, driven by motors, controlled by computers, and able to grasp and apply molecular-scale tools. He argued that assemblers and other machines in molecular manufacturing systems will be able to make almost anything, if given the right raw materials (Drexler 1986, Drexler et al. 1991).

The fourth generation is expected from 2015-2020 and will involve heterogeneous molecular nanosystems, where each molecule in the nanosystem has a specific structure

and plays a different role. Molecules will be used as devices and fundamentally new functions will emerge from their engineered structures and architectures. Nano-bio-info and cognitive sciences convergence will play an increased role in this generation. In nanomedicine, one would include nanoscale genetic therapies, cell ageing therapies, and nanoscale controlled stem cell therapies. In nanoelectronics, one would envision molecular and supramolecular components “by design” as modular components for transistors (Renn and Roco 2006:157).

## **7. Present and Future Applications of Nanotechnology**

### **7.1 Nanomaterials and Nanoparticles**

This area combines nanotechnology and many applications of nanostructured materials. The three most talked about nanotechnologies are carbon nanotubes, nanoparticles and Quantum dots. Carbon nanotubes (CNTs) were first observed by Sumio Iijima in 1991. Carbon nanotubes are large molecules of pure carbon that are long and thin shaped like tubes, about 1-3 nanometres in diameter, and several micrometres (10-6m) to centimetres long. There are two types of CNT: single-walled (one tube) or multi-walled (several concentric tubes). They have assumed an important role in the context of nanomaterials, because of their novel chemical and physical properties (Royal Society and Royal Academy of Engineering 2004:8). They are mechanically very strong. As individual molecules, nanotubes are 100 times stronger-than-steel and one-sixth in weight. They have a wide range of potential commercial applications: for example, sensors, electronic and optical devices, batteries, fuel cells etc. Currently 50% of all lithium batteries incorporate carbon nanofibres, which double their energy capacity (ETC Group Report 2005b:21).

Nanoparticles are often defined as particles of less than 100nm in diameter. Nanoparticles exist widely in the natural world: for example as the products of volcanic activity, and created by plants and algae. They have also been created for thousands of years as products of combustion and food cooking, and more recently from vehicle exhausts. They exhibit new properties as compared with larger particles of the same materials. For



example, titanium dioxide and zinc oxide become transparent at the nanoscale, however they are able to absorb and reflect ultraviolet light, and have found application in sunscreens. Nanoparticles have a wide range of applications in paints, coating composites, cosmetics (Royal Society and Royal Academy of Engineering 2004:9-10).

Nanoparticles of semiconductors (quantum dots) were theorized in the 1970s and initially created in the early 1980s. These particles can be made to emit or absorb specific wavelengths (colours) of light, merely by controlling their size. Their unique properties promise a wide range of applications across several industrial sectors. Quantum dots are being used in composites, solar cells and to label biological material for research purposes. They can be injected into cells or attached to proteins in order to track, label or identify specific biomolecules (Royal Society and Royal Academy of Engineering 2004:10).

## 7.2 Molecular Electronics

Today, Quantum-effect nanoelectric devices have already been fabricated in solid-state structures. Carbon nanotubes and their ability to act as transistors promise new directions. Industry enthusiasts believe that carbon nanotubes will radically improve the performance of tiny sensors, electronic and optical devices, batteries, fuel cells, catalysts. Nanotechnologies based memory chips, due to their simpler and more repetitive structure compared to more elaborate chips such as CPUs, are widely believed to become one of the first components to be commercialised and integrated into solid-state circuits. The smaller component sizes yield higher circuit densities, lower power consumption and other specific advantages (Bastani and Fernandez 2002:475).

Discs and tapes containing engineered nanomaterials can store large amounts of information<sup>18</sup>. The resolution of a television or a monitor improves with reduction of

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<sup>18</sup> In 2008 IBM scientists achieve a breakthrough in a nanoscale memory technology dubbed "racetrack" memory. An electric current is used to slide—or "race"—tiny magnetic patterns around the nanowire "track," where the device can read and write data in less than a nanosecond. This could lead to electronic devices capable of storing far more data than is possible today, with lightning-fast boot times, far lower cost and unprecedented stability and durability. For greater details see "IBM Moves Closer to New Class of Memory", [Online:web] Accessed on 10 August 2009, URL:<http://www-03.ibm.com/press/us/en/pressrelease/23859.wss#resource>

pixel size. Also, flat-panel displays constructed with nanomaterials may possess much higher brightness and contrast than conventional displays owing to the enhanced electrical and optical properties of the new materials (Buzea et al. 2007:63).

### **7.3. Nanomedicine**

Nanomedicine is, in a broad sense, the application of nanoscale technologies to the practise of medicine, namely, for diagnosis, prevention, and treatment of disease and to gain an increased understanding of the complex underlying disease mechanisms. Nanomedicine has many applications in drug delivery, diagnostics, detection, discovery, sensing, imaging, etc. In the drug delivery arena, nanomedicine is poised to deliver more efficient and site specific/targeted delivery systems. Microsurgical devices or nanobots are capable of navigating throughout the body, repairing damaged sites, destroying tumors or viruses and even performing gene therapy. Nanoparticle drug delivery vehicles would allow faster drug absorption, controlled dosage releases, and shielding from the body immune system-enhancing the effectiveness of already-existing drugs (Bawa et al. 2005:153).

Nanomedicine also aims to learn from nature to understand the structure and function of biologic devices and to use nature's solutions to advance science and engineering. This approach is referred to as "biomimicry." Nanomedicine can be characterized as a primitive technology that takes advantage of the properties of highly evolved natural products, such as proteins, by attempting to harness them to achieve new and useful functions at the nanoscale. The construction principles used in this field often originate in biology, and the goals often aimed at the solution of long-standing research problems. The concept of self-assembly is at the heart of the approaches in this field. Self-assembly of ordered elements is a defining property of life. Nanomedicine attempts to exploit the self-assembly and ordered proximity of nanoscale structures found in biology (Morrow et al. 2007:820).

Some nanomaterials such as nanocrystalline ceramics have certain properties such as hardness, wear resistance that may make them of use as implants in the long term. The development of nanoelectronic systems with high detector densities and data processing capability might allow the development of an artificial retina or cochlea (Royal Society and Royal Academy of Engineering 2004: 23).

#### 7.4. Food Science

Nanotechnology has been touted as the next industrial revolution in many industries, including food processing and packaging. The application of nano-based technology in food industry may include food safety and biosecurity (e.g. Nanosensors), and nanotoxicity. Interactive foods and beverages give desired flavours and colors (on-demand delivery) by the addition of nanocapsules which burst at different microwave frequencies. Adding of nanoparticles (silver, titanium dioxide, silicon dioxide, and nano-clay) into packaging materials ensures better protection of foods by modifying the permeation behaviour of foils, blocking ultraviolet lights, and developing antimicrobial and antifungal surfaces. A worldwide sale of nanotechnology products in food is expected to surge to US \$20.4 billion in 2010 (Chau et al. 2007:269-271).

Nanotechnology is rapidly converging with biotechnology and information technology to radically change food and agricultural systems. With new nano-scale techniques of mixing and harnessing genes, genetically modified plants become atomically modified plants. Pesticides can be more precisely packaged to knock-out unwanted pests, and artificial flavourings and natural nutrients engineered to please the palate (ETC Group Report 2004:8). Expected breakthroughs in crop DNA decoding and analysis could enable agrifirms to predict, control and improve agricultural production. And with technology for manipulating the molecules and atoms of food, the food industry would have a powerful method to design food with much greater capability and precision, lower costs and improved sustainability. The combination of DNA and nanotechnology research could also generate new nutrition delivery systems, to bring active agents more precisely and efficiently to the desired parts of the human body (Allianz Group and

OECD Report 2005: 17). For example, the researchers in Thailand atomically modified the characteristics of local rice varieties. The researchers “drilled” a hole through the membrane of a rice cell in order to insert nitrogen atom that would stimulate the rearrangement of the rice’s DNA. So far, they have been able to change the colour of a local rice variety Khao kam from purple to green.<sup>19</sup> With potential applications across the food chain (in pesticides, vaccines, veterinary medicine and nutritionally-enhanced food), these nano and micro formulations are being developed by agribusiness and food corporations such as Monsanto, Syngenta and Kraft (ETC Group Report 2004:13).

### **7.5. Aeronautics and Space Exploration**

Nanotechnology seems to be promising for the aeronautics industry and breakthroughs are expected within the next few years. Space research has been driven by the goal to reduce the lift-off mass of spacecraft, and improving safety and flexibility of space missions. Reduction of costs is also an important parameter for space missions. Nanomaterials research could contribute to the successful achievement of these goals. Carbon nanotubes (CNTs) offer a distinct advantage as lightweight materials and are regarded as one of the core materials in bringing nanotechnology benefits to space. Due to their high mechanical strength and resistance against heat and radiation, nanoparticles have potential applications in various components in space as lightweight structural materials, as heat protection material, or fire protection applications. Nanoscale materials represent a major stake for spacecraft because of the opportunity they bring to build new structures with specific thermal, electrical, optical characteristics, stronger and cheaper structure (Nanoforum 2007: 48-49, 90-92).

Besides providing remarkably light and strong materials for space ships at low cost, nanotechnology will also provide extremely powerful computers with which to guide both those ships and a wide range of other activities in space. Likely, the desire to send

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<sup>19</sup> ETC Group News Release (2004), “Jazzing Up Jasmine: Atomically Modified Rice in Asia”, [Online:web] Accessed on 12 July 2009, URL:[http:// www.etcgroup.org/article.asp?newsid=444](http://www.etcgroup.org/article.asp?newsid=444)

spacecraft away from the sun with diminishing solar power for extended missions, compel continued reduction in size, weight, and power consumption of payloads. The use of nanostructured materials and devices may contribute to the solutions for these challenges (Choi 2003:339-340). Major space agencies (like NASA) are engaged in research concerning nanomaterials with new properties.

## **7.6 Environment and Energy**

Nanotechnology will be applied to both ends of the environment spectrum, to clean up existing pollution and to decrease or prevent its generation. It is also expected to contribute to significant leaps forward in the near future in environmental monitoring and environmental health science. Nanoparticles have a large proportion of surface atoms, and the surface of any material is where reactions take place. Because of nanoparticles' huge surface area and thus very high surface activity, it takes much less time to achieve remediation goals than conventional technology, which, using biological processes, can take years (Hood 2004:744).

Iron nanoparticles with a small content of palladium are tested to transform harmful products in groundwater into less harmful end products. The nanoparticles are able to remove organic chlorine (a carcinogen) from water and soil contaminated with the chlorine-based organic solvents (used in dry cleaners) and convert the solvents to benign hydrocarbons (Buzea et al. 2007:65)

Breakthroughs in nanotechnology could provide technologies that would contribute to world-wide energy security and supply. Although the most significant contributions may be to unglamorous applications such as better materials for exploration equipment used in the oil and gas industry or improved catalysis, Nanotechnology is being proposed in numerous energy domains, including solar power; wind; clean coal; fusion reactors; new generation fission reactors; fuel cells; batteries; hydrogen production, storage and transportation; and a new electrical grid that ties all the power sources together (Allianz Group and OCED Report 2005: 21)

## **8. Worldwide Research and Development in Nanotechnology**

Nanotechnology investment worldwide has been increasing at an accelerated pace for the past few years. In 2000, the U.S. National Science Foundation (NSF) estimated that \$1 trillion worth of products worldwide would incorporate nanotechnology in key functional components by the year 2015. It estimates that about two million nanotechnology workers will be needed worldwide by 2015. They would be distributed across the world regions as follows: 0.8-0.9 million in the U.S., 0.5-0.6 million in Japan, 0.3-0.4 million in Europe, about 0.2 million in the Asia-Pacific region excluding Japan and 0.1 million in other regions. The corresponding industries will require about two million workers in nanotechnology, and about three times as many jobs in supporting activities. These estimates were based on a broad industry survey and analysis in the Americas, Europe, Asia and Australia. This potential of nanotechnology has encouraged a dramatic rise in R&D expenditure and all developed countries and many developing countries have begun to invest in nanotechnology (Renn and Roco 2006: 154-155).

Today over sixty countries, including the U.S., Japan, Germany, Taiwan, China, Israel and Australia, have implemented national nanotechnology initiative. This was stimulated in part by the National Nanotechnology Initiative unveiled by then President Clinton in January 2000. Japan's early strides in Nanotechnology provided the motivation for the U.S. to launch its National Nanotechnology Initiative. Increased government funding for nano-scale science research in Japan began back in 1995 with the passage of Japan's Science and Technology Basic Law No. 130. The law allocated approximately U.S. \$14.8 billion for basic research to universities, industry, and national laboratories from 1996 to 2000. Government organizations and very large corporations are the main source of funding for nanotechnology research and development in Japan (ETC Group Report 2003:60).

The worldwide nanotechnology research and development (R&D) investment reported by government organizations have increased by a factor of 3.5 between 1997 and 2001, and the highest rate of 90% in 2001. The current efforts are dominated by U.S., Japan and

EU, where government investments are comparable. In Asia, there are growing programs in Japan, as well as in China, South Korea, Taiwan and Singapore. In Europe, besides the EU countries, Switzerland has a strong program. Russia and Ukraine maintain research activities, especially on advanced materials synthesis and processing (Renn and Roco 2006:154-155). An estimation of worldwide private and public funding for nanotechnology R&D in 2005 showed that U.S. research community spends more than 3.5 billion Euros for nanotechnology, followed by 2.7 billion in Japan and less than 2.5 billion in Europe (Hullmann 2006:14-15). The U.S. market had a share of 27% global investment in nanotechnology in 2005, followed by Japanese market with more than 24% of share. The Western European market also had a quarter of the market share with major investment in countries like Germany, UK and France. Other countries like China, Russia, South Korea, Canada and Australia hold the rest of the share.<sup>20</sup>

In December 2003 President Bush signed into law the 21st Century Nanotechnology R&D Act, which authorizes \$3.7 billion funding for nanotechnology R&D in several agencies for fiscal years 2005–2008. This legislation puts into law the NNI programs and activities, and provides guidance for enhancing innovation and responsible development of the field (Huang et al. 2004:344). The 2001 Budget provides \$1.6 billion for the NNI, reflecting steady growth in the NNI investment. The cumulative NNI investment since 2001, including the 2010 request, now totals almost \$12 billion.<sup>21</sup>

The European Commission is the largest funding organisation of nanotechnology research in Europe and as an individual agency even worldwide. In the Sixth European Framework Programme for Research and Technological Development (FP6), nanotechnology has been defined, together with materials and production technologies, as a priority for European research. It is estimated that 1.3 billion Euros have been dedicated to nanotechnology projects between 2004 and 2006 (Hullmann 2006:14). In the Seventh

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<sup>20</sup> “The World Nanotechnology Market (2006)”, for greater details see [Online:web] Accessed on 2 August 2009, URL:<http://www.nanoinfo.jp/whitepaper/WP143.pdf>

<sup>21</sup> ‘National Nanotechnology Initiative-supplement to the President 2010 Budget’ (2009), [Online:web] Accessed on 2 August 2009, URL:[http://www.nano.gov/NNI\\_2010\\_budget\\_supplement.pdf](http://www.nano.gov/NNI_2010_budget_supplement.pdf)

European Framework Programme for Research and Technological Development (FP7), the EU Member States have earmarked a total of € 3.5 billion for funding this theme over the duration of 2007-2013.<sup>22</sup>

## **9. Potential Risks Associated with Nanotechnology**

Public and private spending on nanotech R&D is accelerating and over seven hundred new products have already come to market, but a growing number of scientific studies and government reports have recently warned that engineered nanoparticles could pose unique risks to human health, environment and safety problems due to their size and quantum properties. Only a handful of toxicological studies exist on engineered nanoparticles but, it appears that nanoparticles as a class are more toxic due to their smaller size. When reduced to the nano-scale, particles have a larger surface area that can make them more chemically reactive. As particle size decreases and reactivity increases, a substance that may be inert at larger scales, can assume hazardous characteristics at the nano-scale (ETC Group Report 2005a: 13).

Both pioneers of nanotechnology and its opponents are finding it extremely hard to argue their case as there is limited information available to support one side or the other. It has been shown that nanomaterials can enter the human body through several ports: inhalation, dermal exposure, or ingestion. Accidental or involuntary contact during production or use is most likely to happen via the lungs from where a rapid translocation through the blood stream is possible to other vital organs (Hoet 2004:1). This poses a threat to the workers in nanotech industries because they handle nanoparticles at high concentrations and during a long time. Workers may be exposed to nanomaterials during the manufacture of nanomaterials and the formulation or final use of products containing nanomaterials (ETC Group Report 2005a:22).

There are concerns that if nanoparticles penetrate the skin they might facilitate the production of reactive molecules that could lead to cell damage. There is some evidence

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<sup>22</sup> For further details on 'EU Seventh Framework Programme (FP7)', see [Online:web] Accessed on 2 August 2009, URL: <http://cordis.europa.eu/fp7>



to show that nanoparticles of titanium dioxide (used in some sun protection products) do not penetrate the skin but it is not clear whether the same conclusion holds for individuals whose skin has been damaged by sun or by common diseases such as eczema. Limited toxicology so far on animal and human skin appears to indicate that the nanoparticles of titanium dioxide used currently in sunscreens do not penetrate beyond the epidermis and that organic components of sunscreens are more likely to penetrate the skin than are the nanoparticles (Royal Society and Royal Academy of Engineering 2004:44). Nanotoxicology has also revealed adverse health effects of materials previously considered safe. For example, silver, widely used as an antibacterial agent (in air filters, coatings of refrigerators, vacuum cleaners etc), proves to be toxic to humans or animal cells when in nanoparticle form. Silver nanoparticles have been found in the blood of patients with blood diseases and in the colon of patients with colon cancer (Buzea et al. 2007: 18, 54).

Another serious concern is the transformation of properties that engineered nanomaterials undergo and how this may affect their interaction with biologic systems. Fullerenes and nanotubes are attractive candidates for many applications, including high-performance computing, drug delivery; however, these properties and dimensions also may make them dangerous when introduced into the environment. Moreover, different manufacturing methods can produce widely varying products with different amounts of impurities. These differences may explain why fullerenes behave in some contexts as antioxidants and in others as powerful oxidants, capable of working their way into the brain and damaging cell membranes (Morrow et al. 2007:833).

At the March 2004 annual meeting of the American Chemical Society, an academic scientist reported a study indicating that buckyballs, a form of carbon and an important material in nanotechnology, can cause extensive brain damage in fish (Homes 2004). Another study shows that exposure to high dose of single-wall carbon nanotubes in rats produced a dose-dependent lung inflammatory response. In addition, lung tissue thickening as a prelude to the development of fibrosis at a later stage (Warheit et al. 2004: 117, 120)

In any new technology, foresight of possible risks depends on a consideration of the life cycle of the material being produced. This involves understanding the processes and materials used in manufacture, the likely interaction between the product and the individual or environment during its manufacture and useful cycle (Patra et al. 2009:654). The life cycle of nanoparticles is difficult to establish, since the degradation process of nanomaterials and components is only estimated (Burgi and Pradeep 2006:648). Therefore, the adverse effects of nanoparticles on human health depend on individual factors such as genetics and existing disease, as well as exposure, and nanoparticle chemistry, size, shape and electromagnetic properties (Chau et al. 2007:272). The toxicity of nanoparticles depends on a number of particle parameters such as size, surface area and surface chemistry, charge, coating. Therefore, knowledge about only one or two characteristics of nanoparticles is not sufficient to interpret their biological/ toxicological effects (Oberdorster 2007:9).

## **11. Summation**

There is no universally accepted definition of nanotechnology. However, all the definitions that are used to describe this technology have two things in common 1) it is the manipulation in the physical properties of matter and 2) the size limit 1-100 nanometer. The size limit 1-100 is being criticised on the ground that it excludes many devices and materials that should have been included in the definition of nanotechnology. Efforts are underway to develop a common definition and terminology of nanotechnology. However, too broad and too loose definition of nanotechnology will undermine its scope.

Its novelty lies in the quantum and scale effects. Due to these effects it exhibits such magnificent results which are not possible to achieve through other technologies. In nanotechnology, the manipulation is done at the level of atoms and molecules. At this level all the technologies are same. Therefore, it enables technology convergence. It is not just a single technology but multidisciplinary in nature. By reengineering at the level of atoms and molecules, it results in new technological developments that can not only

transform the existing industries but also create new ones. Therefore, it revolutionizes manufacturing across all industry sectors. In comparison to traditional Top-down manufacturing, the Bottom-up manufacturing is more useful in providing devices with fewer defects and less waste. It has huge potential in providing breakthrough solutions to many technical problems in the field of medicine, engineering, food science, aeronautics and space, environment and energy.

Recognising the potential of this technology, all developed countries and many developing countries are investing in nanotechnology research and development. However, there are many risks associated with this technology. A number of scientific studies on the toxicity of nanoparticles reveal that these particles are harmful for human health. However, the toxicity of these particles depends upon various factors. Only a few toxicological studies cannot establish the risks of nanotechnology. Therefore, further research is required in this area.

Due to its multidisciplinary nature, the research in nanotechnology requires collaboration from various disciplines. The tools and techniques require for nanotechnology research is costly and product development cycle is long. Therefore, in order to bring these products from lab to market significant amount of public and private funding is required. Due to the unfamiliarity with this technology and the unknown risks associated with it, the investors will hesitate to invest in this technology. Intellectual Property Rights will provide incentive to the investors to make investment in this technology. Therefore, Intellectual Property protection is important for the research and development in nanotechnology.

**CHAPTER III**

**INTELLECTUAL PROPERTY RIGHTS**

**AND**

**NANOTECHNOLOGY**

**CHAPTER –III**  
**INTELLECTUAL PROPERTY RIGHTS AND NANOTECHNOLOGY**

**1. Introduction**

Ownership and enforcement of intellectual property rights in the emerging field of nanotechnology will become increasingly important as application move from the R&D phase into the commercial market place. With increasing private sector involvement in nanotechnology R&D, the need for a comprehensive framework for regulating nanotechnology intellectual property rights will be pivotal to the commercial success of the technology. As with the emergence of any pioneering technology, nanotechnology will create issues and challenges related to Intellectual Property Rights (Bowman 2007:310).

Patents are the stronger form of intellectual property rights. They provide incentive for industry to invest in research and development programs that produce innovation. The majority of nanotechnology companies are characterized by long product development cycles and significant expenditures on research (Maebius 2007:175). Therefore, patents will provide strong incentives for companies to invest in nanotechnology research and development. Worldwide, industries and Government are not only making huge investment in nanotechnology research but also filing a large no of patent applications in this area. Aggressive patenting by universities, multinational corporations have resulted in a dense patent landscape overcrowded with broad and overlapping patents leading to the development of patent thickets and anticommons.

Most of the patent applications in nanotechnology are for the fundamental research tools or of already patented inventions. Patents on such inventions will stifle innovation in this area. Convergence of nanotechnology with other technologies will complicate the debate over what is patentable. Patenting of nanotechnology raises some unique questions: Can a mere difference in size confer novelty to an invention? Do the criteria of “novelty” and

“obviousness” differ in nanotechnology? Is there a need for a common definition of nanotechnology for patent examining and searching purpose?

This chapter examines the challenges involved in the patenting of nanotechnology. It also aims to analyze the provision of TRIPs Agreement regarding patenting of nanotechnology. Besides comparative study of the patent law of U.S. and EU, other issues such as the problems of patent thicket, anticommons, reverse doctrine of equivalents, will be discussed. The possible solutions for the problem of patent thickets and anticommons will also be discussed.

## 2. TRIPS Agreement

### 2.1 Background

The Uruguay Round of General Agreement on Trade and Tariff (GATT) generated the TRIPs Agreement.<sup>1</sup> The issue of TRIPs got incorporated into the WTO agenda mainly for two reasons. First this was a reaction by the developed countries against the attempt made by the developing countries to call for the reform of the international IPR system through the World Intellectual Property Organization in order to generate greater transfer of technology from the developed countries (Chang 2001:299-300). Second, The United States and some other developed countries were concerned that the existing international obligations under the Berne and Paris Conventions were not enforced adequately by the

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<sup>1</sup> In 1944, in Bretton Woods, New Hampshire, an agreement was concluded between United States of America and Britain for reconstructing the world economy after the war. The Bretton Woods Agreement envisaged the creation of three key new international institutions: the International Monetary Fund (IMF), the International Bank of Reconstruction and Development (IBRD), and the International Trade Organization (ITO). By the end of Second World War, the IMF and the World Bank were duly created, but the ITO did not come into existence. Instead a provisional agreement, negotiated in 1947 among some twenty three major trading countries in the world as a prelude to the ITO and the Havana Charter, i.e. the General Agreement on Tariffs and Trade (GATT), was adopted (Trebilcock and Howse 2005:23-24). Under the GATT some eight rounds of negotiations have been successfully concluded. However, the limited applicability of GATT disciplines and its incompleteness as trade institution caused problems. Therefore, in the Uruguay round began in 1986, the final round of trade negotiations in the GATT regime discussion began to address the need for a new comprehensive trade organization to replace the GATT regime (Lee 2006:15-16).

developing countries, and that WIPO<sup>2</sup> did not provide a credible institutional Framework for the settlement of disputes under these agreements (Trebilcock and Howse 2005:409).

There were basically two broad approaches in the TRIPs negotiations. Developed countries had taken an approach which was generally grounded on the premise that inadequate and discriminatory protections of IPRs constituted a major distortion of and impediment to trade and as such be dealt with in the framework of GATT. On the other hand, the developing countries argued that it was not for the GATT to consider the protection of IPRs through the elaboration of substantive norms and standard to be applied by the countries (Hegde 2005:112-113). Despite the basic differences of perspective between the United States and other developing countries, and most of the developing world, the Uruguay Round was successful in producing a comprehensive Agreement on TRIPs. The reason for eventually signing of the TRIPs Agreement that constitutes Annex 1C of the WTO Agreement was mostly that it was made part of the broader package deal of the Uruguay Round which included other agreements which were perceived as beneficial to developing countries<sup>3</sup> (Cullet 2005: 52-53).

## 2.2 General Framework

The TRIPs Agreement is composed of seventy-three articles in seven parts. The main objective of TRIPs Agreement is to reduce distortions and impediments to international

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<sup>2</sup> WIPO was established by the Convention Establishing the World Intellectual Property Organization Signed at Stockholm on July 14, 1967 and as amended on September 28, 1979. It became one of the specialised agency of the UN (as a consequence of Agreement between the World Intellectual Property Organisation and the World Trade Organisation, Geneva 22 December 1995) to administer the Paris and Berne Conventions and to seek the harmonisation of national property laws. WIPO main task as the preamble states is to promote the protection of intellectual property rights throughout the world. Currently, there are 184 Member states. [Online:web] Accessed on 22 July 2009,URL:[http://www.wipo.int/about-wipo/en/what\\_is\\_wipo.html](http://www.wipo.int/about-wipo/en/what_is_wipo.html).

<sup>3</sup> The Uruguay Round of Multilateral Trade Negotiations that had begun in Punta del Este in 1986 was concluded when Minister of GATT met in Marrakesh on 12-15 April in 1994. At Marrakesh, 114 countries, together with the European Communities, became signatory to the final act embodying the results of the Uruguay Round and parties to the agreement establishing the World Trade Organization, which came into effect on 1 January 1995. Signatories also become parties to the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPs Agreement), annexed to the WTO agreement, as well as to thirteen Multilateral Agreement on Trade in Goods, a General Agreement on Trade in Services and a number of other measures, including an Understanding of the Settlement of Disputes (Matthews 2002:7).

trade and to promote effective and adequate protection of intellectual property rights. It recognizes intellectual property rights as private rights.

It also recognizes the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.<sup>4</sup>As with the previous WIPO-administered conventions, the TRIPs Agreement set down minimum standards for intellectual property protection. Article 1.1 of the TRIPs Agreement states that “Members may, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”.This shows that TRIPs is not intended to be a harmonizing Agreement. It seeks to harmonize national laws but does not provide for uniformity.

The TRIPs Agreement built upon the legal basis provided by the earlier WIPO Conventions, including those of Paris and Berne conventions.<sup>5</sup> It itself requires compliance with these conventions with the exception of Article 6bis of the Berne convention related to moral rights.<sup>6</sup> Thus, the TRIPs Agreement incorporates existing standards and introduces internationally recognized minimum standards which may go beyond incorporated treaties (Cullet 2005:57). The basic principles of TRIPs Agreement are National Treatment (Article 3) and Most Favoured Nation Treatment (Article 4). The National Treatment principle requires the WTO members to “accord the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property”.<sup>7</sup> This obligation is subject to the exceptions (Article 3.2) that already exist in Paris, Bern, and Rome Convention and in the

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<sup>4</sup> Preamble to the Agreement on Trade-related Aspects of Intellectual Property Rights.

<sup>5</sup> Article 2(2) of the TRIPs Agreement

<sup>6</sup> Article 9(1) of the TRIPs Agreements states: “Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. However, Members shall not have rights or obligations under this Agreement in respect of the rights conferred under Article 6bis of that Convention or of the rights derived there from.”

<sup>7</sup> Article 3.1 of the TRIPs Agreement



Washington treaty.<sup>8</sup> In any event, the principle of national treatment is already established by the Paris, Berne and Rome conventions, so in this respect Article 3.1 merely re-emphasizes well-established principles (Matthews 2002: 47-48). The most-favoured-nation measures set out in Article 4 of the TRIPs Agreement states "...that any advantage, favour, privilege, or immunity granted by the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members." This is one of the direct links with other trade agreements of the WTO since the most-favoured-nation clause has been the cornerstone principle of the GATT since 1947. It provides that any advantage granted to a country on a bilateral basis must automatically be extended to all WTO members (Cullet 2005:58).

The objectives of TRIPs Agreement are laid down in Article 7 of the Agreement. It provides that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of right and obligations". Article 8 of the Agreement applies more specifically to measures adopted by state to implement their TRIPs obligations. It states that, "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors vital to their

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<sup>8</sup>The Paris convention for the Protection of Industrial Property of 1883 and the Berne Convention for the protection of Literary and Artistic works of 1886 were the results of attempts to coordinate the international dimensions of intellectual property rights. Under the Paris Convention for the protection of industrial property 1883, signatories agreed to provide national treatment for foreign works under domestic laws for patents, trademarks, industrial designs, trade names, appellations of origin and utility models. The Berne Convention for the protection of Literary and Artistic Works of 1886 sets out similar provisions and minimum terms for copyrights. However, these conventions lacked strong enforcement provisions. (Matthews 2002: 10-11). "Rome Convention" refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October. This convention protects performers, phonogram producers and broadcasting organizations. It also contains a National treatment obligation. "Washington Treaty" refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. The Treaty has not yet entered into force, but the following States have ratified it or acceded to it: Bosnia and Herzegovina (Accession-March 8, 2007), Egypt (Ratification-July 26, 1990) & Saint Lucia (Accession - December 18, 2000). [Online:web] Accessed on 30 July 2009, URL:[http://www.wipo.int/treaties/en/ip/rome/trtdocs\\_wo024.html](http://www.wipo.int/treaties/en/ip/rome/trtdocs_wo024.html).

socio-economic and technological development, provide that such measures are consistent with provisions of this Agreement ”.<sup>9</sup>

One of the main innovations of TRIPs in the field of intellectual property is that it brings together different categories of intellectual property rights which had previously been dealt with separately i.e. trademark, geographical indications, copyrights, industrial designs, patents, topographies of integrated circuits, and undisclosed information. Another is that it contains detailed provisions on enforcement (Part III). Further TRIPs Agreement is one of the treaties which falls under the dispute settlement system of the WTO which ensures a much higher degree of compliance than would otherwise be the case (Cullet 2005:57).

### **3. Patentability of Nanotechnology Inventions**

Proponents of TRIPs argue that patent<sup>10</sup> rights are essential for promoting research and development as well as stimulating innovation. Innovation is encouraged by patent protection and fluidity. Patent right are the cornerstone of the protection of innovation, and they provide the necessary incentive to innovate (O’Loughlin 2007:352-353). Innovation promotes market growth via enhanced competition and thus forms the basis of the economics of a patent system. In a market without 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 result in market failure (Sharma and Chug 2009:436).

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<sup>9</sup> Article 8.1 of the TRIPs Agreement

<sup>10</sup> Patents originally referred to letters patent (a literal translation of the Latin *litterae patentes*). *Litterae* patents were started to be issued in Europe in the sixth century. The adjective “patent” means open, and originally patents were referred to the “letters patent” or open letters which were the official documents by which certain privileges, rights, ranks or titles were conferred by sovereign rulers. They were “open” because they were publicly announced and had a seal of the sovereign grantor on the inside, rather than outside. Prior to being associated with inventions, patent were used for conquest in the colonial period and for establishing import monopolies. Charters and letters which were given by European monarchs to discover and conquer foreign lands on their behalf were referred to as letter patents. Patents have, through history, been associated with colonialism (Shiva 2001: 114).

Kitch's prospect theory of patent says that the patent system operates not as an incentive-by-reward system, giving exclusive rights to successful inventors in order to encourage future invention, but as a "prospect" system analogous to mineral claims. It suggests that patenting in major technological areas provide directional assistance to the follow-up inventions. Kich argues that the primary point of the patent system is to encourage further commercialization and efficient use of as yet unrealized ideas by patenting them, just as privatizing land will encourage the owner to make efficient use of it. Society as a whole should benefit from this equalization of private with social interests (Kitch 1977:271-275).

Patents are essential to start-ups and smaller companies because they may help in negotiations over infringement during competitive posturing with larger corporations. Moreover, patents provide inventors' credibility with their backers, shareholders, or venture capitalists groups who may not fully understand the science behind the technology. For a start-up company, patents are a means of attracting investment and validating the company's foundational technology. Therefore, start-up companies aggressively seek patents as a source of significant revenue (Morrow et al. 2007:812).

Nanotechnology includes a diverse array of companies at different stages of development focusing on different industries, such as drug delivery, electronics, energy, and medical devices. Despite this diversity, the majority of nanotechnology companies are characterized by long product development cycles and significant expenditures on research. Research and development of nanotechnology requires a huge amount of investment. It rather resembles chemistry and gene technology, where progress requires substantial investments, and can be contrasted with software development, which can be accomplished by a great number of contributors without commercial interests. In the area of nanotechnology, giving incentives by providing for patents therefore seems to be necessary (Zech 2009:150). Therefore, a review of the current international patent framework for nanotechnology is crucial.

### 3.1. Patentability Criteria

Article 27.1 of the TRIPs Agreement provides that "...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". It further states that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".<sup>11</sup> Article 27.2 of the TRIPs Agreement requires that "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *order public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment".<sup>12</sup>

Section 101 of the United States Patent Act, 1952,<sup>13</sup> defines patentable subject matter as '...any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof'. The conditions for patentability i.e. novelty and nonobviousness are described by Sections 102 and 103 of the Act, respectively. Whereas, the criterion of patentable subject matter in Europe is defined in Article 52 of the European Patent Convention (EPC)<sup>14</sup> 1973. Article 52 of the EPC states that 'European

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<sup>11</sup> This wording of Article 27.1 seeks to address problems arising in relation to developing countries, where local working requirement are often imposed and certain categories of product, particularly pharmaceuticals and agrochemicals, are excluded from patent protection on public policy ground. It was an important achievement for developed countries during the TRIPs negotiation (Matthews 2002: 57-58).

<sup>12</sup> The exceptions in Article 27.2 have been criticized on grounds that they are very broad and, without a narrowing interpretation, could be read as allowing the continued exclusion of certain pharmaceutical products and processes from patentability (Matthews 2002: 59).

<sup>13</sup> July 19, 1952, c. 950, 66 Stat. 792, Codified as Title 35 of the United States Code, entitled "Patents".

<sup>14</sup> There are three sources of law that govern patent grants in Europe— the agreements of the European Patent Convention ('EPC'), Directive 98/44/EC of the European Parliament and the Council of the European Union on the Legal Protection of Biotechnological Inventions ('Biotech Directive'), and the national laws of the individual European states. The Convention on the Grant of European Patents of 5 October 1973, commonly known as the European Patent Convention (EPC), is a multilateral treaty instituting the European Patent Organization and providing an autonomous legal system according to which European patents are granted. In 1973, the Munich Diplomatic Conference for the setting up of a European System for the Grant of Patents took place and the Convention was then signed in Munich (the Convention is sometimes known as the Munich Convention). The EPC is separate from the European Union (EU), and its membership is different. The Convention is now in force in 36 countries. [Online: web] Accessed on 10 August 2009, URL: <http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma1.html>.

patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step'. The requirements of patentability i.e., Novelty (Art. 54 of EPC), Inventive Step (Art. 56 of EPC), and Industrial Application (Art. 57 of EPC) are analogous to the utility, novelty, and non-obviousness factors required to gain a patent in the United States.

### 3.1.1 Novelty

The first criterion of patentability is that an invention must be novel. An invention is novel if it is not part of the state of art. Article 54(2) of the EPC 1973, defines state of art. It states that "The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application". Section 102 of U.S. Patent Act 1952, states that "...prior art is limited to the patent publications, printed publications other than patent publications; and otherwise publicly known inventions". Most WTO members define the relevant state of the art in the light of any publicly available knowledge. Hence, an invention is novel if it is until that time unknown or undisclosed to the public (Zekos 2006b:319). The novelty requirement ensures that the public actually receives a social benefit from new knowledge in exchange for the social cost of legal monopoly. It also ensures that the fundamental purpose of the patents to reward invention and disclosure is satisfied (Smith 2007:461).

#### a) Size does Matter

Nanotechnology is the miniaturisation of existing technology and it is mainly characterised by its size. Many nanotechnology inventions involve the reduction in size from known structures at the larger micrometer range. The fundamental question which arises in case of nanotechnology patenting is: Whether a nano version of an existing macroscale invention is patentable on the basis of size alone? Under U.S. case law, an invention may not be patentable where the sole element of novelty is a difference in size,

since a mere change in size may be viewed as obvious.<sup>15</sup> The court followed this principle in many cases. *In re Rinehart*<sup>16</sup>, the claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at super atmospheric pressure. The claims were rejected by the Board of Appeals as obvious over a reference which taught the claimed process except for the presence of a solvent. However, the evidence produced by Rinehart showed that the reference did not point to any recognition of the problems which arise from scaling up to a commercial process. The court reversed the board finding and held that there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully. The court held that "... that mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled".

In another important case, *In Gardner v. TEC Sys Inc*<sup>17</sup>, the patent (447') in issue was for the claim of device useful in drying the ink used on the high-glass paper of which periodicals' are made. The device in patent 447' supports and positions the web (in the initial stage of printing process the paper is in the form of a web). The device disclosed in the '447 patent supports and positions the web by floating it on one zone or between two opposed zones of static air under superatmospheric pressure. There was prior art patent (Vits) entitled "Apparatus and Method of Drying Web Material by Directing Hollow Gas Jet Streams Against Opposite Faces of the Web". The trial court held that "patent 447'

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<sup>15</sup> *King Ventilating Co. v. St. James Ventilating Co.*, 26 F.2d 357, 359 (8th Cir. 1928). This case established the legal principle that a "mere difference in dimension cannot add novelty" to a claimed new product. The court followed this rule *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (In this case the court held the difference in degree and size are not patentable. The claims were directed to a lumber package "of appreciable size and weight requiring handling by a lift truck", which were held unpatentable over prior art lumber packages which could be lifted by hand because "the limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art") Online: web] Accessed on 25 July 2009, URL: [www.uspto.gov/web/offices/pac/mpep/.../2100\\_2144\\_04.htm](http://www.uspto.gov/web/offices/pac/mpep/.../2100_2144_04.htm).

<sup>16</sup> 531 F.2d 1048,189 USPQ.143 (CCPA 1976). [Online:web] Accessed on 8 August 2009,URL:[http://www.iplawusa.com/resources/189\\_USPQ\\_143.pdf](http://www.iplawusa.com/resources/189_USPQ_143.pdf)

<sup>17</sup> 725 F.2d 1338, 1346 (Fed.Cir1984). Available at [Online:web] Accessed on 9 August 2009, URL:<http://www.altlaw.org/v1/cases/410280>.

claim represent a combination of old elements. To be patentable such combination must produce a synergistic result i.e. a result greater than sum of the parts". The United States Court of Appeals for the Federal Circuit supported the trial court finding. The court held that "...the prior patent discloses the inventions of claims (patent 447') in suit except for their dimensional limitations. These limitations do not exhibit qualitatively different phenomena from the prior art". The court further held that "the claim 447' the claim device was not patentable distinct from prior art because structural difference over the prior art do not necessarily result in difference in performance over the prior art".

If we apply this finding in nanotechnology then nano scale version of the existing product cannot be patentable on the basis of difference in size alone unless it exhibits qualitatively different phenomena from the prior art. Now, here the question arises: Do the nano-scale inventions exhibit qualitative different phenomenon from prior art? Nanotechnology is not just only a miniaturisation from micron metre scale down to nanometre scale. Matter behaves uniquely at nano-scale. When a matter reduced to nano-scale its mechanical properties, physical properties are distinctively different from the macro scale counterpart. Therefore, as opposed to the microscale, the nanoscale is not just another step towards miniaturization, but is a qualitatively new scale (Lowndes et al. 1999:2). Therefore, the nano-scale inventions exhibit qualitative different phenomenon from the prior art.

However, it is relevant to consider that an invention is not patentable where the change in form, proportion, or size brought about better results than the previous invention, if the invention is anticipated by prior art (Bleeker et al. 2004:48). Prior use, knowledge, or disclosure which render a patent (or patent application) invalid on lack of novelty is said to "anticipate" or even "inherently anticipate" the later disclosure (Smith 2007:460). There are several judicial pronouncements which state that the mere recitation of a newly discovered function or property inherently present in the in prior art does not distinguish the claimed product patentable over the prior art. In order to find out whether the prior art inherently possesses the properties exhibited by the nanoscale version, it is necessary to understand the doctrine of inherent anticipation.

## **b) Inherent Anticipation**

Patents are based upon description of technology which distinguishes it from previous technologies described in the prior art. Technologies may have qualities that are unidentified in a patent description, but which are nonetheless present. These unknown attributes are referred as “inherent” in the product or processes. The doctrine of inherency<sup>18</sup> relies on characteristics which often are not necessarily recognized by persons of ordinary skill in the art; if the person having ordinary skill in the art would know of the presence of an element based on the prior art disclosure, there is a straightforward case of anticipation based on that disclosure and no need for the inherency doctrine (Burk and Lemley 2005: 372-374).

Inherency cases are all ultimately about public benefit. If the public does not benefit from the invention, there is no inherency. This doctrine permits defendants to invalidate a patent by showing that even though the prior art did not expressly disclose what the patentee claims to have invented, all or part of the patentee’s invention was inherent in a particular piece of prior art (Burk and Lemley 2005: 373-374).

The leading case related to inherency is *Continental can Co. USA v. Monsanto C.*<sup>19</sup>. The issue in *Continental can* was whether the district court had properly invalidated a patent for anticipation on summary judgment. The patent (‘324) at issue claimed a plastic bottle with hollow support ribs. A prior art (called ‘Marcus patent’) bottle claimed plastic ribs, but did not specify whether the ribs were hollow or solid. The challenger Monsanto pointed to expert testimony indicating that the manufacturing process for the prior art bottles would inherently produce hollow ribs and therefore argued that the newly

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<sup>18</sup> The story of inherency begins with the 1880 Supreme Court case *Tilghman v. Proctor* 102 U.S. 707 (1880), which is a seminal case for accidental anticipation. In this case the court held that “it would be “absurd” to hold that a patent is anticipated because those skilled in the art later recognize that the discovery was “accidentally and unwittingly produced whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done.” *Tilghman* is not an example of inherent anticipation. Rather, it stands for the corollary proposition that when the claimed invention may have been accidentally made or practiced, but would not have inevitably resulted from such making or practicing, these accidental acts (Mueller et al. 2008: 1114).

<sup>19</sup> 948 F.2d 1264 (Fed. Cir. 1991). Available at [Online:web] Accessed on 22 July 2009, URL:<http://altlaw.org/v1/cases/412137>.



patented bottle was inherently anticipated by this reference. The accused infringer's expert testified that the prior art plastic bottle was made by 'blow moulding', a process, that would inherently produce hollow ribs. Monsanto argued that anticipation lie because the Marcus patent's ribs were "inherently" hollow, regardless of how they were shown in the Marcus patent. The Federal Circuit dismissed the district court judgement that all claims of patent ('324) were anticipated by the prior art. The court held that "In order to find inherent anticipation, the undisclosed element of the prior art had to be a necessary technological fact of the prior art. Inherency, however, may not be established by probabilities or possibilities". The Court further held that "...for anticipation the missing element must necessarily present in the thing described in reference and recognized by a person of ordinary skill. Anticipation accommodates common knowledge of technological facts: that is, where technological facts are known to those in the field of the invention, albeit not known to judges".<sup>20</sup>

To provide complete protection of public knowledge, the law of inherency protects the naturally flowing consequences of prior art already in public domain even if those consequences are unknown. In other words, inherency does not require a person having ordinary skills in the art to have prior knowledge, recognition, or appreciation of the inherent characteristics or property of the claimed invention to be deemed anticipated by the prior art (Matthews and Troilo 2004:785). Therefore, if a substance exhibits certain properties, while in the hindsight those properties are the result of the effects that take place at nano level and the man skilled in the art knows how to arrive at the substance, the substance exhibiting the 'nano level specific' properties is part of the prior art and cannot be patented again (Schellekens 2008:4). For example, Damascus steel was used for sword making in the Middle-East. It is very strong and particularly good at holding an edge. Recent research suggests that its extraordinary properties are caused by carbon nanotubes. Damascus steel does not become novel again because we now know why it is so strong or because we now perhaps have other ways of making it.<sup>21</sup>

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<sup>20</sup> Ibid

<sup>21</sup> For greater details see Sanderson (2006), "Sharpest cut from nanotube sword: Carbon nanotech may have given swords of Damascus their edge", [Online:web] Accessed on 20 august 2009, URL:<http://www.k8science.org/news/news.cfm?art=2932>.

Most notable decision in which Federal Circuit reaffirmed the legal doctrine of inherency is *Schering Corp. (v.) Geneva Pharmaceuticals, Inc*<sup>22</sup>. In this case the dispute centered around two of Schering Corporation patents on antihistamines ('233 and '716). Antihistamines inhibit the histamines that cause allergic symptoms. The prior art '233 patent covered the antihistamine loratadine, the active component of a pharmaceutical that Schering marketed as Claritin. The patent '716 at issue in this case covered a metabolite of loratadine called descarboethoxyloratadine (DCL).<sup>23</sup> Schering sued competitors who were seeking to market their own version of antihistamine with loratadine for infringement of the 716 patent because loratadine necessarily converts to DCL when administered to patients. The district court invalidated the patent '716 on the ground that the disclosure in '233 patent inherently anticipated the broad claims of the '716 patent.

The Federal Circuit affirmed the district court judgment of invalidity and held that "...a limitation or the entire invention is inherent and in public domain if it naturally results from the explicit disclosure of prior art". The Federal Circuit rejected the Schering argument that inherent anticipation requires recognition in the prior art and held that "the case laws does not require one of the skill in the art to recognize the inherent disclosure before the critical date of challenged patent".

Although *Schering case* involved a pharmaceutical compound, its application should extend to nanotechnology. Thus, the patentability of nanoscale invention may turn on whether the nanolevel properties of known materials are inherent to the material or whether new or improved properties, or both, result when the known material is manipulated on the nanolevel. Therefore it is quite likely that the prior art that was

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<sup>22</sup> 339 F.3d 1373, USPQ2d 1664, 1668 (Fed. Cir. 2003). [Online:web] Accessed on 22 July 2009, URL:<http://www.ll.georgetown.edu/FEDERAL/judicial/fed/opinions/02opinions/02-1540.html>.

<sup>23</sup> A metabolite is the compound formed in the patient's body upon ingestion of a pharmaceutical. The ingested pharmaceutical undergoes a chemical conversion in the digestion process to form a new metabolite compound. This means that as a naturally flowing consequence of ingesting loradine, a patient will form DCL in the body.

previously known to exist and function only at the macro scale may nevertheless inherently anticipate their nanoscale counterparts exhibiting new and improved properties (Matthews and Troilo 2004: 794-795). In such a case nanoscale invention cannot be considered as novel for patenting.

But parallel to the legal doctrine that size is not patentable and the doctrine of inherency is the well settled exception that one can rebut a finding of obviousness through a showing of "unexpected" result (Roe 2006:133). The relevant case which throws light on this issue is *In re Soni*<sup>24</sup>. In this case the applicant soni filed a patent application for an invention related to conductive polymer compositions having molecular weight greater than 150,000. The specification in the patent application stated that the claimed compositions have improved physical and electrical properties compared to compositions using polymers having a molecular weight below 150,000. The applicant established this point by describing a number of tests in the specification. The claims were rejected by the Board of Appeal as being anticipated by the prior art, except that the reference does not explicitly disclose polymers having a molecular weight greater than 150,000. Soni argued that it overcame the prima facie case of obviousness because its patent specification contains data showing that the claimed compositions do exhibit unexpectedly improved properties.

The Federal Court reversed the board decision of rejecting the claims and held that "the one way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of "unexpected results," i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. The basic principle behind this rule is straightforward, that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious. This principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results. The unexpected results must be established by factual

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<sup>24</sup> 54 F.3d 746 (Fed.Cir.1995). [Online:web] Accessed on 27 July 2009, URL:<http://www.altlaw.org/v1/cases/413078>

evidence.<sup>25</sup> Therefore, nanoscale inventions can rebut the finding for inherent anticipation by showing unexpected results.

Same findings were given by the European Union Technical board of appeal in *T852/91*<sup>26</sup> case. In this case the issue was whether the novel compounds which were structurally similar to known compounds would reasonably be expected to have the similar biological activity. The patent application was for substances with leukotriene-antagonistic properties (i.e. used in the treatment of allergic and inflammatory conditions). In first instance the application was refused on the grounds that there were known substances having the same type and degree of biological effect and were structurally similar to the claimed ones. The Board of appeal ruled that “to deny inventive step for novel chemical compounds because they are structural similar to known chemical compounds amounted to an allegation that a skilled person would have reasonably expected the same usefulness of both the known and the novel compounds as the means for solving the technical problem underlying the application in question”. The court further laid down that “such an expectation would be justified if the skilled person from common knowledge or from specific disclosure knew that the existing structural differences of the chemical compound concerned were so small that they would have no essential bearing on those properties important for solving technical problem and could be discarded”.

This argument can be used in nanotechnology patent cases. This “structural obviousness” may be overcome by showing new and unexpected properties. Therefore, if a substance exhibits at nano-scale properties that fundamentally differ from the properties that occur in the big counterparts, inherency cannot take away the novelty of the nano-scale substance because these properties are not inherently present in the substance at greater than nano-level (Schellekens 2008:4). At nanoscale quantum effects produced such

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<sup>25</sup> Ibid.

<sup>26</sup> T 852/91 of 06 06 1994. For the fact and detail of the case it is solely relied on (Domeij 2000: 168-169). See also EPO, Case Law of the Boards of Appeal of the European Patent Office, Fifth Edition December 2006, p.151, [Online:web] Accessed on 28 July 2009, URL:<http://www.epo.org/aboutus/publications/procedure/case-law.html>.

unexpected results which are not possible to achieve at macroscale. They cannot be anticipated by macroscale prior art. For example, micrometre sized Titanium dioxide (TiO<sub>2</sub>) is white and opaque, when used in sunscreen it caused it to appear white. Nanoparticles of titanium dioxide are transparent and block ultraviolet light. So, they provide an effective sun block by showing new and unexpected properties. Thus, nano scale substances are novel for the purpose of patenting.

### 3.1.2 Non-Obviousness / Inventive step

The second criterion for patentability is that an invention must involve an inventive step. The statutory requirement for nonobviousness of a novel invention is set forth in section 103 of U.S. Patent Act 1952, which bars the grant of a patent "...if the differences between the invention and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

The judicial doctrine of nonobviousness was first articulated by the Supreme Court in *Hotchkiss v. Greenwood*.<sup>27</sup> In this case the patent was for an improved method of making knobs for "locks, doors, cabinet furniture, and for all other purposes for which wood and metal or other material knobs are used". The improvement consists in making said knobs of potter's clay, such as is used in any species of pottery and also of porcelain. The evidence at the trial showed that it has been common to fasten knobs made of other materials to their spindles as described in the plaintiff specification. The trial court held that the patent was void because there was no ingenuity or skill and it involved only a substitution of materials rather than any real innovation. On appeal the Supreme Court held "...that irrespective of the requirements for novelty and utility, the standard for patentability of an invention is ingenuity and not ordinary skill". The court held that the

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<sup>27</sup> *Hotchkiss v. Greenwood*, 52 U.S. 248, (1850). For the facts and elaborate discussion of the present case, it is solely relied on (Kitch 1966).

patent is invalid as there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention.

The general holding of *Hotchkiss* supports sound public policy considerations. Enforcing a minimal standard for nonobviousness prevents inventors from obtaining rights to products already in the public domain by adding trivial modifications (Hays 2009: 803-804). In the United States, the basic test for the determination of inventive step or obviousness has been promulgated in *Graham v. John Deere Co.*<sup>28</sup> case. In this case the court laid down that the newly enacted section 103 was a mere codification of the prior law dating from *Hotchkiss*. In this case the U.S. Supreme Court established the obviousness standards. According to the Court, obviousness could be determined using a simple four step analysis. First, the scope and content of the prior art are to be determined. Second, the differences between the claimed invention and the prior art are to be ascertained. Third, the level of ordinary skill in the pertinent art is to be resolved. Fourth, secondary factors of non-obviousness, including commercial success and long-felt need in the art are to be considered.

These secondary consideration results from court belief that the reaction of the market will show that certain invention are more deserving of patent protection than others. These factors work best for actual products that are sold rather than for upstream research tools or intermediary products. These factors tend to favour inventions that are significant advances over what came before, rather than incremental improvements. Thus these factors are more likely to apply in pharmaceutical or biotechnology cases than in software cases (Burk and Lemley 2003:144-145).

The *Graham case main* deficiency is that it never established a standard for determining whether an invention is sufficiently nonobvious to warrant patent protection. Therefore

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<sup>28</sup> 383 U.S. 1 (1966). [Online:web] Accessed on 20August 2009, URL:<http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=us&vol=383&invol=1>. Two other cases were argued and decided along with *Graham* case on the same day. i.e. *Calmer Inc v Chemical co*, 383 US 1 (1966) and *United States v Adams*, 383 US 39 (1966). These three cases are known as *Graham's Trilog*y.

the Court of Appeals for the Federal Circuit (“the Federal Circuit”) assumed the burden of defining a workable standard. It has created an extensive body of law on obviousness that developed into the “teaching, suggestion, or motivation” (“TSM”) standard.<sup>29</sup> This TSM standard says that an invention is obvious where a person of ordinary skill in the relevant art would arrive at the same construct by combining two or more concepts in the prior art where there is some teaching, suggestion, or motivation to combine them (Dowd et al. 2007:296-297).

In its landmark decision *KSR International Co. v. Teleflex*,<sup>30</sup> the U.S. Supreme Court announced new standards for obviousness determination in patent examination. In *KSR*, the Court expanded the scope of the *Graham* analysis and criticized the long-standing teaching-suggestion motivation (TSM) test employed by the Federal Circuit to implement the holding of *Graham*. In this case an infringement suit was filed by Teleflex against KSR international for infringing the patent of which the Teleflex was the sole licensee. The patent was related to a computerised adjustable pedal system for controlling fuel supply to the engine of an automobile. The individual elements of the invention were present in the prior art, but the combination of elements had not been previously disclosed.

The Federal Circuit reversed the finding of lower court of patent invalidity and held that “the court failed to identify a motivation in the prior art that would lead a person of ordinary skill in the art to combine the elements”. The U.S. Supreme Court criticized federal court application of the TSM test as a “rigid rule that limits the obviousness inquiry. The Court directed to the federal circuit courts to apply a “flexible” TSM test that considers common knowledge and common sense to assess obviousness in light of prior art. As the court noted “When there is a design need or market pressure to solve a

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<sup>29</sup> TSM was first articulated by the Court of Customs and Patent Appeals (CCPA) in *Application of Bergel*, 292 F.2d 955, 957 (C.C.P.A. 1961). The CCPA (1910-1982), is the predecessor to the Court of Appeals for the Federal Circuit (CAFC, Fed. Cir.) (1983-present). To resolve the question of obviousness with more uniformity and consistency the (TSM) standard, first articulated five years before *Graham*, became the cornerstone of obviousness determination in the lower courts.

<sup>30</sup> *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). [Online:web] Accessed on 26 July 2009, URL:<http://www.supremecourtus.gov/opinions/06pdf/04-1350.pdf>.

problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. In such case the invention might be obvious.”<sup>31</sup>

While KSR has provided a set of test that United States Patent and Trademark Office (USPTO) may apply in determining whether an invention is obvious, it also provides inventors and patent prosecution practitioners with guidelines to avoid to even overcome obviousness-type rejections ( Okuyama et al. 2008: 464). The Supreme Court decision in KSR leads the USPTO to introduce a new set of guidelines that facilitate obviousness rejections of patent claims.

Hays argue that generic obviousness standards do not translate well to biotechnology or other technology. It is implausible to equate biological science with the automotive industry, as artisans in these fields face radically different challenges. With the emergence of new technologies like nanotechnology, uniform rules are no longer appropriate or adequate. An obvious solution would be to address the needs of specific industries directly and separately from those of other industries (Hays 2009: 833).

In cases of predictable technology, both the prior art and the claimed invention are within the same *predictable* subject matter. Therefore, the single embodiment disclosed in the prior art provides for broad enablement of other embodiments of that invention related to size. The same analysis do not apply in case of nano-scale version with respect to its macro-scale prior art, because the claimed invention at nano-scale lies within the realm of *unpredictable* technology. The scientific laws that govern the two inventions, i.e. macro-scale and micro-scale, are fundamentally different. So, it cannot be assumed that persons having ordinary skills in the art can combine his own knowledge with that disclosed by the prior art which predictable technology is, and said to be in possession of claimed nano-scale invention. Thus, if the combined scope and content of all the legally available prior art does not enable a person having ordinary skills in the art to produce the

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<sup>31</sup> Ibid.



nanoscale version of an existing device, it may not be legally concluded that the nanoscale claimed invention is obvious, even if there is no difference other than size (Roe 2006: 153-154).

The Federal Circuit first case that raised the question of non-obviousness with respect to nanotechnology is *In re Kumar*<sup>32</sup>. In this case Sujeet Kumar and others (collectively “Kumar”) filed a patent application entitled “aluminium oxide particles” with the Patent and Trademark Office and assigned the application to Nano Gram Corporation. According to the court, the invention relates to alumina nanoparticles that are useful for chemical mechanical polishing of ultra-smooth surfaces. The examiner allowed the process claims directed to making these particles via laser pyrolysis, but rejected all of the product claims as being obvious over a prior art patent to Rostoker<sup>6</sup> (“the Rostoker patent”) filed in 1993, which showed aluminium oxide particles of nanometer size. Kumar appealed from the examiner’s rejection to the Board of Patent Appeals and Interferences (“the Board”), which found that the particle sizes and size distributions of the Rostoker particles and of Kumar’s claimed particles are overlapping. Kumar appealed the Board’s decision to the Court of Appeals for the Federal Circuit.

The Federal Circuit held that “the Board found Kumar’s claimed invention obvious because the values of the claimed particle size distributions overlapped those in the Rostoker patent. A *prima facie* case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art”. The court cited with approval the proposition that, “in order to render a claimed invention unpatentable, the prior art must enable a person of ordinary skill in the art to make and use the claimed invention”.<sup>33</sup> The Kumar’s case established that a patent applicant may rebut a *prima facie* case of obviousness by presenting evidence that the prior art does not enable the claimed invention in the applicant’s patent application. In Kumar case the court rendered a general ruling that is not specifically tailored to nanotechnology and did not issue any

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<sup>32</sup> 418 F.2d 1361 (Fed.Cir.2005). Available at [Online:web] Accessed on 20 August 2009, URL:<http://ftp.resource.org/courts.gov/c/F3/418/418.F3d.1361.04-1074.html>.

<sup>33</sup> Ibid

special rules for patenting nanotechnology. The Federal Circuit appears to treat a nanotechnology patent appeal no differently than patent appeals in other technologies. However, the court gave a useful argument that if the prior art process is different from the process used to make the claim product; the claim product would not be obvious (Baluch et al. 2005:346).

In the EU the criteria of inventive step is defined in Article 56 of the EPC 1973. Article 56 of the EPC states that “an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art”. The issue of inventive step was discussed in *T116/90*<sup>34</sup> case. It pertained to was the use of derivatives (Ketals) of previously known pharmaceutically active chemicals (Ketones) which were already known to be useful as agents for treating peripheral vascular disease. The prior art has suggested that the use of Ketals would be unsuccessful as they would be metabolised in the body. The opponent argued that this was one of the simplest structural modifications and therefore lacked inventive step. The Board of Appeal ruled that “there is no doubt that Ketals are structurally closely related to the parent ketones. Thus, the skilled person could have considered them as possible and perhaps easily obtainable derivatives of the said parent ketones. This, however, is not the proper question to be asked. ....it has to be investigated, when it comes to the issue of inventive step, whether a skilled person would have prepared the compounds in question with a reasonable expectation that they would successfully solve the technical problem under consideration”.

In this case the inventive step was found to exist because there was no explicit statement in the prior art to the effect that a modification from Ketone to Ketal could be made without the biological effect in the body being influenced. Therefore, for a miniaturisation version of an existing technology to be patentable itself, it must show some unexpected functions and those function must overcome previous problems with

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<sup>34</sup> T 116/90 of 18 12 1991. [Online:web] Accessed on 28 July 2009, URL: <http://legal.european-patent-office.org/dg3/biblio/t900116eu2.htm>. See also (Domeij 2000:167).

miniaturisation. Such unexpected results have been known to occur in nanotechnology. For example, a significant channel to bringing a new pharmaceutical product to market is the poor water solubility of many drugs candidate. It is not always possible to reduce the water solubility by chemical modification of the molecule. Reducing the size of the drug candidate to nanoscale dimensions often has a significant effect on the surface of the particles leading to improved water solubility.<sup>35</sup>

### 3.1.3. Industrial Applicability

The third criterion for patentability according to Article 27.1 of TRIPs Agreement is whether the subject is 'capable of industrial application'<sup>36</sup>. The TRIPs Agreement does not define this concept which leaves countries with sufficient flexibilities. The utility requirement is defined under section 101 of the U.S. Patent Act. It states that the '...invention be a new and useful process, machine, composition of matter, or new and useful improvement thereof'. The USPTO promulgated in 2001 new Utility Guidelines<sup>37</sup> which are also applicable to DNA related inventions. According to these new Guidelines, "an invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention and (2) the utility is specific, substantial, and credible".

With nanotechnology inventions the need to ensure that a specific, substantial and credible utility is asserted at the time of filing is particularly acute. Therefore, in nanotechnology one should assert at least one specific and substantial utility that is credible, instead of speculative uses. For example, assume certain secondary and tertiary structures of DNA molecules useful to make nano-scale computer chips, although their

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<sup>35</sup> Gillard, Richard (2004), "Patenting in the field of Nanotechnology", see [Online: web] Accessed on 26 June 2009, URL: <http://www.azonano.com/details.asp?ArticleID=1055>

<sup>36</sup> A footnote to article 27.1 of TRIPs Agreement clarifies the anomaly between the European Communities and the United States by stating that 'inventive step' and 'capable of industrial application' should be considered synonymous with 'non-obvious' and 'useful', as the last two terms are commonly used in U.S. patent Law.

<sup>37</sup> *Utility Examination Guidelines*, Federal Register 66 (4): 1092-1099, January 5, 2001 Notices, [Online:web] Accessed on 10 August 2009, URL:<http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>

only demonstrated utility is to conduct electricity. So, at least the conductor use should be disclosed to satisfy the utility requirement.<sup>38</sup>

Under European Patent Law, Article 57 of the EPC, 1973, provides that “An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture”. The European Directive on biotechnological inventions Dir. 98/44/EC has already recognised the importance of the industrial application requirement in the framework of DNA inventions. Art. 5(3) of the directive states that the industrial application of a DNA sequence or partial sequence must be disclosed in the patent application. However, it is not clear how this provision must be interpreted because it did not add anything to the general patentability requirement of industrial applicability as defined by Art. 57 of the EPC (Schellekens 2008: 11).

A part of the utility requirement called the inoperability standard requires that all inventions must work as they claimed before they can be patented. The inoperability standard bars an applicant from patenting an impossible invention. A nanotechnology invention has to be possible and operable but nanotechnology is so new, there are not enough experiments to prove that a particular invention works. Thus, nanotechnology inventions lack sufficient rebuttal evidence to convince that the invention is useful (Zekos 2006a: 125). For example, in case of nanobiotechnology which falls under the class of unpredictable technology, there is huge variation in the laboratory results and actual results when such technology 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 (Sharma and Chugh 2009:440).

Another part of the utility requirement is substantial or practical utility. Practical utility requires an invention to have a real world benefit. Practical utility is a low standard that is rarely litigated, especially for mechanical or electrical inventions but it is a real issue for

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<sup>38</sup> Sharrott, Douglas et al. (2004), “Staking a Claim in the Nanoworld”, [Online:web] Accessed on 22 July 2009, URL:[http://www.fitzpatrickcella.com/images/pub\\_attachment/attachment266.pdf](http://www.fitzpatrickcella.com/images/pub_attachment/attachment266.pdf)

chemistry and biotechnology inventions because the usefulness of such inventions is often uncertain (Zekos 2006a:125). In *re Ziegler*<sup>39</sup> case, the issue of practice utility was discussed by the Federal Court. The patent claim in this case involved the discovery of polypropylene. The applicant disclosed only that solid granules of polypropylene could be pressed into a flexible film and that the polypropylene was solid plastic. The court rejected the patent on utility grounds because the application failed to disclose a practical utility of the claimed polypropylene. The court laid down that "...an invention cannot be considered 'useful' unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious". The court further held that "practical utility for the invention is determined by reference to, and a factual analysis of, the disclosures of the application."

In nanotechnology the patent applications may suffer the same problems, e.g., in case of assembler<sup>40</sup> there is an uncertainty about how an assembler will work, and whether it will work, which creates practical utility problems. Such uncertainty may make it difficult for the applicant to assert a specific use for an assembler (Zekos 2006a: 125). Due to the multidisciplinary nature of nanotechnology, the first utility problem in this case is to determine in which context it fits. Patent law applies uniformly to all technologies but applies in different context.<sup>41</sup> For example, the same utility standard applies to both chemical and mechanical inventions, but courts apply the standard with more force in evaluating the patentability of chemical inventions. Each new technology requires courts to determine the context to which utility belongs. Courts typically placed an emerging

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<sup>39</sup> 992 F.2d 1197(Fed.Cir 1993) [Online:web] Accessed on 2 August 2009, URL:<http://openjurist.org/992/f2d/1197>.

<sup>40</sup> An assembler is a nanomachine.. that can both build nanomachine and reproduce itself in the same process. For details see chapter one.

<sup>41</sup> Law increasingly treats patents from different industries differently. The most striking examples arise in biotechnology and computer software. In biotechnology cases, the Federal Circuit has gone to inordinate lengths to find biotechnological inventions nonobvious, even if the prior art demonstrates a clear plan for producing the invention. On the other hand, the court has imposed stringent enablement and written description requirements on biotechnology patents that do not show up other disciplines . In computer software cases, the situation is reversed. The Federal Circuit has essentially excused software inventions from compliance with the enablement and best mode requirements, but in a manner that raises serious questions about how stringently it will read the nonobviousness requirements. It appears that while patent law is technology neutral in theory, it is technology specific in application (Burk and Lemley 2002: 1159).

technology in an existing context by analogizing it previous technologies. But it is not easy for courts to fit new technologies into old context because each new technology presents unique problems, which means nanotechnology promises to be even more problematic because of its interdisciplinary nature <sup>42</sup>(Almeling 2004: 10).

Almeing is of the opinion that utility requirement is unlikely to present insurmountable obstacles to nanotechnology inventions. The technology of nanotechnology is emerging and thus uncertain industry. An overwhelming utility standard may hinder technological development. A utility standard that balance all of the factors today would fail tomorrow when new invention changed the balance. In the early stages of the rapidly changing nanotechnology industry, it would be futile to fashion a different utility standard (Almeling 2004: 3-4). However, in the long run little problems in the way of determining industrial applicability of nanotechnology are to be expected. The nature of nanotechnology inventions often points the way to their industrial applicability: nanotubes for making light and strong constructions, nano drug delivery systems, or nanotechnology used to create high electric conductivity are self-evident industrially applicable (Schellekens 2008: 6).

#### **3.1.4. Sufficiency of Disclosure**

Article 29 of the TRIPs Agreement requires Members “to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode of carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the date of application”.<sup>43</sup> This provision reflects one of the main rationale for the existence of patent protection. By disclosing the invention in a detailed manner, the inventor

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<sup>42</sup> Nanotechnology spans industries; it includes all industries that develop technology at the nanometer scale. For example, quantum dots, which are essential semiconductor nanocrystals. So while quantum dots are within “pharmaceuticals arts”, they also fit within several arts which make it hard to cabin quantum dots in one context.

<sup>43</sup> In comparison to mere enablement, the best mode requirement goes a step further. It forces the inventor to disclose the best version of the invention that is known to him at the time the patent application is filed or at the priority date

expands the scope of the existing technological knowledge. The full disclosure makes sure that after patent protection is expired, the invention can be exploited by others. Article 29 of the TRIPs Agreement reiterates the common principle of patent law, although national regulations used slightly different terminologies (Cottier and Veron 2008:90).

The rationale of the disclosure requirement is the *quid pro quo*, i.e., a monopoly right is granted in exchange for a description of the invention in the patent application, which allows the public and others active in the same field, to make use of the technology disclosed in order to make further technological developments. In other words, technological development is stimulated by disclosure (Bostyn 2004:26).

In the United States, the enablement required is covered by Section 112 of the U.S. Patent Act 1952. The first Para of section 112 describes the three disclosure requirements—written description, enablement, and best mode.<sup>44</sup> The written description requirement purports to determine whether the written description in a patent disclosure ‘reasonably convey to one of skill in the art that the inventor possessed’ the claimed subject matter. In order to comply with written description requirement, a patent has to describe an invention in adequate detail that one skilled in the art could undoubtedly conclude that the inventor had possession of the invention (Zekos 2006b:345). The enablement requirement ensures that the public is put in the possession of the patented invention by disclosing to a person having ordinary skills in the art both ‘how to make’ and ‘how to use it’. The enablement analysis is inherently fact specific to each case (Roe 2006:149). The best mode requirement compels the public disclosure of the most valuable form of the patented invention known to the inventor as of the application date (Zekos 2006b: 345).

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<sup>44</sup> 35 U.S.C. 112(1) states: “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention”.

While the enabling disclosure and written description requirements are separate and distinct under section 112, together they establish the limitations of what the patent may later claim. The ‘scope of the enablement’ is generally related to whether the patented invention is within “predictable” or “unpredictable” technology. In cases involving unpredictable factors like chemical reactions and physiological activity, “the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved”.<sup>45</sup> Whereas, in cases involving increasing predictability, the claims are interpreted broadly allowing the patentee to dominate the subsequent variation in his patented invention that a person having ordinary skills in the art would have regarded as “interchangeable” with the specified claim invention because it can be said that the subsequent invention was enabled by the initial patent.<sup>46</sup> The relevant inquiry regarding the scope of prior patent claims in terms of enablement requirement under section 112 is whether the enable disclosure permits a person skilled in the relevant art to make and use the claimed invention without “undue experimentation” (Roe 2006:149-151).

In certain industries, such as software, the enablement requirement is easily satisfied and therefore virtually plays no role in limiting the scope of claims. Whereas, in biotechnology, examiners and courts have used the enablement requirement to narrow the scope of overly broad claims (Koppikar et al 2004:5). For example, *In Fiers v. Revel*<sup>47</sup> case, the patent application in issue claimed the human DNA sequence that produces the protein fibroblast betainterferon ( $\beta$ -IF). One of the applicants, Revel relied for priority upon his Israeli patent applications, which disclosed the methods for isolating a fragment of the DNA sequence coding for  $\beta$ -IF and isolating messenger RNA coding for  $\beta$ -IF. But it did not disclose a complete DNA sequence coding for  $\beta$ -IF. The court considered whether the disclosure in Revel’s Israel application satisfied the U.S. written description

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<sup>45</sup> It means that as the unpredictability of factors increases the scope of the enablement decreases and the claims are interpreted narrowly.

<sup>46</sup> This correlation also embodies the reverse doctrine of equivalents in cases involving unpredictable technology by limiting the scope of the claims when the subsequent invention has “so far changed the prior art”, that it cannot be said that the prior patent enabled the subsequent invention. This issue is discussed later in this chapter.

<sup>47</sup> 984 F.2d 1164, (Fed.cir.1993). [Online:web] Accessed on 9 August 2009, URL:<http://www.altlaw.org/v1/cases/409356>



and could be patented. The Federal Circuit held that “..the Revel’s disclosure was not an adequate description, because it failed to disclose the actual sequence of DNA molecule at issue”. The court reasoned “...disclosing a method for obtaining a DNA is not the same as disclosing the DNA itself”.

Providing an adequate disclosure can be problematic for nanotechnology inventions because of their complexity, unpredictability and lack of full development. While being the first to file and obtain a patent in a pioneering field can secure a stronghold on the market, the relative lack of prior art means that the hypothetical “person of ordinary skill,” against whom the adequacy of the disclosure is measured, will bring very little to the table.<sup>48</sup> Nanotechnology, as noted above, is likely to be considered a complex, unpredictable and undeveloped art, and thus the lack of working examples, test data, and/or direction in a patent application may raise an issue of inadequate enablement. However, nanotechnology applicants can overcome an enablement rejection by arguing that the specification does provide a “representative” group of examples in relation to the scope of claim, based on the relative predictability of the area in question (Koppikar et al. 2004:7).

In Europe, the disclosure requirement is laid down in Art. 83 of the European Patent Convention 1973. It states that “the European application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art”. It encompasses two requirements: 1) practicability 2) reproducibility. Practicability means that the person skilled in the art can on the basis of the disclosure can rework the invention without undue burden. It requires that if a general principle has been disclosed according to which the inventive teaching is applicable to an entire class there must not exist serious doubt as to the effectiveness of the principle across the class. Reproducibility means that the result of the invention can be reached over and over again

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<sup>48</sup> Sharrott, Douglas et al. (2004), “Staking a Claim in the Nanoworld”, [Online:web] Accessed on 22 July 2009, URL:[http://www.fitzpatrickcella.com/images/pub\\_attachment/attachment266.pdf](http://www.fitzpatrickcella.com/images/pub_attachment/attachment266.pdf)

and not just on the basis of chance or only with a smaller or larger degree of predictability (Schellekens 2008:6).

In case of a nanotechnology patent which has been defined by a range, the invention must be practicable in the entire range. With nanotechnology however, it may be difficult to ascertain this fact due to the small scale at which the invention must be practised. In nanotechnology, being a new technology, analytical methods, tools and metrologies are often not available to the person skilled in the art. Without these the reproducibility of an invention may be difficult to ascertain. Hence an inventor in the nanotech field may be obliged to disclose these in the patent in order to make his claim verifiable (Schellekens 2008:6). Therefore, due to the unpredictability of field a greater level of disclosure is required in nanotechnology.

### **3.1.5. Invention Vs Discovery**

The TRIPs Agreement does not specify what an ‘invention’ is, and since there is no “universal” concept of what it means, countries can, within certain limits, opt for various alternatives. The scope of the concept can be determined by national legislation, in a broad or narrow sense. Thus, there is no obligation under the TRIPs Agreement to adopt an expansive concept of ‘invention’, as is currently done by many developed countries. In particular, nothing in the agreement obliges members to consider that substance existing in nature, biological or not, are not patentable, even if isolated and claimed in purified form (Khor 2002: 70).

If a nanotechnology patent application satisfies the criteria of novelty, inventive step (or non-obviousness within the United States), utility and public disclosure, members of the WTO are prohibited from excluding it from patent protection under their domestic legal framework. However, not all nanotechnology applications may be protected, as Article 27(1) provides patent protection only for inventions and not mere discoveries. While the TRIPs Agreement fails to provide a definition of ‘invention’, it would appear that article 27(1) is an attempt to discriminate between rapidly blurring distinctions of ‘inventions’

and 'discoveries'. This distinction has been maintained with current nano-products including CNTs and Fullerenes.<sup>49</sup> Since these compounds are naturally occurring, Article 27(1) technically prohibits the patenting of the compounds themselves. Article 27(1) does, however, enable that a requisite inventive step be deemed as the process of creation, rather than the creation itself (Bowman 2007: 311).

The development of cutting edge technologies including nanotechnology has resulted in blurring the distinction that previously existed between discoveries and inventions (Bastani and Fernandez 2002: 473). The blurring of this distinction can be best illustrated by examining the patentability debate of 'patents on life' within the biotechnology industry. During the negotiations on the TRIPs Agreement, consensus was not reached on the controversial area of biotechnological inventions. The United States and some other developed countries pushed for no exclusions to patentability, while some developing countries members along with European communities preferred to exclude plant and animals from patenting (Matthews 2002: 58). Article 27.3(b)<sup>50</sup> of the TRIPs Agreement is the text that ultimately prevailed on biological product and processes. It states that plants and animals as well as essential biological processes may be excluded from patentability. However, WTO members must offer protection for plant varieties either by an effective *sui generis* system. Developing countries were given until 2000 to pass laws in this direction, and least developed countries (LDCs) were given until 2006.<sup>51</sup> By stipulating compulsory patenting of micro-organisms (which are natural living things) and microbiological processes (which are natural processes), the provisions of Article

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<sup>49</sup> CNTs (Carbon Nanotubes) are naturally-occurring hollow tubes of rolled carbon sheets, which have potential applications across the fields of nano-electronics, fuel sensors, and drug delivery mechanism. They consist of only pure carbon molecules (ETC Group Report 2003: 21-22).

<sup>50</sup> Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

<sup>51</sup> The transitional period for LDCs has now been expanded until 1 July 2013. By that date even 'least developed countries will be obligatory by the World Trade Organisation's TRIPs to recognize and enforce nanotechnology patents.'

27.3(b) contravenes the basic tenets on which patent laws are based that: that substances and processes that exist in nature are a discovery and not an invention and thus not patentable. Moreover, by giving members the option whether to exclude the patentability of plants and animals, Article 27.3(b) allows for life forms to be patented (Khor 2002:71).

The controversy and debate surrounding the patentability of biotechnological inventions is relevant to a discussion on nanotechnology patents because nano-scale materials and processes especially those inventions that claim both living and non- living matter- raises many of the same fundamental questions like patenting of life forms (Shand and Wetter 2007:112). Nanomaterials are chemical elements or compounds less than 100 nm in size. Taking advantage of quantum physics, nanotech companies are engineering novel materials that may have entirely new properties never before identified in nature. The “raw materials” for creating nanomaterials and devices are the chemical elements of the Periodic Table<sup>52</sup> – the building blocks of everything – both living and nonliving. Whereas biotechnology patents make claims on biological products and processes-nanotechnology patents may literally stake claim to chemical elements, as well as the compounds and the devices that incorporate them. With nano-scale technologies the issue is not just patents on life – but on all of nature. In short, atomic-level manufacturing provides new opportunities for sweeping monopoly control over both animate and inanimate matter. In essence, patenting at the nano-scale could mean monopolizing the basic elements that make life possible (ETC Group Report 2005b: 11).

When Harvard University’s Charles Lieber obtained a key patent (U.S. patent 5,897,945) on nano-scale metal oxide nanorods, he didn’t claim nanorods composed of a single type

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<sup>52</sup> The Austrian monk, Felix Mendel, published his treatise on genetic inheritance in 1865. Four years later Dmitri Mendeleev, a Russian chemist, published his textbook including the first chart of the Periodic Table of elements. Mendel described the regeneration of life; Mendeleev charted the elements of life. The Periodic Table is a list of all known chemical elements, approximately 115 at present. The symbols for each chemical element are arranged in columns and rows, grouped according to chemical properties. Matter-the elements of the Periodic Table-are not static. For more than 60 years, scientists in Europe and North America have been making their own contributions to the Periodic Table. Thus far, at least 17 elements have been created (ETC Group Report 2003: 15-18).

of metal but instead claimed a metal oxide selected from up to 33 chemical elements. In a single patent, Lieber's claims extend to nearly one-third of the chemical elements in the Periodic Table – spanning 11 of the 18 Groups. Similarly, a key U.S. patent number 5,505,928 on semiconductor nanocrystals (quantum dots) held by the University of California (licensed to Nanosys, Inc. and Quantum Dot Corp.) claims semiconductor nanoparticles from elements in Groups III-V of the Periodic Table<sup>53</sup> (ETC Group Report 2005b :11).

While biotechnology raw materials are biological, nano-scale technologies involve the manipulation of both living and non-living materials, sometimes in combination. When this is the case, the discipline is known as 'Nanobiotechnology'. A nanostructured material used inside the body as a bone replacement is one example of nanobiotechnology, but so is a hybrid organism created from living and non-living materials. Closely related to and something overlapping nanobiotechnology is the new field of 'synthetic biology' in which living organisms are built to order and then programmed to perform specific tasks (ETC Group Report 2005b:12). It has significant universal applications in the field of medicine, food and agriculture and environment and biodiversity conservation. 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 particular, human welfare (Sharma and Chugh 2009: 434-435).

In ETC Group parlance, nanotechnology patents are 'second nature patents'.<sup>54</sup> Patents on the products of nanobiotechnology provide the opportunity to monopolize the basic elements that are the building blocks of the entire natural world, bringing a whole new dimension to the notion of "life patenting" (ETC 2005b:12). It is likely that the

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<sup>53</sup> The claims in patent extend to boron, aluminium, gallium, indium, nitrogen, phosphorus, arsenic, antimony as well as those compound semiconductors that result from combining elements in Groups III-V of the periodic table.

<sup>54</sup> ETC Group draws strong parallels with biotechnology. Biotechnology triggered nature patents, i.e. patents on living matter, which ETC Group sees as an undesirable extension of the patentable domain. ETC group called nanotechnology as 'second nature patents' i.e. patents on the elements from which living matter is built up (Schellekens 2008: 7).

convergence of nanotechnology with biotechnology (nanobiotechnology) within the short to medium term will further complicate the debate over what is patentable. Bowman is of opinion that in the longer term, the convergence of nanotechnology and biotechnology may require policy makers to explore the utility of a 'sui generis' patent regime for nanobiotechnology (Bowman 2007: 311-312).

The indeterminate wording of the TRIPs Agreements provides scientists and potential patentees with too much flexibility in what they can and cannot patent. The classes of patents based on mere discovery have become 'patentable' despite fulfil the 'invention' criteria. These include the discovery of human cells such as umbilical cord cells, plant genes including rice genome sequencing and therapeutic cloning and stem cell isolation procedures. This argument lends itself to the interpretation that the processes leading to such 'discoveries' fall outside the spirit of the TRIPs Agreement, and should not be patented. The technological changes in the biotechnology industry have resulted in a broadening of the scope of international patent law and a blurring of the invention /discovery interface. While such distinction may appear to be pedantic in nature, this distinction remains pivotal due to its role in defining the scope of patentable subject matter (Bowman 2007: 311).

The definition of what an invention is against a mere discovery depends on whether it is technological applicable. For example, gene technology provided ways of newly discovered (but already existing) genes. It yields fundamental innovations that, if patented, have a potential to monopolise naturally occurring systems and block further development. The mere description of a naturally occurring substance is not a patentable invention but a discovery. If, however a way of synthesising and/or isolating the substance is found, the discovery becomes an invention.<sup>55</sup> The difference is that the inventor has shown a way of providing the substance instead of merely describing it

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<sup>55</sup> For ex, DNA patent claims do not cover life, the human genome, or the genetic alphabet; but they are directed to one or more specified DNA molecules in isolated and purified forms. A DNA molecule is generally considered to be in 'isolated' if it has been removed from its natural environment, and 'purified', if it is an environment that is considerable free of other large molecules. Isolated and purified compound from nature are not found in human body and have long been patentable (Zekos 2006b:311 )

(Zech 2009:151). Discovery of natural matters using a new technique even in nanoscale cannot be considered an invention. The invention should bring forward a new practical usage of the new substance or a new product. The principles of purification or modification of products of nature are hardly applicable to nanotechnology inventions. However, purification or modification can be used if nanotechnology is merely used as a tool to produce biotechnology inventions (Zekos 2006a: 123).

It is obvious that the products of nanotechnology cannot be considered to be products of nature and therefore patentable. Furthermore, nanotechnology products are patentable as human-made inventions. Usefulness, novelty, adequate disclosure, and non-obviousness are all required for a patent regarding nanotechnology invention to be valid as well but the substance of the terms has to be adjusted to the context of nanotechnology and the characteristics of the new science in order for a discovery to be transformed into an invention ( Zekos 2006a: 123).

### **3.2 Non-Patentable Subject Matter**

All inventions are not patentable. Inventions concerning diagnosis and therapy of the human body are not patentable, as are the inventions the publication and exploitation of which offends public order or morality. It has been argued that nanotechnology raises some doubt regarding the applicability of such exclusion from patentability. Article 27.3(a) of the TRIPs Agreement states that “Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals”. The use of word “may” indicates that it is not obligatory for the member states to exclude such methods from patentability. It is left to their discretion whether to allow such patents or not. Similar provisions also find place in Article 52(4) of the EPC 1973. It states that “Methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application”. Therefore, the use of the nanoparticle for treatment of the human body will not be a patentable subject matter under Article 52(4) of the EPC 1973.

However, in the United States patenting of medical methods is possible if they meet the other criteria for patentability. Section 101 of the U.S. Patent Act 1952, states that a "...patent may be obtained for any new and useful process, machine, manufacture or composition of matter. Accordingly the patentability of medical methods patent is not excluded. It is also contended that medical and surgical methods may be placed in the category of process- an art which is patentable under section 101 of U.S. Patent Act (Sharma and Chugh 2009:445).<sup>56</sup>

Therapeutic, surgical and diagnostic methods are used to produce effects on the human or animal body, directly or indirectly. These methods do not fit within the usual patentability requirements because they lack any industrial application or effect (Correa 2008:109). It is argued that exempting medical methods from the purview of patentability is, on one hand, in favour of public policy, whereas on the other hand, allowing patent in this field would draw unwarranted ethical, moral and practical problems (Sharma and Chugh 2008:445).

It is speculative that established player in the pharmaceuticals 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 act would restrict the entry of generic players in the market (Harris et al. 2004:2). Therefore, in case of nanoparticle used for drug administration; there is possibility of over 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 body; the medical device used; and the processes of the particle. The important question here is the distinct classification of methods as surgical, curative, diagnostic, and therapeutic and the subject matter that each

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<sup>56</sup> Some countries have directly excluded such methods from patentability. For example, Section 3(i) of the Indian Patents Act 1970, states that "any process for the medicinal, surgical, curative, prophylactic 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" is not an invention within the meaning of the Act. However, a direct exclusion in this manner is not the only approach. Whereas, some countries have applied rationale approach for such exclusion. For example, under Article 52(4) of the EPC, the rationale for exclusion is that these methods



of them encompasses (Sharma and Chugh 2009:444). The problem is that application of nanomedicine may be both treatment and product: it is not clear whether a drug delivery system is treatment (delivery of medicine in the part of the body) or a substance (a dendrimer carrying the medicine) (Schellekens 2008:7).

Morality can be a reason to exclude some methods from patentability. Article 27.2 of TRIPs Agreement states that “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”. The term ‘ordre public’ and ‘morality’ are not defined in TRIPs Agreement, although references to human, animal or plant life or health and the environment provides some context.

Dutfield argues that TRIPs compatibility requires governments to apply the ordre public and morality exclusions narrowly on a case by case basis rather than to broad classes of patents such as life forms in their broader sense (Dutfield 2003:68). In nanotechnology certain inventions will raise moral and ethical concerns. 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 inventions are likely to cloud over the possibility of patenting such inventions. (Sharma and Chugh 2009:442)

#### **4. Patenting of Abstract Ideas**

There are, however, a few judicially created exemptions from the scope of patent protection. Courts have denied protection for theoretical or abstract ideas, natural laws, naturally occurring products and mathematical algorithms. The rule against the patenting of abstract ideas originated in the case of *O’Reilly (v) Morse*,<sup>57</sup> which involved Morse

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<sup>57</sup> 56 U.S. 62 (1853). Available at [Online:web] Accessed on 4 August 2009, URL:<http://supreme.justia.com/us/56/62/case.html>

patent on the telegraph. Morse was the first and original inventor of the electro-magnetic telegraph, for which a patent was issued to him in 1840. In this case he filed patent application on a good version of the system and attempted to claim any process that transmitted printed communications via an electric signal, however developed. He was allowed a broad patent for a process of using electromagnetism to produce discernible signals over telegraph wires. But the court denied Morse's claim, in which Morse claimed the use of "electro magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances...". The U.S. Supreme Court held that "...granting a patent over yet undiscovered applications of the invention would "shut the door against inventions of other persons". The court laid down that "the mere discovery of a new element or law or principle of nature, without any valuable application of it to the arts, is not the subject of a patent. It would deny the public the benefit of such discoveries without the permission of the original patentee whose prior art failed to implement the newly discovered benefit".

The rule that a law of nature cannot be the subject of a patent was applied by the courts in many cases. In *Gottschalk (Vs) Benson*<sup>58</sup>, the U.S. Supreme Court held that the discovery of a novel and useful mathematical formula may not be patented. In this case the patent application was for an invention which was described as being related "to the processing of data by program and more particularly to the programmed conversion of numerical information" in general purpose digital computers. They claimed a method for converting binary-coded decimal (BCD) numerals into pure binary numerals. The court held that the "process" claim is as abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion. The Court held the claims as unpatentable as they "were not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end. The court laid down that the "phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work".

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<sup>58</sup> 409 U.S. 63 (1972). Available at [Online:web] Accessed on 4 August 2009, URL:<http://supreme.justia.com/us/409/63/case.html>

Similarly, in *Parker (v.) Flook*<sup>59</sup>, the U.S. Supreme Court held in this context that “The rule that the discovery of a law of nature cannot be patented rests not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of “discoveries” that the statute was enacted to protect. The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious”. The problem described above is also sometimes called the product of nature doctrine. According to that doctrine, products of nature as such are not patentable, but products derived from nature are.

Patenting an abstract idea or concept would permit the patentee to “engross a vast, unknown, and perhaps unknowable area”. The rule that abstract ideas and function of an invention cannot be patented has two potential effects. First, it prevents patents from covering entire concepts, limiting them instead to particular implementations. This gives room for subsequent innovators to work out new implementations of the abstract idea without fear of patent liability. Second, the abstract ideas rule prevents those who discover abstract ideas or natural rules— $E=mc^2$  is the example most commonly cited — from asserting control over the entire idea, rather than concrete implementations of that idea (Burk and Lemley 2003: 126-127).

Nanotechnology is the first new field in almost a century in which the basic ideas were patented at the outset, in contrast to the enabling technologies --- computer, hardware, software, internet, and even biotechnology-- where the basic building blocks all ended up in public domain. Basic software inventions were not patented because during 1960s, 1970s, and 1980s, the court took the position that software was not patentable at all. The basic protocols of the internet are in public domain because they developed with federal funding and at universities in the late 1960s and early 1970s, and public inventions were not generally patented at that time.<sup>60</sup> In nanotechnology, by contrast companies and

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<sup>59</sup> 437 U.S. 584 (1978). Available at [Online:web] Accessed on 20 July 2009, URL:<http://supreme.justia.com/us/437/584/case.html>

<sup>60</sup> That is no longer true today, in large part because of the Bayh-Dole Act of 1980, 35 U.S.C 200-212, which permits universities and other receiving federal funding for research to patent the result of that funded research.

universities are patenting early and often. While some of these patents are on industry specific improvements to existing work above the nanoscale, particularly in semiconductor industry, other patents cover basic building blocks of nanotechnology. Indeed, many of the most basic ideas in nanotechnology are either already patented or may well end up being patented <sup>61</sup>(Lemley 2005: 608, 613).

Patents on “upstream” building block materials or on initial experimental protocols may deter “downstream” investigations and efforts to translate basic science into useful drugs. Upstream research discoveries enable further scientific investigation and downstream inventions lead directly to commercial products. The absence of patent restrictions allows scientists to work for the pure satisfaction of discovery. A new theory must be subject to normal scientific processes of falsification and validation; only reliable affirmation of an insurgent theory provides the required predicate for a paradigm shift. Free access to research tool closely associated with an insurgent theory of natural causation would permit members of the scientific community to engage in the fundamental process of testing, refuting and possibly validating that theory (Zekos 2006a:120-121).

In Nanotechnology most of its patents will be for basic inventions, not for fully developed products. This will create problems because patents granted on basic inventions tend to cover larger areas than final products. However one is allowed to patent purely abstract ideas only with the proviso of developing them in the future into more specific inventions. If abstract ideas are patentable in nanotechnology merely in order to cover the companies’ and universities’ profits, then all the old scientific theories must be patented retroactively, because many inventions are based on the transformation of those ideas (Zekos 2006a:126-127). Therefore, patenting of upstream research tools in nanotechnology will stifle innovation in this area.

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<sup>61</sup> Patents have issued on carbon nanotubes, semiconducting nanocrystals, metal oxide, atomic force microscope, etc. There are only a few basic building blocks in nanotechnology that is unpatented, notably Buckminsterfullerene. It was discovered in 1985 by Curl, Smiley, and Kroto, is unpatentable as a naturally occurring product of nature but hundreds of patents on implementation of molecule has been issued. For greater details see Fullerene Patent database, [Online:web] Accessed on 20 July 2009, URL:<http://www.godunov.com/bucky/patents.html>.

## 5. Nanotechnology Patent Trends and Classification

The world 's largest transnational companies, leading academic labs and nanotech start-ups are all rushing to the patent office in record numbers to patent nanotechnology inventions. A study conducted by the researchers from the University of Arizona and the U.S. National Science Foundation examined nanoscale science and engineering patents at the U.S Patent and Trademark Office from 1976-2003. They found that 8,630 nanotech-related patents were issued by the USPTO in 2003 alone, an increase of 50% over the previous three years. The top five countries represented were: U.S. (5,228 patents), Japan (926), Germany (684), Canada (244) and France (183). The top five entities winning nanotech-related patents included four multinational electronic firms and one university: IBM (198 patents), Micron Technologies (129), Advanced Micro Devices (128), Intel (90) and University of California (89) (Huang et al. 2004: 329-336).

A study of patenting activity of countries in different sectors of nanotechnology in 2003 showed that the United States is the most active patenting country in each subfield of nanotechnology, both for applicants and for inventors. Germany, France and Canada rank higher for nanobiotechnology, the Netherlands and Sweden come up in nanoelectronics, while Belgium and Taiwan rank high in nanomaterials. Switzerland is in particular strong in nanodevices, and the UK in nanooptics. Japan is equally strong in nanomaterials and nanotools, above average in nanodevices and very weak in nanobiotechnology (Hullmann 2006: 24).

A study of growth of nanotechnology patents from 1997 through 2004 shows that the top ten countries with the largest number of nanotechnology patents are the United States (56,828), Japan (7574), France (2087), United Kingdom (871), Switzerland (419), Taiwan (382), Italy (377), Republic of Korea (368), the Netherlands (308), Australia (307), Sweden (264). The fastest growth has been in chemical and pharmaceutical fields, followed by semiconductor devices (Huang et al. 2003: 333-334).

A comparative study of USPTO, EPO, and JPO nanotechnology patents from 1976-2004 shows that the nanotechnology patents issued by the USPTO and EPO experienced quasi exponential growth during the period. The nanotechnology patents issued by the JPO followed the same trend until stabilizing after 1993. The United States and Japan published large number of patents with high citation averages in both repositories, indicating their important roles in international nanotechnology development. The U.S. patents in the USPTO had broader impact on worldwide nanotechnology development and attracted more citation from other countries than did EPO patents (Li et al. 2007: 1000). In 2006, the largest number of nanotechnology patents was held by U.S. (11734), followed by EU (638) which was far behind than U.S, Asia (349) and the rest of the world (140) (UN-NGLS 2008:47). Large numbers of nanotechnology patents are being held by the developed countries. The major corporations holding the nanotechnology patents are also from developed countries. There is a gap between developed countries and developing countries in nanotechnology patenting activity.

### **5.1 Classification of Nanotechnology Patents**

The lack of uniform definitions for nanotechnology means that identifying the number of nanotech-related products granted over the past decade is very imprecise science. Nanotech patents often use broad search terms (for example, the prefix “nano”), which can result in exaggerated counts (ETC Group Report 2005b:7). Nanotechnology due to its multidisciplinary nature creates some significant difficulties in patent examination, classification, and analysis. For example, the broad definition of ‘nanotechnology’ leads to challenges in classifying new inventions for patent office purpose. On one hand, an application may use other terms, such as ‘microscale’ or ‘quantum dot’, to describe a nanotechnology invention. On the other hand, an applicant may incorrectly describe his invention as ‘nanotechnology’, or use terms like ‘nano-second’ that arise in other context (Bowman 2007: 312).

Nanotechnology is a new area so it is important to reach a common definition of “nano” and its scope. If the term “nano” is not well-defined there is a risk that novelty of pending

patent claims cannot be verified easily. This might result in granted patents that fulfil the novelty requirements because of their use of the term “nano”. Clarity about the definition of “nano” in the context of a specific invention that is claimed is required because this directly relates to the scope of the invention that is claimed. If there is no clarity about the term “nano” this has an impact on the determination of novelty because it is difficult then to decide whether a certain prior art embodiment is detrimental to novelty or not. In case of infringement it is essential that the scope of an invention can be determined from the claims without ambiguity (Velzen 2008: 296).

In the 1980s and the 1990s, judicial decisions in the United States cleared the way for inventors to patent inventions in the expanding areas of biotechnology and internet business methods. The patent office recognized the importance of these new technologies and eventually responded to the surge in applications by establishing two new groups solely devoted to examining internet methods and biotechnology inventions (Bleeker at al. 2004: 46). Prior to 2004 it was not possible to search topically for patent relating to nanotechnology because such patents were not in a separate class. In October 2004, the USPTO created a new classification for nanotechnology patents—Class 977—which would serve as a cross reference to help examiners, among others to search prior art. Before Class 977 existed, examiners relied on key words searches to find relevant information and related patents (ETC Group 2005b: 8). As defined by the USPTO, nanotechnology patents in Class 977 must meet the following criteria:

- Relate to research and technology development in the length scale of approximately 1-100 nm in at least one dimension.
- Provide a fundamental understanding of phenomena and materials at the nano-scale and create and use structures, devices, and systems that have size-dependent novel properties and functions.<sup>62</sup>

The USPTO classification is consistent with the definition of National Nanotechnology Initiative (NNI), which is scale and unique phenomena dependent. It is a cross-reference

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<sup>62</sup> “The USPTO classification” , Available at [Online:web] Accessed on 25 July 2009, URL:<http://www.uspto.gov/web/offices/opc/documents/1850.pdf>

art collection of 263 new subclasses provides a place for organising most nanotechnology-related subject matter and assist examiner in classifying new disclosure and patents (O'Neill et.al 2007:597). Bawa argues that the PTO's flawed definition of nanotechnology, which is essentially copied from the NNI, has resulted in a skewed preliminary classification system, particularly with respect to nanomedicine and bionanotechnology (Bawa 2005: 346). In the field of nanomedicine, sometimes a better efficacy (e.g., reduced toxicity, lower dose, enhanced solubility) may be achieved in a size range greater than 100 nm but less than 1000nm (mathematically, 1micron= 1000nm). In such situations, it becomes challenging to classify them as nanopharmaceuticals (Sharma and Chugh 2009:443).

Class 977 is a secondary classification, meaning that patents will still be placed in classes related to their technology; however, they will also be placed within the nanotechnology class. In this way, the nanotechnology classification functions as a system of cross-referencing that enhances searching abilities and simultaneously ensures that the new classification does not remove patents from other classes, thereby complicating searches. Although there is presently a nanotechnology class; no art unit assigned to nanotechnology currently exists. Most patent classes have an art unit, a group of patent examiners dedicated to patents related to that class. Because the nanotechnology class lacks an art unit, there is no official group responsible for examining patents in that discipline, although the USPTO is making an effort to route applications to examiners with expertise in that area (Smalley 2009).

Due to its multidisciplinary nature nanotechnology inventions will fall in a number of different International Patent Classifications (IPC)<sup>63</sup>. IPC classifications are applied to all granted European patents. The European patent office uses the European Classification ECLA for carrying out patent searches. ECLA is based on the IPC but is more detailed.

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<sup>63</sup> The International Patent Classification, which is commonly referred to as the IPC, is based on an international multi-lateral treaty administered by WIPO. This treaty is called the Strasbourg Agreement concerning the International Patent Classification, which was concluded in 1971 and entered into force in 1975. The Agreement is open to States party to the Paris Convention for the Protection of Industrial Property. International patent classification is a five-level hierarchical ontology that contains eight first-level categories ("section"), 120 second-level categories ("class"), and 631 third-level categories ("subclass"). For greater details see [Online:web] Accessed on 2 August 2009, URL:<http://www.wipo.int/classifications/ipc/en/>



The B82B nanotechnology definition according to ECLA/IPC is very “narrow” and only a limited number of patents fit in this definition. Therefore in January 2006 a tagging system (Y01N) has been introduced as an additional tool for identifying nanotechnology patents. This tagging system is further divided into six sub-classes according to technology and /or applications. The nanotechnology subclass (Y01N) covers:

- Entities with a controlled geometrical size of at least one functional component below 100 nanometres (nm) in one or more dimensions susceptible to make physical, chemical or biological effects available which are intrinsic to that size.
- Equipment and methods for controlled analysis, manipulation, processing, fabrication or measurement with a precision below 100 nanometres (nm).<sup>64</sup>

The initial purpose of EPO in developing a tagging system was to facilitate the work of the patent examiners and to identify developments in this emerging field in order to respond upfront to increased need of new patent examiners and interdisciplinary cooperation. The introduced ‘tagging’ (Y01N) method also serves researchers who are interested in patent analyses in the field of nanotechnology. It has the clear advantage that nanotech patents can be identified more adequately and that worldwide comparisons are more reliable because no world region is favoured (Hullmann 2006:22).

## **5.2 Examiners Lack Relevant Expertise**

The rapid growth in nano-related patents suggests that the institutional capacity of national patent offices will be critical component in protecting investment in innovation. Because few individuals have an in-depth and complete knowledge of nanotechnology, patent examiners may not have the necessary tools to understand the complexities of the field. Specifically, the lack of technical skills and comprehensive knowledge by national patent offices may compromise the effectiveness of patent rights by issuing overlapping patent claims. The multidisciplinary nature of nanotechnology places an increased burden on patent examiners, who lack focused expertise in this new area. If examiners are

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<sup>64</sup> “The classification Scheme of Y01N” [Online:web] Accessed on 20 July 2009, URL: <http://forums.epo.org/espacenet-archi ve/topic405.html>

unfamiliar with or untrained in nanotechnology, applications are more likely to be rejected improperly because the examiner mistakenly concludes that the invention is not novel, or else they may issue broad claims. In either case, the nanotechnology industry and public will suffer (Bleeker et al. 2004: 46-47).

Issuance of patents of poor quality or too many invalid patents on early-stage research is likely to cause enormous damage to the global nanotechnology industry by suppressing growth and innovation; causing a loss of revenues, resources and time; and discouraging industry from conducting R&D and inducing unnecessary licensing; and resulting in flood of appeals and infringement lawsuits (Bawa 2004: 20).

## **6. Cross Industry Patents Rights**

Nanotechnology field has the unique cross-industry structure. A basic nanotechnology patent may have implications for semiconductor design, biotechnology, material science, telecommunications, and textiles, even though the patent is held by a firm that works in only one of these industries. Unlike other new industries in which the patentees are actual or at least potential participants in the market, a significant number of corporate nanotech patentees will own rights not just in the industry in which they participate, but in other industries as well (Lemley 2005: 614-615). The crucial aspect to understand about nano IP is not simply that the patents span a broad range of fields, but that a single invention can be relevant for widely divergent applications. This is clear from the following examples from USPTO's Class 977:

- US Patent No 5, 874,029 – University of Kansas, 23 February 1999: Methods for particle micronization and nanonization by recrystallization from organic solutions sprayed into a compressed antisolvent: The invention can be used in the pharmaceutical, food, chemical, electronics, catalyst polymer, pesticide, explosives, and coating industries, all of which have a need for small diameter particles.
- US Patent No US6, 641,773 – The USA as represented by the Secretary of the Army, 11 November, 2004: Electro spinning of submicron diameter polymer

filaments: An electro spinning process yields uniform, nanometer diameter polymer filaments...The filament is particularly useful for weaving body armor, for chemical/biological protective clothing, as a biomedical tissue growth support, for fabricating micro sieves and for microelectronics fabrication.<sup>65</sup>(ETC Group Report 2005b:12).

These cross-industry rights may significantly affect the nanotechnology patentee's incentives to license their patents. Companies that want to use nanotechnology to produce products may need to use a range of different building block inventions- For example, using patented atomic force microscopes to detect and align atoms into patented materials that are then manipulated into patented structures used in constructing a patented end product. If each step has one or perhaps several different patents, all owned by different people, the company will need a lot of licences (Lemley 2005: 618).

According to a LUX research report<sup>66</sup>, almost 4000 U.S. nanopatents have been issued as of late march 2005, with another 1777 patent applications pending. The report focused on five fundamental nanomaterials: carbon nanotubes, dendrimers, fullerenes, nanowires, and quantum dots. The study found that quantum dot patent claims tend to cover the materials themselves rather than specific applications, and the patent situation for using carbon nanotubes in electronics looks messy. The report concludes that the nanoscience researchers around the world are steadily filing patents with the hope of creating toll booths for future product development.

## 7. Universities and Nanotechnology Patents

One of the unique features of nanotechnology patents is that universities and public research foundations hold a grossly disproportionate share of nanotechnology patents.

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<sup>65</sup> The reason that the same invention can be used inside the human body, in clothing and in computers, is that at the molecular level biological and non- biological material can be integrated – whether this is a seamless integration is a matter yet to be determined by toxicological research.

<sup>66</sup> “Nanotechnology gold rush yields crowded, entangled patents”.. New York: LUX Research; 2004 [cited 2005 April 21]. [Online:web] Accessed on 12 August 2009, URL:[http://www.nanotech-now.com/news.cgi?story\\_id=09134](http://www.nanotech-now.com/news.cgi?story_id=09134).

University and public research foundations hold about one percentage of the patents issued in the United States each year, but in case of nanotechnology at least 12 percent patents are assigned to universities, a proportion that is a dozen times as high as the proportion of university patents in general. University conducts basic research so they are the drivers of early stage nanotechnology just as they have been with many other enabling technologies. But unlike the government sponsored research of past generation, universities in the modern era are extremely aggressive patentees largely because of the Bayh-Dole Act of 1980.<sup>67</sup> Before 1980, universities worldwide obtained about 250 U.S. patents a year. By the year 2003, the number of university owned patents increased sixteen fold to 3933 (Lemley 2005: 615-617).

Another reason for the comparative dominance of universities in nanotech patenting is that it is relative easy to keep many nanotechnology inventions secret, and even when technology products are released in the open market reverse engineering them may be significantly more difficult than in other fields. As a result companies may choose to forgo patent protection in favour of trade secrecy, at least in early stage. By contrast, universities have no such incentive; the benefit they receive from IP protection of nanotechnology inventions comes entirely from licensing revenue. Thus, universities may be more likely than private companies to patent their inventions (Lemley 2005: 617).

Because university labs are not in the business of commercializing products, they try to re-coup their research cost by patenting their employee's early scientific innovations' in the hope of earning royalty or licensing fees. Exclusives licensing is a generally the more lucrative deal and therefore universities are acting more and more like business these days. Not only the universities patenting nanotechnology early and often, they are more

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<sup>67</sup> The Act was passed in 1980 with the purpose of promoting the transfer of technology developed as a result of government funding. The Act established a uniform policy, providing that patents for the results of government-funded research may be held by the research entity, and that the entity may issue exclusive licenses to promote the commercialization of the results. However, comparing university research in the United States during the 1980s with the progress of the biotechnology industry in other countries after the passage of Bayh- Dole lends credence to the idea that the Bayh-Dole Act in fact played substantial role in the success of new biotechnology firms in the United States ( Kesan 2009: 2175-2178). Bawa is of the opinion that the Bayh-dole act will also assist nano-medicine related companies in the same wayas it helped biotechnology start-ups by liberalizing the transfer of university owned patents funded by government grants to the private sector ( Bawa 2005: 346).

frequently licensing their inventions on an exclusive basis. The policy makers who favour Bayh-Dole would argue that universities are benefiting society by transferring science and technology to the private sector for commercialisation. But in many cases, consumer end up paying twice- once by paying taxes to support government funded research, and again when they purchase a new proprietary technology developed with taxpayer funds (ETC Group Report 2005b: 13).

Patent on upstream discoveries hinder subsequent research by permitting owners to charge a premium for the discoveries that might be more cheaply available in a competitive market or public domain. Downstream patents are generally far more important in motivating private firms to develop end products than upstream products. Overpatenting by universities may lead to the risk of “anticommons” in which people underuse scarce resources because too many owners can block each other transaction cost<sup>68</sup>(Rai and Eisenburg 2003:295-296).

The anti-commons<sup>69</sup> is characterized by fragmented property rights, the aggregation of which is necessary to make effective use of the property. Aggregating such fragmented property rights entails high search and negotiation costs to locate and bargain with the many rights owners whose collective permissions are necessary to complete broader development. Anticommons theory emphasise the problems of divided entitlements among complements (Burk and Lemley 2003: 66-68). Complementarily exists where two or more separate components must be combined into an integrated system.<sup>70</sup> Basic upstream patents tend to be complicated by later, downstream technologies. This theory

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<sup>68</sup> Transaction cost mount quickly when the basic research discoveries necessary for subsequent work are owned not by one entity, but by a number of different entities. Therefore, the subsequent researchers will need licenses not from one entity, but from a number of different entities (Rai and Eisenburg 2003: 297).

<sup>69</sup> Anticommons property can be best understood as mirror image of commons property. In a commons, by definition, multiple owners are each endowed with the privilege to use a given resource, and no one has the right to exclude another (Heller 1998: 623-624).

<sup>70</sup> If a product must include components A and B, and A and B are each covered by patents that grant different companies monopoly control over the components, each company will charge a monopoly price for its component. As a result, the price of the integrated product will be inefficiently high and output inefficiently low because it reflects an attempt to charge two different monopoly prices (Burk and Lemley 2003: 68).

maps very well in biotechnology industry where product development times from creation to market are long and costly, but DNA patent are numerous and narrow. Production of any give product may require bargaining with multiple owners (Burk and Lemley 2003: 90-96).

Widespread patenting in nanotechnology is anticipated to lead to a 'tragedy of the commons' as well as a 'tragedy of anticommons' (D'silva 2008:3).<sup>71</sup> The same 'anticommons' problem aroused in biotechnology industry. The enactment of Bayh-Dole Act and the granting of first U.S. patent on a genetically modified form in *Diamond* (v) *Chakrabarty*<sup>72</sup> provided the spark for the biotechnology anticommons. In response to the Bayh-Dole Act, universities and professors quickly patented many aspects of biotechnology. Due to the lack of significant expertise and prior art in biotechnology, the USPTO issued broad and overlapping biotechnology patents to the universities. These university patents were subsequently licensed by the professors and researchers to the biotechnology startups. The complexity of the licensing arrangements with the universities, and the concomitant transaction cost, eventually escalated to the point that biotechnology innovation was hampered. Tullis argues that given the similarity between nanotechnology and biotechnology, it is likely that nanotechnology will face analogous impediments if numerous and potentially overlapping nanotechnology patents are granted and exclusively licensed (Tullis 2005: 4). || How?

## 8. Risks of Overpatenting in Nanotechnology

The race to hurriedly patent anything 'nano' has produced a flood of untruly broad nanopatents. Currently a sort of "patent land grab" is underway by these "nanopatent prospectors" as start-ups and corporations compete to acquire pioneering patent these

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<sup>71</sup> The term 'tragedy of the commons' was introduced by Garrett Hardin, to explain overpopulation, air pollution, and species extinction (Hardin 1968:1243). The 'tragedy of commons' refers to a situation when too many owners have the privilege to use a given resource, and no one has the right to exclude another. The 'tragedy of anticommons' is the inverse of term 'tragedy of commons'. It refers to a situation when multiple owners each have a right to exclude others from scarce resources and no one has an effective privilege of use (Heller 1998:623-624).

<sup>72</sup> 447 U.S. 303 (1980).

early critical days (Bawa et al. 2005:155). The above facts in combination means that patents will cast a larger shadow over nanotechnology than over any other modern science at a comparable stage of development. The ownership of nanotechnology patents is too fragmented, risking the development of a patent thicket (Lemley 2005: 618) This larger role for patents will interfere with innovation in nanotechnology. While in theory patents spur innovation they can also interfere with it.<sup>73</sup> Broad patents granted to initial inventors can block up or retard improvements needed to take a new field from interesting lab result to commercial viability. The dispersion of overlapping patents across to many firms can create patent thickets problem, making effective use of technology difficult, if not impossible (Lemley 2005: 620).

### **8.1. Patent Thickets**

Innovation in most technological sectors is a cumulative process. The theory of cumulative innovation states that innovation is an ongoing, iterative process that requires the contributions of many different inventors, each building on the work of others. This theory is based on the division of property rights. It emphasize that the law must divide property entitlements in order to provide incentives to each improver in the process (Burk and Lemley 2003:82). New inventors have the benefit of the insights made by their predecessors. Any person who wishes to improve upon a patented invention must either secure permission from the patentee or risk harsh consequences (Ayres and Parchomovsky 2007:870).

Patent thicket is defined as a dense web of overlapping intellectual property rights that a improver must hack its way through in order to actually commercialize true technology. Patent thickets, as a result of multiple blocking patents<sup>74</sup>, can discourage and stifle

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<sup>73</sup> Especially when it limits access to essential knowledge, as may be the case in emerging technological areas when innovation has a marked cumulative character and patents protect foundational inventions. In this context, too broad a protection on basic inventions can discourage follow-on inventors if the holder of a patent for an essential technology refuses access to others under reasonable conditions (OECD 2004:9).

<sup>74</sup> Blocking patents refers to the situation in which an inventor obtains a patent on an improvement of a previously patented invention. This inventor infringes the original patent, but the first patentee has no rights to the patented improvement. Because the first patentee usually has an incentive to obtain access to the

innovation (Shapiro 2000:120). When a given organisation has all of the necessary patents to develop a given technology, it can proceed without intellectual property entanglements. When multiple organisations each own individual patents that are collectively necessary for a particular technology, however, their competing intellectual property rights form a “patent thicket” (Clarkson and Dekorte 2006: 181). In such a case, the improver must obtain permission from all relevant patentees that involve higher cost. On the margin, the higher fees may not leave enough profits to justify the investment in the innovation. Alternatively, the improver can try to invent around all the relevant patents and thereby avoid the need to negotiate permissions. However, inventing around may prove impossible or as costly as negotiating. Inventing around a patent thicket would often require a new technological or conceptual breakthrough that most innovators are incapable of achieving. They have another option also; they can simply ignore all blocking patents, commercialize the new innovation and deal with infringement suits after the fact (Ayres and Parchomovsky 2007: 871-875).

Patent thickets occur when multiple intellectual property rights cover the same technology and therefore overlap. The theory of patent thickets emphasizes the importance both of limiting the issuance and the scope of such overlapping patents and the need for bargaining mechanism that permits the efficient clearance of patent rights. The patent thickets problem maps well onto the semiconductor industry. Semiconductor companies obtain patents on components that may represent only a minor part of the whole chip. Circuit designs, materials, packaging, and manufacturing processes are all the subject of different patents. The result is that a new microprocessor may of necessity infringe hundreds of different patents owned by dozens of companies (Burk and Lemley 2003: 98).

Complementary monopolies not only raise prices for downstream manufacturers but also lower the combined profits of the monopolists (Shapiro 2000:123). Patentees return on

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improvement, the blocking patent gives the infringer some bargaining power in negotiations. By helping to overcome market defects ranging from high transaction costs to strategic behavior in negotiations, the blocking patents doctrine should increase the probability that the parties will reach a mutually beneficial licensing agreements (O'Rourke 2000: 1194).



innovation depends in part on the licensing fees they collect from follow on innovators and consumers. When a technology or a product get entangled in a patent thicket, the cost of using it goes up and licensing fees go down. Consequently, the emergence of a patent thicket might prevent original patentees from recouping their investment in innovation. Thus, patent thickets put a drag on all levels of innovation (Ayres and Parchomovsky 2007:877).

The nanotechnology patent landscape experiences an even greater level of patent thicket problems as nanotechnology has a wide area of application, reaches across several established scientific domains and tends to bring together several already patented aspects of technological innovation (D'silva 2008: 4). The Action group on Erosion, Technology and Concentration (ETC) report showed that patent thickets exist in carbonnanotubes, dendrimers, quantum dots and scanning probe microscopes. According to the report, patent offices have already granted hundreds of patents on carbon nanotubes, so if a company developed a new product or process involving carbon nanotubes, the innovation would undoubtedly infringe existing patents. The scanning tunnel microscope market is densely populated. Since IBM's pioneering patent in 1982, the USPTO has issued 735 patents that refer to AFMs/SPMs in their abstracts. The report further shows that there is enormous potential for overlapping and conflicting patents in the quantum dot arena (ETC Group Report 2005b: 20-31).

The pharmaceuticals industry is likely to be the biggest beneficiary sector from nanobiotechnology. It is speculated that the pharmaceutical sector would make the use of newly patented nanoparticle based drug delivery systems in conjunction with drugs whose patent have expired, thereby introducing new drugs. Such acts would restrict the entry of generic drug players in the market (Harris et al. 2004:2). In case of nanoparticle drug delivery system, there is 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 process of the nanoparticle (Sharma and Chugh 2009:444-445). In the nanomedicine, there is high risk that the granted patents are overlapping thereby creating patent thickets.

Not only do patent thickets raise the cost of certain patented products and technologies to consumers but they also create uncertainty as to the legal rights in such products and technologies (Ayres and Parchomovsky 2007:18). Because of the large number of overlapping and conflicting patents, large number of nano-scale patent litigation is inevitable, and its likely to be ugly (ETC Group Report 2005:10). Lemley is of the opinion that nanotechnology patent may be difficult to enforce because it is hard to detect infringement because much of whatever infringement occurs is confined to research laboratories. So, it is possible that the nanotechnology industry will avoid a patent thicket at the research stage in much the way the biotechnology seems to have done; not by limiting the scope or issuance of patents but by simply ignoring them (Lemley 2005: 623).

## **8.2. Doctrine of Equivalents and Reverse Doctrine of Equivalents**

It is argued that risk of patent thicket may be exacerbated by the application of pre-nanotechnology patent to nanotechnology inventions. For example, a last generation patent on an invention in microprocessors might call for a “sub-micron gate”. Such a claim would be literally infringed by a gate of 100nm, even though the design and behaviour of the materials in the nano-sized gate might be different than those of a gate of 950 nm. If pre-nanotechnology patents are interpreted to cover their nanotech counterparts, it would multiply significantly the number of patents with which nanotech companies have to deal (Lemley 2005: 621).

Infringement of a claim takes place when there is literal infringement or infringement under the doctrine of equivalents. Literal infringement occurs when every element in a claim is found in the accused device. The ‘doctrine of equivalents’ is an important tool of law to determine infringement in cases of non-literal infringement. The doctrine proposes that despite an absence of literal infringement of express terms of a patent claim, the infringement can still be proven if an element of an accused product or service and a

claimed element of patented invention are found to be legally equivalent<sup>75</sup> (Patodia et al. 2007:314-315). The theory behind this doctrine is that “if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape”.<sup>76</sup> Thus, a pioneer patentee may invoke the doctrine of equivalents and proceed against the producer of the subsequent device in an infringement action if that device “performs substantially the same function in substantially the same way to obtain the same result” (Roe 2006: 141).

It is a venerable principle of patent law that pioneering patents i.e. important patents that open up a new field should be entitled to a broader range of protection than more modest inventions or improvement on existing ideas. The rationale for this rule is expressly policy based; if we do not give broad equivalents protection to pioneers in the new fields, they will be unable to get adequate returns from their invention, as subsequent improvers figure out commercial applications of new idea that avoid the literal scope of the patent (Burk and Lemley 2003: 152-153).

The primary use of the doctrine of equivalents is to expand the scope of patent claims to cover any variation in the patented invention that a person having ordinary skills in the art would regard as “interchangeable” with the specified claimed invention. A corollary of the interchangeable test is to use the doctrine of equivalent to expand the scope of claims to cover subsequent variations of the patented invention made possible through the use of technological innovations which occurred after the patent was filed (Roe 2006:145-146).

The existence scope and extent of the doctrine of equivalents represents a balance between the fair scope for the patent and the notice the patent provides for the public, along with a balance between incentives to innovate and the cost of uncertainty. It removes the unfairness that could result from an overemphasis on the literal language of

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<sup>75</sup> For example, the claim reading ‘a device comprising A+B+C’ would be (non-literally) infringed by a product consisted of A+B+D, if D is an equivalent of C.

<sup>76</sup> This is known as tri-partite test, or function –way –result test, which is the most traditional test for determining what, is equivalent under the doctrine of equivalents.

patent claims. On the other hand, guiding rules, i.e. all elements rule; tri-partite test; insubstantial difference test; obviousness test, and known interchangeability test, limits the application of the doctrine<sup>77</sup> (Patodia et al. 2007:315).

The doctrine of equivalents is a double-edged sword because it is used in certain situations against the pioneer patentee to compel an equitable excuse of literal infringement, which is referred to as the Reverse Doctrine of Equivalents (Wasson 2004: 3-4). A clear formulation of the reverse doctrine of equivalents was given by the U.S. Supreme Court in *Graver tank and Mfg. Co. (v) Linde Air Prods. C.*<sup>78</sup>. The court held that “The wholesome realism of the doctrine of equivalents is not always applied in favour of a patentee but is sometimes used against him. Thus, where a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal word of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee’s action for infringement” So, when an accused device is so different from the claimed invention, a ruling of non-infringement may be justified even though the accused device falls squarely within the claims .

In *Texas Instruments, Inc. (v) U.S. Int’l Trade Comm’n*<sup>79</sup>, the U.S. Court of Appeals for the Federal Circuit held that “invocation of reverse doctrine of equivalent requires both that (1) the accused infringer must have literally infringed the accuser’s patent claim; and (2) in order to avoid infringement, the accused device must be “sufficiently different”

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<sup>77</sup> The ‘All element rule’, states that the test for equivalents must be applied on an element-by-element basis. Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. The “Insubstantial different” test requires proof of insubstantial differences between the claimed and accused products or processes. The ‘Obviousness test’ states that” if the differences between the accused product and the claimed invention meet the test for non-obviousness, then the differences are substantial and the accused product does not infringe under the doctrine of equivalents (Patodia et al. 2007: 317).

<sup>78</sup> 339 U.S. 605 (1950). Available at [Online:web] Accessed on 24 July 2009, URL:<http://supreme.justia.com/us/339/605/case.html>

<sup>79</sup> 846 F.2d 1369 (Fed.Cir.1988), Available at [Online:web] Accessed on 25 July2009, URL:<http://www.altlaw.org/v1/cases/409896>

from the accuser's device". The court further held that "the reverse doctrine of equivalents is invoked when claims are written more broadly than the disclosure warrants. The purpose of restricting the scope of such claims is not only to avoid a holding of infringement when a court deems it appropriate, but often is to preserve the validity of claims with respect to their original intended scope". Therefore in order to invoke the reverse doctrine of equivalents, the nano-scaled invention must first show that the subsequent invention literally infringes the pioneering claims.

With regards to nanotechnology, since the claims of the prior art will rarely define the limiting size or scale of the invention, subsequent nano-scaled inventions will likely fall within the scope of prior art's claim that are devoid of any mention of scale and thus literally infringe the prior macro scale art (Roe 2006:142-143). To fulfil the second requirement of the reverse doctrine of equivalents the accused defender would have the burden of showing that the product is sufficiently different from the claimed subject matter. In such a situation the nanotechnologist could make a strong argument that there are sufficient differences by pointing to the unique behaviour of matter at such a small scale (Wasson 2004:7). Due to the scale and quantum effects a nanomaterials would behave in a completely different way from the macroscale particles

However, the reverse doctrine of equivalence is appropriate when a technical development that falls within the literal scope of a previously granted claim has a considerably higher value than the uses that the skilled person can deduce from the patent. It fulfils an important function as a remedy in situations where it is difficult for the inventor of a valuable dependent invention to reach an agreement with the owner of the dominant patent. If the reverse doctrine of equivalence is not applied in such cases the market introduction of particularly valuable developments may be stifled (Domeij 2000:126-128).

The doctrine can apply to radical improvements in any area of technology, and it has indeed been used to cover technological paradigm shifts within an industry. But radical improvements are more likely occur in some industry than others for example, software

industry<sup>80</sup> where changes occur through iterative steps, therefore they are less likely qualify under the reverse doctrine of equivalents (Burk and Lemley 2003:155-156). However, nanotechnology represents a drastic paradigm shift from traditional manufacturing because of the different physical laws applicable to nanoscale dimensions. Insofar as nanoscale improvers must face unique challenges in development of their inventions, nanotechnology presents a prime candidate for successful implementation of the doctrine (Wasson 2004: 9). Therefore, the reverse doctrine of equivalents is possibly applicable in the field of nanotechnology.

### 8.3. Patent Trolls

Certain enterprises buy patent with no actual intention of working them, and instead use these patent to extort settlements from manufactures of related goods. These companies or enterprises are often termed as “patent trolls”. Like in Scandinavian folklore where the troll lives under the bridge without actually building it and prevent the passerby from crossing without paying a toll. Rather than promoting innovation such actions are likely to cripple legitimate research and development (D’silva 2008:6-7).

In nanotechnology most of the research is conducted by the universities and they are the major patent holders. So the question can arise whether universities are patent trolls. Lemley argues that universities are not patent trolls for many reasons. Universities conduct basic research and patent their federal funded research. They do not engage in tactics to demand royalty, like troll companies. Most universities licenses have a major technology transfer component, thereby giving the licensee not just the right to avoid a lawsuit, but also provide valuable know-how. Therefore universities are not trolls when they contribute previously unknown technology to society, rather than just imposing cost

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<sup>80</sup> Software innovation typically involves considerable reuse of existing code, and because much of the innovation that occurs is not formally documented as prior art, software patents may be extended more broadly than patents on other inventions of comparable technical merit. Because their economic lives tend to be much shorter than the uniform patent term, courts may apply the doctrine of equivalents too broadly in software infringement disputes, and thus may stifle efforts by second-comers to design around existing patents (Cohen and Lemley 2001: 39, 56).

on others by asserting legal rights over inventions independently developed by others (Lemley 2008: 628-629).

However, universities are increasingly enforcing their patents, leading to several lawsuits. In order to find out whether a university is a patent troll or not, a lot will depend on how critical the technology is and whether the university is protecting its patents to maximize the social impact of the technology or purely for financial gains (D'silva 2008:7). Therefore, given the amount of investment in nanotechnologies it becomes important to find an appropriate solution to deal with nanothickets as well as patent trolls. Without appropriate strategies, firms and companies will be unable to capitalise on their investments and researchers are likely to be prevented from conducting essential research as patent thickets and patent trolls are likely to constitute an obstacle ( D'silva 2008: 8).

## **9. Possible Solutions to the Problem of Overpatenting in Nanotechnology**

### **9.1 Cross Licensing**

A Cross license is simply an agreement between two companies that grants each other the right to practise the other's patent. Cross licences are negotiated when each of two companies have patents that may read on the other's products or processes. Rather than blocking each other and going to the court or ceasing production, the two enter into a cross-licence (Shapiro 2000: 127-129). When the total number of owners in the conflicting intellectual property rights is small, the response to the patent thicket problem has often been cross- licensing (Clarkson and Dekorte 2006:188). However, In patent thickets, where more than two parties are involved, the transaction cost of cross-licensing between all the parties can be prohibitive, and additional economic barriers exist such as 'hold out' and 'double marginalisation'<sup>81</sup> (Clarkson and Dekorte 2006:188).

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<sup>81</sup> The double-marginalization theorem shows that it is inefficient to grant two monopolies in complementary goods to two different entities because each entity will price its piece without regard to the efficient pricing of the whole, resulting in an inefficiently high price (Lemley 2005:625).

In nanotechnology universities are the major patent holders. There are several reasons which show that university patents will be more restrictive of nanotechnology. Universities are non-manufacturing entities. They do not sell products. They are interested only in maximizing their licensing revenue rather than cross-licensing. Universities grant exclusive rather than non-exclusive licences, as the exclusive licensing royalty rates are higher than non-exclusive rates (Lemley 2008: 614-615).

Many nanotechnology companies have entered into cross licensing agreement. A successful example of cross-licensing in nanotechnology patents involves two emerging companies BioCrystal limited, and Crystalplex Corporation. Each company owned technology associated with producing fluorescent semiconductor nanocrystals and nanobeads. In the cross licensing agreements, BioCrystal provided Crystalplex with the right to use its proprietary technology related to nanocrystals-encoded beads and nanocrystals-enhanced filter set. In return, Crystalplex provided BioCrystal with the right to use, via a sublicense, its proprietary alloyed nanocrystal technology. By entering into cross-licensing agreements each party gains access to nanotechnology that may be necessary for continued development and commercialisation of individual technology (Harris et al. 2004: 12).

Lemley doubts whether the interests of nanotechnology patents owner are in fact symmetrical. If patents are distributed asymmetrically, but are concentrated in established firms in different industries rather than nanotech tool firms, it is reasonable to expect the patent owner to license the invention outside its industry for a royalty. They will possibly grant exclusive licences which tend to produce higher royalty rates but their effect may be to shut down competitors out of the market, or at least out of the use of a particularly technology. Therefore, nanotechnology specific firms that do not make downstream products themselves will be more interesting in licensing exclusively than non-exclusively (Lemley 2005:624). Exclusive licensing arrangements can be tremendously profitable. Indeed, exclusive licensing agreements can be “one of the more solid foundations a company can start with (O’Loughlin 2007:356).



However, for basic inventions like nanotechnology exclusive licensing has significant social and private costs, because it limits competition in the exploitation of those building blocks and so interferes with the resulting follow-on innovation. Therefore if universities do continue to grant exclusive licences, it will matter greatly whether those licences are to large players with incentive to cross-licence the patents or to small upstream players who will in return seek royalty (Lemley 2005: 627). A field-exclusive license, on the other hand, would not prevent entities in other fields from obtaining a license. A field exclusive licence might be most effective in nanotechnology, where the building blocks of the discipline may be used in research and development across many different fields (Kesan 2009: 2203).

## **9.2 Patent Pools**

A patent pool is an agreement between two or more patent owners to licence one or more of their patents to one other or third parties. A patent pool may also be defined as “the aggregation of intellectual property rights which are the subject of cross-licensing, whether transferred directly by patentee to licensee or through some medium, such as joint venture, set up specifically to administer the patent pool”. The concept of patent pool is not new. The first patent pool was formed in 1856, where the Sewing Machine Combination formed a patent pool consisting of sewing machine patents, while an aircraft patent pool was privately formed in 1917 encompassing almost all aircraft manufacturers in the United States. In 1998, Sony, Philips and Pioneer formed a patent pool for inventions that are essential to comply with certain DVD-Video and DVD-ROM standard specifications (Clark et al. 2000: 4-5).

When two or more companies hold patents necessary to make a given product, and when at least some actual or potential manufacturers may not hold such patents, a patent pool can be the natural solution of thicket problem (Shapiro 2000:127). There are several benefits of patent pools. First, patent pools eliminate the problem of patent thickets by creating a centralized location for parties to obtain all the essential licences from a single entity. This, in turn, can facilitate rapid development of new technology since it opens the

playing field to all members and licensees of the patent pool. A second benefit is that patent pools have the potential to significantly reduce the transaction cost and licenses. Patent pools address the anticompetitive “hold out” problem by providing a means in which most necessary licenses are obtained at one time. A third major benefit from patent pooling is the distribution of risks. Like an insurance policy, a patent pool can provide incentive for further innovation by enabling its members to share the risks associated with research and development. Finally, a patent pool provides a mechanism for free sharing of technical information related to patented technology among its contributing members and its licensees (Clark et al. 2000: 8-9).

There are several factors which need to be considered in order to determine whether the application of patent pool is suitable for a particular industry or not. Such as, there should be moderate fragmentation of patent landscape, members must be willing to negotiate and determined to reach an agreement in order to show their commitment to creation of the pool, and certainty of patent ownership (Lee 2006a: 17-20). Therefore, the formation or need for patent pools will ultimately depend upon the patent landscape in the particular area of application of the nanotechnology (D’silva 2008:10). For example, in case of Dendritic nanotechnology, the patent pool will not be necessary for the continued advancement of this application. The reason is that a huge amount of patents are in control of one company alone, Dendritic Nanotechnologies, which seems to be the primary source for the most highly sought after patents. DNT which was founded in 2003 originally held more than 30 patents in this area and already sold and licensed more than 200 variations of dendrimers to pharmaceutical, biotechnology, and diagnostic companies (Lee 2006a:24)

Lee argues that patent pools have several anticompetitive effects. One objection of patent pool is that it led to possible inflation of cost of goods as it can stifle competition if multiple parties that hold blocking patents enter in a pool, and the pooling of these patents will expand monopoly pricing. A second reason why critics feel patent pools should not be encouraged is that pools shield invalid patents. Companies who fear that their patents will be invalidated in court enter into pool agreements, which will force the

public to pay royalties on technology that would have become part of the public domain if the patents were actually litigated in the court. Another criticism of patent pools is that such pools eliminate competition by encouraging collusion and price fixing. The reason is that the companies that are not involved with the pool are at competitive disadvantage since they will not be able to obtain the needed licences in order to produce a good (Lee 2006a: 16-17).

Patent pools have the advantage of not only decreasing costs for acquiring multiple technological licenses in complex technology applications, it also provides a source of revenue and income to patent pool members as a result of royalty that generated from non-member licensees. Subscribing into patent pools may be an economical means to acquiring needed technology for protecting and practicing your product in the commercial marketplace (Halluin 2006:34). Patent pools seek to ameliorate the anticommons problem by requiring participants in the pool to licence their patents on reasonable and non-discriminatory terms (George 2007:558).

Unlike in other fields, nanotechnology patent holders are not likely to come together to form a patent pool because exclusivity in patents and licensing potentially can result in such tremendous profits that parties are more likely to keep their patents than consider sharing them in a patent pool. Another reason is that due to its multidisciplinary nature the nanotechnology research requires the use of a diverse set of similar techniques that may be concurrently patented. Therefore, the researchers specializing in one area are likely to find it difficult to compare the values of patent from other branches of science (Tullis 2005: 6). However, it cannot be denied that stable patent pools can be formed in nanotechnology by clearly defining patent essentials, stakeholders interest and scrutinising economic incentives (D'silva 2008:12). Such nanopooling strategy provides a mechanism for clearing the nanothickets and bringing nanotechnology based products to the market place (Clarkson and Dekorte 2006:198).

## 10. Intellectual Property Litigation

Given the novelty of the technologies involved, the patentability of some nanotechnology inventions may ultimately be addressed by the courts rather than by the patent offices. There has been very little patent litigation in nanotechnology area since there are as yet few nanotechnology products on the market. To date, litigation over nanotechnology scale patent infringement has been primarily focused on biotechnology products such as nanogold particle labels used in diagnostics, microfluidic devices and microarrays (Tullis 2004).

Companies are now bringing nanotech products to the market and nanoparticles- based drug delivery systems may be among the first products to generate serious disputes as the multi-billion dollar pharmaceutical industry begins to adopt them (Harris et al. 2004:17). Some companies are already marketing their patented drug delivery system. For example, Elan Pharma International is marketing its proprietary NanoCrystal technology, which delivers drugs in particle about 200nm size. This NanoCrystal technology has already been used for drug manufacturing by Merck and Wyeth, as well as licenced to other pharmaceuticals companies such as Bristol-Meyers Squibb, Aventis Pharma (Bawa et al. 2005:155).

Therefore, companies bringing nanomedicine will certainly faced uncertainty regarding the validity of broad patents held by others and end up in legal disputes. The first patent litigation in the area of the nanopharmaceutical was between Elan pharmaceuticals International and Abraxis Biosci Inc. In July 2006 Elan Pharmaceuticals filed a complaint in the US District Court for the district of Delaware alleging that the cancer treatment, "Abraxane", manufactured by Abraxis Biosci Inc, infringes two of Elan's patents. After two years of discovery battles, the dispute went before a jury on 2 June 2008, which rendered a verdict in favour of Elan for \$55.2 million (Prendergast and Schafer 2008:157).

There will be an increasing amount of patent litigation as more drug delivery based system come to market and companies began to assert their patents. In most of the patent

battles, the larger entity with the deeper pockets will rule the day, even if the brightest stars of innovation are on the other side. In the future, the nanomedicine start-ups will become attractive acquisitions for larger companies because takeover generally is a cost-effective alternative to litigation. This situation is all too familiar to business and patent communities. Ultimately, companies introducing new products to the market will face considerable uncertainty regarding the validity of broad and potentially overlapping patents held by others. The ongoing land grab will worsen the problem for companies striving to develop commercially viable products. In fact, start-ups may soon find themselves in patent disputes with large, established companies, as well as between themselves (Bawa 2005:348-349).

## **11. Summation**

Patents are necessary for the growth of nanotechnology industry. They provide incentives for the venture capitalists to invest in nanotechnology research and development. Nanotechnology raises some unique issues in patent law. In order to be patentable a nanotechnology invention must satisfy the patentability criteria as defined in the Article 27 of the TRIPs Agreement. Among the patenting requirements the determination of 'novelty' and 'inventive step' will be challenging. However, the novelty requirement can be easily fulfilled as nanoscale inventions exhibit completely different properties from the macroscale substances due to the quantum and scale effects. Nanoscale inventions produce such unexpected results that cannot be anticipated by the prior macroscale art. In case of nanotechnology size does matter for the purpose of patentability. The determination of the requirement of 'inventive step' is little difficult in nanotechnology inventions. However, by showing that the new and unexpected functions arise from the nanoscale component and they have overcome a technical difficulty, this requirement can be met.

Because of its multidisciplinary nature, a nanoscale invention may be useful in various fields. However, the utility requirement of nanoscale inventions can be met by asserting their substantial utility. Nanotechnology is a new field, the tools and techniques necessary

to determine the practicability of these inventions are not easily available to examiners. Therefore, high level of disclosure is required. The basic elements of nanotechnology inventions are the chemical elements, which are the building block of both living and non-living things. Therefore, patenting of nanotechnology inventions raises the issue of monopoly on nature. Patentability of some nanotechnology inventions also raises moral and ethical concerns. Most of the patents in nanotechnology are for basic inventions as this technology is still developing. These patents will create obstacle for the downstream inventions and thereby stifling innovation in this field.

Universities are the major nanotechnology patent holder as they conduct basic research in this field. Realising the potential market of this technology, universities and nanotechnology companies are aggressively patenting their basic nanotechnology inventions. Nanotechnology is a new field so there is not enough prior art available. Due to the confusion about the clarity of term “nano”, different nanotechnology terms are being used to refer the same invention. This creates difficulty for the examiners to search nanotechnology patents. Nanotechnology has cross industry structure. A nanotechnology patent may have effect in other industries as well. All this have resulted in grant of overly broad and overlapping patents in this field. To deal with this situation and to avoid issuance of broad and overlapping patents in future, the USPTO and EPO has created new classification of nanotechnology patents—Class 977 and nanotechnology Subclass (Y01n). The purpose of developing these classifications is to help examiners to search prior art in this field and to identifying nanotechnology patents more adequately. However, because of the multidisciplinary nature of nanotechnology further elaboration of these classifications is required.

Aggressive patenting in this field and grant of broad and overlapping patents has led to the risk of creation of patent thickets and anticommons. Therefore, a large number of nanotechnology patent litigation will arise in future as more nanotech products will enter in the market. Reverse doctrine of equivalents is possibly applicable in the field of nanotechnology. As, companies and nanotech firms are collecting and licensing a large number of nanotechnology patents, patent trolls will interfere in the nanotechnology

market in the near future. Cross licensing and patent pools can be a viable solution for the problems of patent thickets and anticommons. Since most of the nanotechnology patents are for basic inventions, therefore universities and nanotechnology firms will prefer exclusive licensing. Patent pools have several benefits and disadvantages. Companies holding a large number of nanotechnology patents will not opt for the formation of patent pools. Multidisciplinary nature of nanotechnology also creates problems for the formation of patent pools. However, the formation of patent pools in nanotechnology cannot be denied in near future. Therefore, issuance of quality patents in nanotechnology is necessary to prevent the problem of patent thickets and to realize the full potential of this technology.

## **CHAPTER IV**

# **NANOTECHNOLOGY AND DEVELOPING COUNTRIES**



## CHAPTER IV

### NANOTECHNOLOGY AND DEVELOPING COUNTRIES

#### **1. Introduction**

Most of the developing countries have already established national nanotechnology initiative. The rapid and broad involvement of developing countries in nanotechnology is often interpreted as a feature of the global character of the nanotechnology revolution and as a trait of global production of science. Different from previous technological revolutions, these characteristics place developing countries in a more favourable position to face this revolution and benefit from it (Invernizzi et al. 2008:124). However, there is another side to this debate. Developing countries are lagging far behind than developed countries who are heavily investing in nanotechnology research. It is also important to note that most of developed countries hold a large number of nanotechnology patents in all relevant sectors. The United States is the most active patenting country in each subfield of nanotechnology. The major companies holding large number of nanotechnology patents are also from the developed countries.

However, not all the developing countries in the South are making huge investment in nanotechnology research. According to UN millennium<sup>1</sup> project report the developing countries can be categorized into three groups on the basis of nanotechnology activity. The front runner countries are China, India, and Republic of Korea. The countries who are on middle ground in nanotechnology research are Brazil, Chile, the Philippines, South Africa, Thailand, Argentina and Mexico (United Nation Millennium Project Report

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<sup>1</sup> In September 2000, building upon a decade of major United Nations conferences and summits, world leaders came together at United Nations Headquarters in New York to adopt the United Nations Millennium Declaration, committing their nations to a new global partnership to reduce extreme poverty and setting out a series of time-bound targets - with a deadline of 2015 - that have become known as the Millennium Development Goals. There are eight Millennium Development Goals (MDGs): End poverty and hunger, universal education, promoting gender equality, maternal health, child health, Combat HIV/AIDS, environmental sustainability and global partnership. For details on "Millennium Development Goals" See [Online:web] Accessed on 10 October 2009, URL:<http://www.un.org/millenniumgoals/index.shtml>.

2005:70). The least developed countries face challenges in institutional, human, and physical capacities. Therefore, they are lagging behind the developing countries in nanotechnology research and development.

The debate about the potential impact of nanotechnologies on developing countries is polarized in two groups. On the one hand there are nanoscientists and scholars who claim that it will address the specific needs of the people of developing countries. This group argument is that nanotechnology will help in eradication of poverty which results due to the lack of technological capabilities. Whereas, on the other hand there are critics who argue that the major beneficiary of this technology will be the consumers of developed countries not the poor people. They argue that nanotechnology will widen the gap between developed and developing countries. It will not only create a north-south nanodivide but also a south-south nanodivide. They are also skeptical about the social and ethical issues related to nanotechnology. In the context of this debate the following question arise: To what extent nanotechnology would be able to meet the specific needs of the developing countries? This chapter aims to analyse this debate. Indian position in nanotechnology R&D will also be discussed. The social and ethical issues will also be considered.

## **2. Nanotechnology as an Opportunity for Developing Countries**

The ongoing industrialization and modernization trend in the developing world has generated a variety of problems that culminated in the global phenomena of environmental pollution, widespread diseases and urbanization. The situation in the developing world has not significantly improved and in certain countries, the state of the people's conditions has even deteriorated (Burgi and Pradeep 2006: 654). Billions of people around the world still suffer from inadequate access to clean water, energy, information, shelter, healthcare, and other basic needs. Nanotechnologists claim that all this will change with the exploitation of this new technology. This view has been supported by the United Nation Millennium Project Report, Task Force on Science, Technology and Innovation. According to the report "Nanotechnology is likely to be

particularly important in the developing world, because it involves little labour, land, or maintenance and it requires only modest amounts of materials and energy. It can contribute new tools with which to address sustainable development problems, and it can strengthen the technologies already available and make them more efficient” (United Nation Millennium Project Report 2005:70).

Fabio Salamanca Buentello and several others from the Joint centre of Bioethics at the University of Toronto interviewed sixty-three experts in nanotechnology from several developed and developing countries. They identified top ten nanotechnology applications including: Energy storage, water treatment and remediation, disease diagnosis, drug delivery system, food processing and storage, which could contribute to achieving United Nation Millennium Development Goals (MDGs) (Salamanca et al. 2005:384-385). Developing countries are rich in human capital and their brain power in the medium and long term will reshape the imbalance between the north and south. The wide range of possible applications of nano-scale technologies suggest that if the industrial sector of developing countries is involved in the manufacturing of nanomaterials, it will enhance its competitiveness in manufacturing at the global level (Burgi and Pradeep 2006:654). Potential areas where nanotechnology can make a significant difference in the developing world could be briefly examined.

## **2.1. Water Purification**

Access to safe drinking water is one of the most important needs in many developing countries, since almost half of the world population has no access to safe drinking water and basic sanitation. It has been argued that nanotechnology will provide a solution for the problem of clean drinking water. Water purification systems, equipped with nanomaterials and using new kinds of membrane technologies with variable pore sizes as filters could provide people in any area with safe drinking water. It is claimed that a combination of nanotechnologies will be useful in providing cost-effective and safe drinking water, which will have less dependence on energy (Burgi and Pradeep 2006:655). Nanomaterials have a number of key physicochemical properties that make

them particularly attractive as separation media for water purification. Titanium Dioxide (TiO<sub>2</sub>) nanoparticles are very versatile; they can serve both as oxidative and reductive catalysts for organic and inorganic pollutants. Research shows that the removal of total organic carbon from waters contaminated with organic wastes was greatly enhanced by the addition of TiO<sub>2</sub> nanoparticles in the presence of ultraviolet Light. Therefore, it is anticipated that TiO<sub>2</sub> nanoparticles will help solve challenging water purification problems (Savage and Diallo 2005: 334).

A range of water treatment devices that incorporate nanotechnology are already on the market, with others either close to market launch or in the process of being developed. The Indian research team from the Atomic Research Centre in Mumbai is currently investigating how water filtration systems based on carbon nanotubes could be used to remove arsenic, fluoride, heavy metals and toxic organic chemicals. According to the researchers carbon nanotubes have several advantages over traditional purification systems like polycarbonate in that they're simple and inexpensive to install, operate and maintain than conventional systems (Bruno 2008). Researchers at Rensselaer Polytechnic Institute (U.S.) and Banaras Hindu University (India), working in collaboration, have devised a simple method to produce carbon nanotube filters that efficiently remove micro- to nano-scale contaminants from water and heavy hydrocarbons from petroleum (ETC Group Report 2005a:25).

## **2.2 Health Diagnosis and Monitoring**

Nanoscale techniques have the potential to revolutionize the health sector, in particular in the fields of diagnosis, screening and monitoring of diseases and health conditions. Lack of accurate, affordable and accessible diagnostic tests impedes global health efforts, especially in remote and in accessible regions and poor settings. Widespread communicable diseases like HIV/ AIDS, malaria, tuberculosis, etc. could be diagnosed with screening devices using nanotechnology. Standard diagnostic tests for widespread diseases in the developing world are costly, complex and poorly suited to resource limited setting (Burgi and Pradeep 2006:655). Nanotechnology is being used worldwide

by scientist to improve the treatment of these diseases. The U.S. National Science Foundation predicts that nanotechnology will produce half of the pharmaceutical industry product by 2015 (Roco and Bainbridge 2006: 41).

The World Health Organization (WHO) has assessed the status of the Tuberculosis epidemic and progress in control of the disease every year since 1997. WHO estimates that the largest number of new TB cases in 2005 occurred in the South-East Asia Region, which accounted for 34% of incident cases globally. However, the estimated incidence rate in Sub-Saharan Africa is nearly twice that of the South-East Asia Region, at nearly 350 cases per 100000 population.<sup>2</sup> India, China, Indonesia, Nigeria and South Africa rank first to fifth in terms of the total number of TB cases. Asia (the South-East Asia and Western Pacific regions) accounts for 55% of global cases and the African Region for 31%; the other three regions (the Americas, European and Eastern Mediterranean regions) account for small fractions of global cases (WHO Report 2009).

In India research is underway into the role of nanotechnology in control of tuberculosis. The Central Scientific Instruments Organization (CSIO) has developed a nanotechnology based TB diagnostic kit. The kit will be around 1 cm by 1 cm cube and would cost around Rs 30 per piece. It would reduce the time taken and the cost of a test for tuberculosis at present. This type of kit will also require very less amount of blood sample reducing it to only a few microlitre. It is ready for clinical trial.<sup>3</sup>

South African scientists have used nanotechnology to enhance the absorption of tuberculosis drugs in the body so that fewer, smaller doses are needed. Clinical trials for the antibiotic, Rifanano-a combination of the four main first-line TB drugs are scheduled for 2012 and the drug should be available in government clinics in 2016. Most TB antibiotics must be taken daily for up to six months and often cause debilitating side effects, such as nausea and fatigue. Rifanano needs to be taken just once a week for two months and there are no adverse reactions (Campbell 2009).

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<sup>2</sup>“Tuberculosis”, for greater details see [Online:web] Accessed on 20 September 2009, URL:<http://www.who.int/mediacentre/factsheets/fs104/en/>.

<sup>3</sup>“CSIO Develops Nanotechnology for TB Diagnosis Kit”, *The Times of India*, 3 January 2004.

The same technology is being applied for Malaria, HIV/Aids and other diseases where patient compliance is high. *Plasmodium falciparum*, the most widespread malaria parasite, is responsible for the most deaths worldwide. Malaria is a common disease in most part of the developing world. Subra Suresh and his team of the Institute's Department of Materials Science and Engineering at Massachusetts Institute of Technology (U.S.), has lead a study using 'optical tweezers' (a nanotechnology tool) to show how the elasticity of red blood cells changes when they are infected with the malaria parasite. The flexibility of these cells determines how they and the parasites within them move through the body. Understanding this is important to understand the disease. The team also used a technique called tomographic phase microscopy, which was developed in MIT laboratory and is based on the same concept as a CT scan: To create a 3-D image. Images generated by tomographic phase microscopy revealed the degradation of hemoglobin as the malaria parasite interacted with the cell. They argued that the microscopy technology could be used to develop a diagnostic tool to detect human diseases by measuring cell membrane properties. It could also be used to test the efficacy of potential drugs (Trafton 2008).

Cancer is a leading cause of death worldwide: it accounted for 7.4 million deaths in 2004. More than 70% of all cancer deaths occurred in low- and middle-income countries. Deaths from cancer worldwide are projected to continue rising, with an estimated 12 million deaths in 2030.<sup>4</sup> Therefore, cancer in the developing world as widely diffused as elsewhere, is a big challenge to human health. Latest results obtained in cancer detection and treatment with nano-scale techniques provide hope that nanotechnology could be heading for a breakthrough in defeating this disease (Burgi and Pradeep 2006:656). In 2003, Jennifer West and her team at Rice University, Houston, developed Gold "nano-bullets" that can destroy inoperable human cancer. The tiny silica particles are plated with gold and heat up with near infrared light and injected directly into the tumours of living mice, the tumours were destroyed within days (Bhattacharya 2003).

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<sup>4</sup> For greater details on "Cancer" see [Online:web] Accessed on 20September2009, URL: <http://www.who.int/mediacentre/factsheets/fs297/en/index.html>

Recently a revolutionary cancer treatment using microscopic magnets to enable 'armed' human cells to target tumours has been developed by Professor Claire Lewis and his team at the University of Sheffield. The study shows that inserting these nanomagnets into cells carrying genes to fight tumours, results in many more cells successfully reaching and invading malignant tumours. Professor Lewis explains that "the research could herald a new era in gene therapy - one in which delivery of the gene therapy vector to the diseased site is much more effective. This new technique could also be used to help deliver therapeutic genes in other diseases like arthritic joints".<sup>5</sup>

### 2.3. Solar Energy

Access to inexpensive, safe and renewable energy is the key to sustainable development worldwide. In the developing world, an estimated two billion people lack access to modern energy sources. Since almost all sources of energy are not renewable, soon the world will face a global energy supply problem. Solar energy is an interesting and valid alternative, especially in the sun-rich South. Scientific studies have demonstrated that nano-scale techniques involving nanotubes and nanoparticles lead to increased conversion efficiencies (Burgi and Pradeep 2006: 656).

Semiconducting particles of titanium dioxide coated with light-absorbing dyes bathed in an electrolyte and embedded in plastic films are cheap and easy to manufacture and offer an alternative to conventional energy production and storage. Because of their low cost-structure, photovoltaics using nanotechnology are a valid alternative to overcome the problem of power shortage, especially in the developing world (Burgi and Pradeep 2006: 656). What makes photovoltaic particularly interesting for developing countries is their decentralise use in rural areas; they do not depend on central power plants and grids, and their sustainability (Schummer 2007:297). Apart from these areas nanotechnology is also useful in solving the problem of environment pollution. The potential application of nanotechnology in this area has been described in second chapter.

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<sup>5</sup> Biotechnology and Biological Sciences Research Council (2009), "Tiny Magnets Offer Breakthrough In Gene Therapy For Cancer", *ScienceDaily*, 21 April 2008, [Online: web] Accessed on 11 October 2009 URL:<http://www.sciencedaily.com/releases/2008/04/080417095908.htm>.

### **3. Nanotechnology Research in Developing Countries**

Several developing countries have recognized nanotechnology as a catalyst for economic, human, social, technological and environmental development and launched national nanotechnology initiatives. Worldwide, more than one third of all nations are promoting research and development, including education and training of nanoscientists and nanotechnologists and more than seven countries belong to the developing world (Burgi and Pradeep 2006:654).

According to a survey conducted by Maclurcan in 2005, at least sixty two countries had initiated or were beginning, national nanotechnology activities. Out of sixty two countries eighteen of them were 'transitional' and nineteen 'developing', engaged with nanotechnology on a national level. A further sixteen countries demonstrated either individual or group research in nanotechnology, three of which were 'transitional' and twelve 'developing' (including one least developed country (LDC). An additional fourteen countries have expressed interest in engaging in nanotechnology research. Of these countries, one is categorized as transitional and thirteen as developing, including three LDCs (Maclurcan 2005:4).

Many developing countries and emerging economies are actively involved in nanotechnology research and development. The Asian region has emerged as a leading centre for nanotechnology. In Malaysia, nanotechnology R&D started in 2001 and categorized as a strategic research (SR) program in Eight Malaysia plan which spans from 2001 to 2005 and funded by MOSTI. At the end of the eight Malaysian plan, MOSTI has awarded about RM 160 million to nanotechnology related research projects. In the Third Industrial Master Plan that will span a 15 year period (2005-2020) is reported to recognize nanotechnology as the new emerging field. MOSTI is now entrusted to spearhead the planning and development of the national nanotechnology initiative (NNI) (Hashim 2009: 122-123).



In Thailand, the National Nanotechnology Center (NANOTEC) under the umbrella of National Science and Technology Development Agency (NSTDA) was proposed and won approval from the Cabinet on August 13, 2003. Thailand's National Nanotechnology Policy Framework (2004-2013) is a framework for which National Nanotechnology Strategic Plan uses as a guideline to set the direction of nanotechnology development. It proposed that the target of overall annual investment in nanotechnology in Thailand should reach 12 billion baht (roughly 300 US\$) in 2015 with 30% coming from the private sector (Tanthapanichakoon 2005: 64-68). In January 2002, the Nanoscience & Nanotechnology Initiative was established in the National University of Singapore. The area of strength is the development of nanomaterials (Choi 2003:347-351).

Nanoscience and nanotechnologies have received increased attention in China since the mid-1980s. China has been advancing rapidly in nanoscience and technology development in the last few years with increased government allocation of funds and coordinated programmes. China is principally focused on carbon nanotubes (CNTs) and the use of nanoscale carbon materials as catalysts in synthesis and processing of other nanoscale materials (Choi 2003:347). China has established itself as a global leader in nanotechnology research and development. A further boost will come from the £400bn economic stimulus package announced by the Chinese government for year 2009, £12bn of which has been ringfenced for research and development. China will be on a par with the EU and U.S. by 2012.<sup>6</sup>

The developments of nanotechnology in Latin American countries have been accelerated in recent years. In Latin America, Brazil has been a leader in nanotechnology research and the first country to implement public programs to support its development. In 2000, the Brazil ministry of science and technology prepare an agenda for work on nanoscience and nanotechnology. Later in 2004, the Brazilian federal government released its Pluri-annual plan (2004-2007) scheduled around US\$30 million for the development of nanoscience and nanotechnology plan. The aim of the program is to increase the

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<sup>6</sup> Mackenzie, Tom (2009), "China's Giant Step into Nanotech", *The Guardian*, Thursday 26 March 2009, [Online:web] Accessed on 9 October 2009, URL:<http://www.guardian.co.uk/technology/2009/mar/26/nanotechnology-china>

competitiveness of Brazilian government (Foladori 2006: 205). The total investment in different nanotechnology programs reached \$100 million for the period 2001-2007.

U.S., France, and Germany, have increased their scientific collaboration in nanotechnology with Brazil in the period 1998-2007. In the region, there are increasing regional collaborations with Argentina and relatively stable collaborations with Chile.<sup>7</sup> Cuba could become a big player in nanobiotechnology. The strength of Cuban technological infrastructure is depth of training and qualification of Cuban scientist. In 2002, the Cuban academy of science voiced the need to incorporate nanotechnology into the offered study programs. The main obstacle is lack of modern equipment, which explain Cuba's effort to obtain funding from overseas and establish agreement with laboratories in other countries (Foladori 2006: 208).

South African research in nanotechnology currently focuses on applications for social development and industrial growth, including synthesis of nanoparticles, development of better and cheaper solar cells, highly active nanophase catalysts and nanomembrane. The South African Nanotechnology Initiative (SANI), founded in 2003. SANI aims to establish a critical mass in nanotechnology R&D in South Africa for the benefit of all its citizens. Projects include the development of better and cheaper solar cells and nanomembrane technology for water (Barker et al. 2005:12).

### **3.1. India**

Several academic institutions in both public and private sectors in India have initiated nanoscience and nanotechnology research and development. The Department of Science and Technology launched the Nano Science and Technology Initiative (NSTI) in 2001 under the leadership of Prof. C. N. R. Rao. The primary objectives of the programme are: to promote basic research in nanotechnology, infrastructure development for nano science & technology research, public private partnerships and nano applications and

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<sup>7</sup> Kay, Luciano (2008), " Nanotechnology Research Networks in Brazil Structure, Evolution, and Policy", [Online:web] Accessed on 10 October 2009, URL:<http://www.spp.gatech.edu/faculty/WOPRpapers/Kay.WOPR.pdf>

technology development centres, human resource development and international collaborations.<sup>8</sup> In India the nanotechnology research is carried out by three Government departments, namely the Department of Science and Technology (DST), the Defence Research and Development Organisation (DRDO) and the Department of Biotechnology (DBT). Amongst the three it is the DST that is overseeing the disbursement of research funds and activities under the NSTI. The DST is therefore responsible for the overall coordination of nano initiatives undertaken through government funding in the country.

The NSTI funded about 100 research projects, and provided funding for setting up ten core groups in nano science, six centres of nanotechnology, and one of computational materials science at different institutions across India. The main Nanoscience and technology R & D institutions in India supported by NSTI are: Indian Institute of Science (IISc), Bangalore, Various Indian Institute of Technology, National Physical Laboratory (NPL), Delhi; Saha institute of Nuclear Physics (SINP), Kolkata; National Metallurgical Laboratory (NML), Jamshedpur. NSTI also supports many universities like University of Delhi, Banaras Hindu University, Anna University, University of Hyderabad, Madras University, Pune University. The research funded under the NSTI focuses on four specific areas of research; nano materials for surface coating purposes, nano metallurgy, nanosensors and nano drug delivery systems. The choice of these four areas reveals a distinct plan on the part of the government to focus and direct our research energies in the sectors wherein nanotech research (in the west) has been able to produce significant results in terms of commercially successful products or product enhancements (Chowdhury 2006:4731-4732).

In May 2007, the Government of India has approved the launch of Nano Mission and approved Rs. 1000 crores for five years. It is the second phase of Department of Science and Technology activities in Nano Science and Technology. It is the successor of Nano Science and Technology Initiative. The technical programmes of the Nano Mission are also being guided by two advisory groups, namely the Nano Science Advisory Group (NSAG) and the Nano Applications and Technology Advisory Group

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<sup>8</sup> "National Mission on Nano Science and Technology (Nano Mission)", [Online: web] Accessed on 26 December 2009, URL: [http://www.dst.gov.in/about\\_us/ar07-08/nano-mission.htm](http://www.dst.gov.in/about_us/ar07-08/nano-mission.htm).

(NATAG). The Nano Mission funded about 130 research projects. Seven centres for Nano Technology focusing on development of specific applications have been established. A centre of excellence on Computational Materials Science has also been established at Jawaharlal Nehru Centre of Advanced Scientific Research (JNCASR) Bangalore. Three national Institutes of Nano Science & Technology are being set up at (i) Mohali, co-located with Indian Institute of Science Education & Research (IISER) (ii) Jawaharlal Nehru Centre of Advanced Scientific Research, Bangalore (iii) Indian Association for the Cultivation of Science, Kolkata.<sup>9</sup>

The allocation for the research and development on this technology has increased from Rs. 120 crores in 2007-08 to Rs. 145 crores in 2008-09.<sup>10</sup> India has also entered into international collaboration in the field of nanotechnology with many countries namely UK, U.S., Germany, France, Italy, Russia, Japan, and Israel. International Advanced Research Centre for Powder Metallurgy and New Materials (ARCI) has set up a Centre for Knowledge Management of Nanoscience and Technology (CKMNT) in 2009. This is India's first Nano knowledge centre. The Centre has been set up with partial financial assistance from the Nano Mission of Government of India's Department of Science and Technology (DST). It aims to be a comprehensive resource centre providing services concerning nanotechnology-related activities to a wide cross-section of information seekers spanning academia, research institutions, industry, venture capitalists and policy makers. The sponsored project (CKMNN) is being implemented at two locations, namely Gurgaon and Hyderabad<sup>11</sup>

Several Indian institutes and firms are already working on nanotechnology products for drug delivery, water filters, arsenic removal, reducing water and air pollution, antimicrobial coatings and river cleaning projects. The Council for Scientific and Industrial Research (CSIR) holds numerous nanotechnology-related patents, including

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<sup>9</sup> "National Mission on Nano Science and Technology (Nano Mission)", [Online: web] Accessed on 26 December 2009, URL: [http://www.dst.gov.in/about\\_us/ar07-08/nano-mission.htm](http://www.dst.gov.in/about_us/ar07-08/nano-mission.htm).

<sup>10</sup> "Nanotechnology Initiatives by Govt. of India", R&D India, *Newsletter*, March 2008, [Online:web] Accessed on 26 December 2009, URL: [http://www.rndindia.info/newslet/newsletter\\_8.htm#Union](http://www.rndindia.info/newslet/newsletter_8.htm#Union)

<sup>11</sup> See "Asia Nano Forum Society Newsletter, Singapore, Issue 8, November 2009, [Online:web] Accessed on 22 December 2009, URL: <http://www.asia-anf.org/ANFNewsletter.php>

novel drug delivery systems, production of nano-sized chemicals and high-temperature synthesis of nano-sized titanium carbide. Nano Biotech Ltd, an industrial enterprise in the private sector, has been doing research on nanoscience and nanotechnology for multiple diagnostic and therapeutic uses. Dabur Research Foundation is involved in developing nanoparticle delivery systems for anticancer drugs. Similarly, Panacea Biotech, a pharmaceutical company, has made advances in novel drug controlled-release systems. Although in India impressive research initiatives have been taken, the research in the area of nanoscience and nanotechnology is still in its infancy compared to the degree of sophistication in R&D already achieved by the developed countries (Patra et al. 2009:652).

In 2002 U.S. national science foundation developed partnerships with India and the Asia Pacific economic cooperation group and since then, has been integral in the development of national nanotechnology initiative in Vietnam and Costa Rica. The Asia Pacific Nanoforum (APNF) involves 13 countries including China, India, Indonesia, Thailand, Malaysia, and Vietnam. The APNF was formed as the Asia Pacific centred catalyst and thought leader in Nanotechnology and related development area. Since its inauguration in February 2002, the APNF maintained a key role as supporting organization of a number of initiatives and major nanotechnology events in Asia, Europe, and the U.S.<sup>12</sup> Similarly European Commission negotiated bilateral nanotechnology partnerships with Argentina, India, China, Russia and South Africa (Maclurcan 2005:8) Encouraging international partnerships between the North and the South are certainly important, but also scientific exchange and alliances between developing countries are becoming a necessity of the ongoing regionalisation trends in politics and economics (Burgi and Pradeep 2006:656).

### **3. Challenges before Developing Countries**

Overcoming poverty is not just a matter of fulfilling basic needs for water, food, and shelter, but also of being included in a system of rights and relationships that secures

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<sup>12</sup> "Asia Pacific Nanotechnology Forum", for greater detail see [Online:web] Accessed on 10 October 2009, URL:<http://www.apnf.org/> -

access to resources, and supports social, political and economic cooperation (Bruns 2004). Even if opportunities related to nanotechnology are identified, there is still a risk that small minorities of people will benefit from its opportunities, while large majorities, mainly in the developing world, will not (Barker et al .2005:10).

Concerns are being raised that innovation will be tied up by the private sector of the north, with broad sweeping patents limiting the development of new technologies and increasing global science's ties to market demand. An example of market pressure was witnessed with the 2004 'Nanowater' conference, held in North America. Following the claim by researchers at Oklahoma State University (U.S.) that they could utilise the ability of zinc oxide nanoparticles to remove arsenic from water, Bangladesh was presented as an example in which nanotechnology could address the serious problem of arsenic level in portable waters. The conference aimed "to focus the attention of the nanotechnology community on the potential of technology to change the world for good". However, the conference did not involve any developing country in its proceedings, and developing country issues were not directly addressed (Maclurcan 2005: 9).

### **3.1. Societal Implications of Nanotechnology**

Science, technology and society are intrinsically interlinked and characterized by mutual interdependency. Application of scientific knowledge and associated developments are two of the major factors determining social progress and prosperity. Advances in any discipline inevitably lead to changes in social relations, meanings and societal patterns. However, technological and social changes may not occur contemporaneously, since the social system needs its own time to respond to alteration and to find its new equilibrium. Society reacts to technological changes with new form of institutions and develops its own responses to technological innovation. The innovation process shapes the evolution of society (Burgi and Pradeep 2006: 647). Therefore in order to serve the needs of the poor, technology has to be used in a favourable socio-economic context (Invernizzi and Foladori 2005:109).

Invernizzi and Foladori are of the opinion that nanotechnology's novel solutions and potentially laudable achievements may never come to fruition in developing countries because the main problem for a developing country is not so much the fixed costs of a laboratory of average sophistication, but the social context that is necessary for really incorporating nanotechnologies into the economy. A country's ability to foster and support technological careers requires a social context that supplies the necessary equipment and human capital in the long term. It will be difficult for many Third World countries to find the staff necessary to work interdisciplinary in nanotechnology (Invernizzi and Foladori 2005:109).

Given the higher stakes and more interdisciplinary nature of nanotechnology, therefore, it is possible that the race for qualified scientists will heat up and increase the brain drain from the Third World into more advanced countries. This polarization of the labour market will punish poorer countries with less qualified labour. Even if large developing countries that could join the nanotechnology wave (such as China, India, Brazil, etc.) can produce nanoproducts that could eventually result in clean and cheap energy options, in clean drinking water or in greater agricultural yields, this does not mean that the poor majority will benefit. (Invernizzi and Foladori 2005:110). It is controversial as to whether such products will be accessible to the poor. The other efficient and even cheaper technologies already exist to adequately address the same problems, and even these are not available to poor people (Invernizzi et al. 2008:137).

None of nanotechnology product has been scaled up to industrial levels yet – a major prerequisite to bring prices down – and by looking around at what nanotech products are commercially available it appears that some even claim a price premium. Not a single product out there advertises to be cheaper because it is nanotechnology-enabled. Nanotechnologies, in theory, could make it easier to solve these problems if the hurdle of commercialization can be overcome; because as long as nanotechnology-enabled products are more expensive than their non-nanotech alternatives people will face the same problems that they already are having today (Berger 2007). For the poor, socio-economic structure is a much more difficult barrier than technological innovation.

Nanotechnology, even where fully integrated in developing countries, does nothing to change these socio-economic structures; instead, it could serve to exacerbate existing gaps and further the technological and socio-economic isolation of the poor (Invernizzi and Foladori 2005:110).

### 3.2. Patent Barriers

Nanotechnology products are already being patented, typically by the most important and largest corporations in the world. The rigours of patenting system have used monopolistic economies to drive medicine pricing for the last twenty years. It makes it impossible for poor to buy medicine from companies that hold patents. A study of health related nanotechnology patents from 1994-2004 shows that the leading countries are the U.S (32.8%), China (20.3%) and Germany (12.9%). The participation of transitional countries is as follows: South Korea (3.9%), Israel (0.9%), Russia (0.5%), Singapore (0.2%), Bermuda and Slovenia (0.1%). Developing countries patent holders include china (20.3%), India (0.5%) and Brazil (0.1%). The research also analysed the distribution of health-related patents, by continent: Europe (36.7%), North America (34.2%) and Asia (28.8%). Few or no patents are held in South America (0.1%) and Africa (0%) (Maclurcan 2005:9-12). The major patent holders are multinational corporations (MNCs). For example, one of the top ten pharmaceutical companies on the U.S. market, GlaxoSmithKline, AstraZeneca and Merck have all engaged in nanotechnology patenting. Two drug Giants: Elan Pharma International and Novartis hold strong patent positions in health- related nanotechnology (Maclurcan 2005:10-12).

The World Health Organization (WHO) regards artemisinin-based drugs as the best hope for treating malaria. Artemisinin, a natural product extracted from the leaves of the sweet wormwood plant *Artemisia annua*, has successfully treated all known strains of malaria. The Chinese have used the wormwood shrub as a medicinal plant for over 2,000 years. However, a global shortfall in the supply of natural artemisinin has kept the price of this much-priced compound out of reach for poor people (Roco and Bainbridge 2006:40-41). In 2004, Keasling's Berkeley professor of chemical engineering at the University of



California Berkeley and his start-up company Amyris develop a microbe-derived version of artemisinin. In April 2006 Keasling and 14 collaborators announced in *Nature* journal that they had succeeded in engineering a yeast strain to produce artemisinic acid, which is a necessary step in the production of artemisinin itself. According to Keasling, what's left to do is to increase the yields of artemisinic acid, and then use "high-yielding chemistry" to convert artemisinic acid to artemisinin. Though they've produced only tiny quantities of artemisinic acid so far, Keasling's bacterial factories are already churning out copious amounts of priceless PR for the fledgling synbio industry (Roco and Bainbridge 2006:40-41).

For example, one of the microbicides<sup>13</sup> in human trials, Starpharma's "VivaGel," is based on nano-scale molecules called dendrimers – synthetic, three-dimensional molecules with branching parts. VivaGel is being developed as a topical microbicide that has the potential to prevent the transmission of HIV. VivaGel is the first dendrimer to go through the FDA process and is now being tested around the world in various populations. In 2005 the U.S. National Institute of Health awarded Starpharma (based in Melbourne, Australia) US\$20.3 million to support the development of VivaGel for the prevention of HIV. Starpharma holds rights to three broad-based U.S. patents in the dendrimer pharmaceutical area. Dendritic Nanotechnologies', Inc. (DNT) is a wholly owned subsidiary of Starpharma and holds more patents on dendrimer technology than any other company (Roco and Bainbridge 2006 :45-46).

It is obvious that 'VivaGel' will be out of the reach of the people of poor countries. As we discussed in the third chapter, excessive patenting in nanotechnology has created a danger of 'patent thicket' and 'tragedy of anticommons'. Patent on basic nanoparticles and processes using nanoparticles could end up being so finely and acutely propertized that the ability to create a novel material –for instance a water filtration system that uses carbon nanotubes to produce clean drinking water could face nearly unnavigable complexity in terms of competing and overlapping patent claims. It will introduce a need

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<sup>13</sup> Microbicides" refer to a range of compounds now under development that aim to reduce or prevent the transmission of HIV.

for legal expertise even before research can begin. The chilling effect could drive all but richest away from some kind of research. Even the use of information about nanoscale products could require licensing fees and contracts (UNESCO 2006:18). Therefore, Researchers in the global south are likely to find that the participation in the 'nanotech revolution' is highly restricted by patent tollbooths, obliging them to pay royalties and licensing fees to gain access (Shand and Wetter 2007:116).

### **3.3. Ethical Issues Related to Nanotechnology**

There has been increasing concern that nanotechnologies will intensify the gap between rich and poor countries because of their different capacities to develop and exploit nanotechnologies, leading to a so called 'nanodivide'. Nanotechnology development may yield the uneven utilization of technology on both national and international level. Those who participate in the nano revolution stand to become not only wealthy but also powerful. Medical benefits that result from nanotechnology development will be very good news for those who can financially afford it. It is natural that development of high-tech equipment will not be cost-reasonable since so much investment is made in nanotechnology. In the long run such equipment and devices may be available for many people, but as of now it is only for those who can financially afford it (Roco and Bainbridge 2006:357).

The level of financing and investment, access to scientific and technical infrastructure and materials, and cooperation across countries varies a great deal. As with previous advances in science and technology, developing nations risk being distanced by a 'knowledge divide' if they cannot find ways to participate on equal footing with other countries (UNESCO 2006:13). It is also argued that the patenting and licensing systems favour the control of nanotechnologies by developed countries, which can block research aimed at development concerns, leading to a widening of the North-South divide (Invernizzi et al. 2008:130). Although increased investments in a number of developing countries have narrowed the North-South nanodivide, such investments have widened the South-South divide. Today, Research and development in nanoscience and

nanotechnology in Brazil, India, and South Africa bears closer resemblances to the research environment in Europe, Japan, and United States than it does, for example, to the research environment in the Laos, Rwanda, or Dominican Republic (Hassan 2005:66).

Nanotechnologies promises considerable advances in developing small and cheap sensing devices, enabling a range of features that will make smaller, longer-lasting sensors possible. Devices might be used in ways that limit individual or group privacy by covert surveillance, by collecting and distributing personal information (such as health or genetic profiles) without adequate consent, and by concentrating information in the hands of those with the resources to develop and control such networks (Royal Society and Royal Academy of Engineering 2004:53). Nanotechnology is capable of dramatically improving surveillance devices, and producing new weapons. It raises concerns that nanotechnology research may be used to contribute to the creation of new and nefarious kinds of weapons by terrorists, or such weapons created by national governments may end up in the hand of terrorists (UNESCO 2006:19).

Another issue which has raised concern among critics is the fear of so-called 'grey-goo' scenario. Drexler argued that an assembler capable of replicating themselves. These replicating assemblers and thinking machines pose basic threats to people and to life on Earth. He further argued that dangerous replicators could easily be too tough, small, and rapidly spreading to stop - at least if we made no preparation (Drexler 1986). This argument of Drexler gave rise to the grey-goo scenario. The 'grey-goo' scenario is based on the fear that nanotechnological devices will either be programmed to self-replicate, or that they will 'evolve' into devices capable of self-replicating and if they proceed to do so they may destroy the natural world (UNESCO 2006:19).

However, Richard Smalley, co-discoverer of the buckyballs, has a dramatically different conception of nanotechnology from Drexler, one that does not include the concept of molecular assemblers. Smalley does not think molecular assemblers as envisioned by Drexler are physically possible. In a September 2001 article in *Scientific American*, he stated that "self-replicating, mechanical robots are simply not possible in our world. To

put every atom in its place—the vision articulated by some nanotechnologists—would require magical fingers”.<sup>14</sup> Later, Smalley reversed himself to invoke again before the President’s council of Advisors on Science and Technology, stating that “the ultimate nanotechnology builds at the ultimate level of fineness one atom at a time, and does with molecular perfection”. In the opinion of Drexler he has returned to endorsing the Feynman thesis<sup>15</sup>, at least in a promotional rhetoric. Drexler further argued that denial of Feynman thesis has failed, but the community has yet to embrace its consequences (Drexler 2004:24).

A similar concern is being raised about the issue of ‘human enhancement’. Nanotechnologies are contributing to the development of some human ‘enhancement’ applications; the closest to development being improved cochlear and retinal implants, to improve or restore hearing and eyesight that enhance human capacities. Such enhancement runs the gamut from nanoscale sensors that might be added to the retina that improve sight to cochlear implants that improve hearing to performance enhancement technologies for athletes to new forms of plastic surgery (UNESCO 2006:20). Critics have objected to proposed interventions that enhance human capacities on the grounds that this might lead to stigmatisation of those without enhanced capacities. They argue that certain new medicines may not be available to everyone perhaps they are too expensive, or incompatible with the genetic makeup of the potential patient (Roco and Bainbridge 2006:197).

The emphasis on human performance enhancements will ultimately create an “ability divide” which will widen the gap between North and South and between rich and poor

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<sup>14</sup> In April 2000, Wired published Sun Microsystems cofounder and chief scientist Bill joy’s influential article, “Why the Future Does not Need Us”, which referred warnings regarding nanoreplicators and called for the suppression of nanotechnology research. Notions about the darker side of nanotechnology have rapidly entered the public consciousness. The nanoscale research community reacted with horror to this threat to funding. Smalley’s objections to molecular assemblers go beyond the scientific. He believes that speculation about the potential dangers of nanotechnology threatens public support for it. For greater details see Baum, Rudy (2003), “Nanotechnology: Drexler and Smalley make the case for and against ‘Molecular Assemblers’”, *Chemical & Engineering News*, December 1, 2003, 81(48): 37-42, [Online:web] Accessed on 5 October 2009, URL: <http://pubs.acs.org/cen/coverstory/8148/8148counterpoint.html>

<sup>15</sup> Drexler argued that “The idea that nanomachines can build with atom-by-atom control is the foundation of the Feynman vision of nanotechnology—call it the Feynman thesis” (Drexler 2004:22).

everywhere (ETC Group Report 2006: 42). Some Anthropologists argue that nature might not be perfect, but it is believed that humans, with the help of nanotechnology, might be able to 'correct' its imperfections. One such 'error' of nature is the aging and death of cells, causing the aging and death of humans. With the help of nanomachines cells could be repaired and new cells built, allowing humans to live forever. Just as the cloning debate today is asking questions about what kind of society we want to live in, the 'nano-debate' of tomorrow will ask what kind of world we want to create with the new technology (Johansson 2003:6).

As the tools and techniques of nanoscale science and technology continue to improve, research involving artificial organisms, synthetic biology, genetically modified organisms and chimeras (human-animal hybrids) accelerates. These research programs push at the boundaries of life forms. They alter life forms at their most basic (i.e., genetic) level; they create novel life forms that would not otherwise exist; or they combine aspects of different life forms that would not otherwise exist (Sandler 2009:31). Synthetic biologists and nanobiotechnologists aim to harness nature's self-replicating "manufacturing platform" for industrial uses. Today, researchers are building biological machines – or hybrid organisms employing both biological and non-biological matter. The fields of synthetic biology and nanobiotechnology raise many moral and ethical concerns (UN-NGLS 2008:58-56).

#### **3.4. Lack of Public Information and Public participation**

Public engagement is a critical factor in the sustained development of new technologies and their successful integration into the lives of our communities, particularly if potentially negative health, safety, environmental, social, and ethical issues are involved. Public engagement also has the benefit of leading to faster uptake of commercial applications, broader investment, and increased involvement of young people in educational pathways that lead to further development of the new sector. It connotes interactivity and truly meaningful multidirectional discussion over the implementation of new technologies in which scientists, industry, investors and government regulatory

agencies work together with citizen representatives of the diverse communities that are most likely to experience the impact of the new technologies and will need to deal with whatever unintentional fallout may occur (Roco and Bainbridge 2006:267).

Public awareness of risk tends to be higher if the technology is stigmatised (e.g. uncertain scientific knowledge and media hype); and if insufficient information is communicated to them concerning how risks are and can be controlled (Renn and Roco 2006:161). Therefore the lack of dialogue between researchers' institutes, granting bodies, and the public on the implications and directions of nanotechnology may have devastating consequences, including public fear and rejection of nanotechnology without adequate study of its ethical and societal implications (Mnyusiwalla et al. 2003:11).

A number of high-profile events – from the Asilomar controversy over the invention of recombinant DNA, through the disasters at Chernobyl and Bhopal, to the public controversy in Europe of genetically modified foods have made both governments and publics wary of trusting the statements of scientists. (UNESCO 2006:19). The widespread rejection of GM food by public occurred not as the result of a particular health or environmental catastrophe, but from a concern that it was being promoted uncritically by government and corporations, at the expense of the wider public interest. The most important lesson from the case of GM foods is that uncertainties should be openly acknowledged (Uskokovic 2007:53).

In the biomedical arena, for example, we can find cases of independent determination of standards in biomedical trials compromised or auto-censored by the influence of pharmaceutical corporations and there are examples of funds given by pharmaceutical corporations to universities in order to have influence on decisions pertaining to research and development (“R&D”) and to gain the right for subsequent licenses. Even still, there are examples of pharmaceutical companies' bankrolling academic studies that downplay their interests. Pharmaceutical corporations have also been accused of putting pressure on researchers to impede the flow of detrimental information into public forums (Invernizzi and Foladori 2005:107).

These experiences show that citizens' expectations and concerns as well as perceptions of risks and benefits have to be taken into account, since they present an important impact on the acceptance of new technologies on the market and can decide market success or failure. The ongoing debates on nanotechnology show that some controversies exist and that market success could be jeopardised if public opinion feels that it is not being addressed and consequently takes over a critical view about nanotechnology as such, due e.g. to health and environmental risks of nanoparticles or ethical concerns about privacy. When talking about economic potentials of nanotechnology, these debates have always to be addressed and must be taken seriously (Hullmann 2006:16).

In March 2006 the International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers' Associations (IUF)<sup>16</sup>, with a membership of 365 unions from 122 countries, has raised a public declaration on nanotechnology. The Latin American Regional Secretariat of this federation (Rel-UITA) met in October, 2006, in Santo Domingo, for its 13<sup>th</sup> regional conference. With the presence of thirty-nine workers' organizations from fourteen countries and ninety-five delegates a resolution was passed on nanotechnologies. The declaration called for public debate, warning that products containing nanocomponents were being launched onto the market before civil society and social movements had a chance to assess their possible implications in economic, environmental and social terms and their effect on human health. Furthermore, the declaration warned of the need to make sure that the debate of a matter that will lead to deep social changes should not be left to the "experts".

Months later, in March, 2007, the 25<sup>th</sup> Congress of the IUF was held in Geneva. Rel-UITA introduced the Santo Domingo resolution into the talks, and it was approved, thereby extending its impact to all 122 countries and over 12,000,000 workers. A resolution of this nature, clearly questioning the way nanotechnologies and their products

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<sup>16</sup> It is an international federation of trade unions of workers in agriculture and crops, the preparation and processing of food and drinks, hotels, restaurants and catering services, and all phases of the production and processing of tobacco. It is founded in 1920 and International Labour Solidarity is its guiding principle. Today its membership is made up of 365 unions from 122 countries, representing a total of twelve million workers. For greater details see [Online:web] Accessed on 10 October 2009, URL: <http://www.iuf.org/www/en/>

are being introduced, certainly means that reflection on this issue is necessary (Invernizzi N. and Foladori 2007).

## **5. Summation**

Nanotechnology applications have the potential to provide solution to the problem of water purification, energy, healthcare etc. Many developing countries are actively engaged in nanotechnology research and some of them have established national nanotechnology initiative but only a few countries like China, South Africa, and India are making significant contribution in this area. These countries have developed scientific collaborations with other countries in this field. In India, the Government has announced some major initiatives for the growth and development of this industry. The Government departments namely Department of Science and Technology and Department of Biotechnology has been encouraging research and development in this area. The Nanoscience and Technology Initiative launched by the Indian Government in 2001 have stimulated research in this area. Recognising the importance of research and development in this area the Indian government has increased the funds for research and development on this technology and approved the second phase of Nano Science and Technology Initiative (NSTI), known as Nano mission. However, there is still need of significant amount of capital funding for the long term development of this technology.

Most of the nanotechnology products are being patented by developed countries and they are holding patents in each subfields of nanotechnology. In such a case, these products will never reach to the poor people. Nanotechnology patents will prevent the developing countries from exploiting these benefits. However, scientifically advanced developing countries like China, India, Brazil, will not be deprived from the benefits of these technologies. These countries bear close resemblances to the research environment in developed countries. In the developing world there exists a nano-divide. Therefore, collaboration between developed and developing countries is required in this area. Nanotechnology is an emerging field so most of its risks are not fully known. However, concerns are being raised about the toxicity of nanomaterials and their impact on human and environment. It is necessary that there should be more widespread participation of



public in nanotechnology debate, and then only the research in this area can be used to solve the problems of the poor people.

## **CHAPTER V**

## **CONCLUSION**

## CONCLUSION

Various definitions that are being used to describe nanotechnology create confusion about this term. However, one thing is common in all definitions i.e. the manipulation of matter should be in the scale range of 1-100nm. The size range is critical for nanotechnology as it exhibits quantum and scale effects which are not visible at macro level. However, this range is being criticised on the ground that it excludes some fields of nanotechnology where better results are achieved above this range. Nanotechnology possesses unique properties due to these effects. Therefore, it cannot be denied that it is a unique technology different from other technologies due to its unique characteristics. To avoid the confusion about the term nanotechnology, public and private institutions are developing a common definitions and terminology of nanotechnology.

Nanotechnology's ability to converge with other technologies results in such breakthrough technological developments that are not possible to achieve by other technologies. The present applications of this technology demonstrate the powerful impact that it is already having. The toxicity of these nanomaterials is also raising concern. Although, there is no conclusive data about the potential risks associated with this technology, it is necessary to develop a strategy to deal with these issues before its risks are materialised.

Patents are crucial for the development of nanotechnology as it requires extensive research and huge investment. Nanotechnology raises some unique issues regarding patentability. Article 27 of the TRIPs Agreement provides that patent protection must be extended to all fields of technology provided the patentability requirements are met. The determination of novelty requirement in nanotechnology is not so difficult. Nanotechnology inventions due to their unique size exhibit such new and unexpected results which are not possible for the person skilled in the prior art to anticipate. However, the determination of inventive step in nanotechnology invention will require effort. Size consideration is not enough to determine an inventive step. Nanotechnology inventions must exhibit unexpected results and provide solution to previous technical

problems in order to be nonobvious. Therefore, the claimed nanoscale invention by exhibiting some technological advantage related to nanoscale dimensions can establish inventive step.

The determination of industrial applicability of nanotechnology inventions will not be problematic. The industrial applicability of the basic nanoscale materials is already known. However, in the case of unpredictable arts like nanobiotechnology, the applicant should assert at least one specific and substantial utility that is credible in the application. However, in the case of later generation complex products like assemblers the demand of a different utility standard may arise due to the complexity of these inventions. But, as of now there is no need for a heightened or different utility standard for nanotechnology. Nanotechnology inventions will require high disclosure as there is lack of prior art. This requirement can be met by providing greater details of work, the data related to experiment, the example how the invention will work.

Therefore, the current nanotechnology inventions fall within the scope of patentable subject matter as defined by TRIPs Agreement provided the terms of the agreement are adjusted in the context of nanotechnology. However, in the medium to long term nanotechnology inventions will pose many challenges for the current patent regime. It is important to note that nanotechnology will develop in several stages. There are four generations of nanotechnology inventions ranging from the basic building blocks to the complex machines and structures. The third and fourth generation products will consist of nanobiotechnology inventions that involve both living and non-living matter. Therefore, in the medium to long term the convergence of nano and bio not only complicate the invention/ discovery debate but will raise ethical and moral concerns. The raw materials of nanotechnology inventions are the chemical elements of periodic table-of which all living and non-living things are made of. Therefore, Patenting of nanotechnology inventions will provide monopoly on nature. This will accelerate the debate on “patenting of life forms”.

Nanotechnology is an emerging field so there is not enough prior art. Lack of uniform definition and confusion about the scope of term nano, has resulted in nanotechnology applications with broad claims. The multidisciplinary nature of nanotechnology and the lack of relevant expertise by examiners in this area has resulted in a large number of broad and overlapping patents. Therefore, a common definition of nanotechnology and a classification system is required, as it will limit grant of broad claims and help examiners to search prior art. Nanotechnology is multidisciplinary technology, each technology has different characteristics and applications. Therefore, a common definition should be framed in such a way that it will not result in unreasonable classification of technologies. The USPTO nano classification (class 977) and the EU nano classification (Y01N) is a good start. These nano classifications will help the examiners in searching prior art, and may decrease the granting of broad and overlapping patent. However, these classifications are not sufficient to address the multidisciplinary nature of nanotechnology and need further elaboration. Until a common definition and classification of nanotechnology is created, other countries should follow the USPTO and EU approach and create their own nano classification.

The cross industry nature of nanotechnology and granting of broad and overlapping claims is creating patent thickets and anticommons problem in nanotechnology. These problems can be solved by creation of patent pools and cross licensing. However, it is important to note that universities are the major holder of nanotechnology patents and tend to license exclusively in order to generate revenue. Whereas, large corporations that are holding nanotechnology patents on particular inventions will be most interested in licensing exclusively than enter cross licensing. Therefore, very few nanotech companies will enter into cross licensing. The formation of patent pool will depend upon the patent landscape in particular area of nanotechnology. Therefore, a single company holding a large number of patents in a particular area of nanotechnology will not opt for the formation of patent pool. However, the formation of patent pools in nanotechnology does not seem impossible in near future as the nanotech patent litigation has already begun.

Due to the quantum and scale effects, nanotechnology inventions are completely different from their macroscale counterpart. Therefore, the reverse doctrine of equivalents should be available to nanotech inventors to excuse literal infringement. As companies are collecting a large number of nanotechnology patents on basic research, patent trolls will interfere in the commercialisation of this technology in near future. A large number of nanotechnology patent litigation will arise in future as more nanotech products will enter in the market.

Nanotechnologies pose challenges for patent law. The problems of patent thickets, anticommons, were also there in previous technologies. Therefore, by developing common definition and terminology and recruitment of expert examiners quality patents can be granted in nanotechnology. Therefore, currently there is no need to amend the patent law. However, it is necessary to address these issues at this stage as this technology is developing at a faster pace. As more developed nanotechnology products will appear in markets these issues will pose greater challenge for nanotechnology patents. Therefore, it is the right time for the governments and the policy makers to discuss these issues so that the existing patentability criteria can be modified to accommodate the need of nanotechnology as and when the need arises.

In India, the Nanoscience and Technology Initiative have stimulated research and development in this area. The private and public institutions in India are making significant contribution in nanotechnology research. The Indian government is making major investment in this area and identified it as one of the main science and technology priority area. For the commercialisation of this technology direct funding from the government is necessary.

Nanotechnology applications have the potential to address the specific needs of the developing countries, but these products will not be accessible to the poor people. Developed countries hold a large number of nanotechnology patents. Therefore, technologically advanced countries will dominate in nanotechnology research. The countries not fully advanced in technology, i.e least developed countries, will not be able

to exploit these technologies. There is possibility that a nano divide will occur between developing and the least developing countries. Therefore, it is necessary that the developing countries should effectively participate in the nanotechnology dialogue to ensure that the nanotechnology research develop in the right direction and would not enforce nano divide. So, far the grey-goo scenario is concerned, it is a matter of future. No such nanodevices exist now which can replicate itself, it seems a lot of hype has been created about it. It is necessary that a close attention should be paid on the possible negative effects that it could have on humans and society at large before it is too late.

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